

CENTRAL RESEARCH LABORATORY

Introduction

Advances in medicine and science come from new ideas and approaches developed through research. Central Research Laboratory (CRL) is a facility that provides centralized research infrastructure to benefit investigators in multiple disciplines across RajaRajeswari Medical College and Hospital (RRMCH). CRL is Located on the second floor of the college building and our mission is to provide a comfortable, safe and effective environment to conduct professional, high-quality research. This is achieved by providing the necessary environment, equipment and personnel to achieve research goals. CRL acts as a single point of contact for investigators to accelerate their research study and provides structured environment where researchers, undergraduates, Postgraduates and clinicians can work together on projects that are relevant and fundamentally important. Genomics Lab at CRL is useful for doing research at the advanced level as well as for diagnosis and confirmation of certain genetic disorders at the molecular level. This facility is extensively used by our staff for completing their External and Internal Research funding projects, postgraduates for completing their thesis/research projects as well as by undergraduates to complete their ICMR projects and for any short term research projects.

Services Provided By CRL

The CRL has dedicated and well qualified faculty, infrastructure and state of art research facilities for carrying out advanced research.

PRRT2 gene sequencing for patients with benign familial infantile epilepsy and Paroxymal Dyskinesias (PDs).

Reporting microRNAs expression in Post-Menopausal Osteoporosis Women.

Screening for early prediction and diagnosis of pre-eclampsia in Indian women by congo red dot test.

Conducting and reporting PFT, EEG and ENMG test for the patients.

Hands on Training for the Graduates, Postgraduates and Staff on advanced Instruments like PCR, RT PCR, Agarose Gel electrophoresis, High Performance Liquid Chromatography; HPLC, Nanodrop Spectrophotometer, Fluorescent Microscope, Cobase e 411 Autoanalyzer, Fully Automated IHC/ISH Slide Staining Instrument, EEG and ENMG instruments.

To Guide and support the faculty in completing their External Funding Research Projects like ICMR Govt. of India, RGUHS and VGST Govt. of Karnataka.

To Mentor and support the Postgraduates in completing their Research Projects and Thesis.

To Guide and support the Undergraduates, to complete their STS ICMR Projects and Research projects.

Supporting for completion of Collaborative Research projects.

Mission:

Our mission is to provide a comfortable, safe and effective environment to conduct professional, high-quality research involving human and animal subjects. Our students are given proper assistance to enable them gain the knowledge, skills and behaviours necessary to recover, build and maintain health as well as balance lifestyles.

VISION:

Dedicated faculty, infrastructure, interactions with specialists as well as the practical experience gained in the research labs ensures that both graduates and postgraduates are given the best possible education. Supports all aspects of biomedical research, from exploration at the basic science level to translating fundamental discoveries into treatments that can improve human health and cure certain ailments.

EQUIPMENTS LIST

High-Performance Liquid Chromatography, Nanodrop Spectrophotometer, ELISA Reader, Gel documentation system, Gradient PCR, RT PCR, Electrophoresis unit, CO₂ Incubator, Centrifuge-Refrigerated, Fluorescent Microscope, Tissue culture Microscope, Deep Freezer (- 20°C, - 40°C and 80°C), Cobas e 411, Ice making Machine, Automated IHC/ISH, Micro Balance, Electronic balance, EEG, ENMG etc.,

Ref no: RRMCH&H/BIOLAB/008/2019

Bangalore

From

Dr. C.M.Bindu

Professor & Clinical Lab In charge

Department of Biochemistry,

RRMC&H,

Bangalore.

To

Dr.S.M.R.Usha

Prof& HOD of Biochemistry,

RRMC&H,

Bangalore.

Madam,

Subject: Amendments to be made in the lab manual

With reference to the above subject, I would like to make some amendment in the Biochemistry Laboratory service department manual. The following changes have to be made.

1. Competency Matrix (6.0)
2. Roles and Responsibilities (7.0)
3. Department Working Hours (8.0)
4. Scope of services(10.1.1.-10.1.2.)
5. Policy (10.3. -10.24)
6. Annexures

Thanking you,

Yours faithfully

(Dr. C.M.Bindu)



**RAJARAJESWARI MEDICAL
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**LABORATORY SERVICES
DEPARTMENT MANUAL**

Doc. No.	NABH/RRMCH/DM/LAB/01
Issue No	03
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CONTROL OF THE MANUAL

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable condition.

The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

HOD – Laboratory department is responsible for issuing the amended copies to the copyholders, the copyholder should acknowledge the same and he /she should return the obsolete copies to the HOD.

The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

The manual is reviewed once a year and is updated as relevant to the hospital policies and procedures. Review and amendment can happen also as corrective actions to the nonconformities raised during the self-assessment or assessment audits by NABH. The authority over control of this manual is as follows:

Preparation	Approval	Issue
HOD, Laboratory Department	Medical Superintendent, RRMCH Hospital	Accreditation coordinator

The procedure manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy'.

Distribution List of the Manual:

Sr. No.	Designation
1	Accreditation Coordinator
2	HOD, Laboratory Department



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RAJARAJESWARI MEDICAL COLLEGE & HOSPITAL, BANGALORE

Service Name :	LABORATORY MANUAL LABORATORY SERVICES NABH/NABL/LAB/01
Date Created :	18.12.2018
Approved By :	Medical Director Name :Dr. D.L.Ramachandra Signature :
Reviewed By :	Medical Superintendent Name :Dr.Govindaraj Signature :
Issued By :	Accreditation Coordinator Name :Dr. Sahajananda Signature :
Responsibility of Updating :	Head of the Department Name :Dr S.M.R.Usha Signature :



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AMENDMENT SHEET

Sl.no	Section /Page	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority
1	6.0	Competency matrix	Updation		
2	7.0	Roles and Responsibilities	Updation		
3	8.0	Department Working Hours	Updation		
4	10.1.1.- 10.1.2.	Scope of services	Updation		
5	10.3. - 10.24	Policies	Updation		
6		Annexures	Updation		



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1.0 PURPOSE:

- 0.1 The objective of this document is to define the services that will be provided by Department of Laboratory medicine, RRMCH & Hospital.

2.0 SCOPE:

- 2.0 The scope of this document is restricted to the services provided by RRMCH & Hospital.

The following scope of services: List of Investigations done in the Clinical Biochemistry Laboratory (AnnexureXX).

3.0 ABBREVIATIONS:

- 3.0 NABL: National Accreditation Board of Laboratories.

- 3.1 HOD: Head of the Department

4.0 DEFINITIONS:

- 4.0 **Accuracy of measurement:** Closeness of the agreement between the results of measurement and a true value of the measured.

- 4.1 **Accreditation:** Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

- 4.2 **Laboratory Capability:** Physical, environmental, information resource, personnel, skills and expertise available for the examinations in question.

- 4.3 The management of Medical laboratory has the responsibility for design, implementation, maintenance and improvement of Quality management system.



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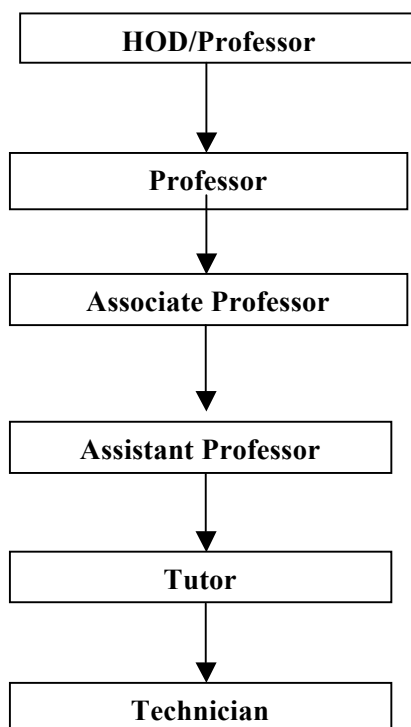
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5.0 DEPARTMENTAL HIERARCHY:





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6.0 COMPETENCY MATRIX:

Sl.No	Name of the Teaching Staff	Designation	Educational Qualification	Experience		
				RRMC&H	Previous	Total
1	Dr.S.M.R.Usha	Professor & HOD	MBBS, M.D.	10 years	11 Years	21 Years
2	Dr.Priyadarshini.K.S	Professor	MBBS, M.D.	09 years	09 Years	18 years
3	Dr.C.M.Bindu	Professor	MBBS, M.D.	09 years 05 months	06 Years 06 months	16 years
4	Dr.Deepti Gupta	Associate Professor	M.Sc, PhD(Medical)	07 years 07 months	-	07 years 07 months
5	Dr.Reena.R	Assistant Professor	MBBS M.D.	06 years 04 months	01 year 08 months	07 years 04 months
6	Dr.Manjula.K.S	Assistant Professor	MBBS, M.D.	6years	-	6 years
7	Dr.Sadaf Idris	Assistant Professor	MBBS, M.D.	03 years	03 years	06 years
8	Mrs. Sowrabhi.H.G	Assistant Professor	M.Sc. (Medical)	06 years	-	06 years
9	Dr. Sumantara N.S.	Assistant Professor	MBBS, M.D.	01year	3 years	04 years
10	Dr. Rajshree Badami	Assistant Professor	MBBS, M.D.	09 months	03 years 06 months	04 years 03 months
11	Mrs.Shruthi.A.N	Tutor	M.Sc. (Medical)	03 years	-	03 years
12	Mrs.Shweta Kumari K	Tutor	M.Sc. (Medical)	5 months	-	5 months



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7.0 ROLES AND RESPONSIBILITIES:

7.1 Head of the Department: Head of the department shall be responsible for the overall smooth functioning of clinical biochemistry laboratory.

- Implementation of Quality management systems.
- Conducting meetings regarding Administration & Management of laboratory activities.
- Reviewing and updating the quality manual
- To propose procurement of new instruments/reagents.
- Signing of MOU with accredited laboratories for outsourcing and proficiency testing.
- Posting of teaching staff to the hospital.

7.2 Laboratory In charge: Administration & Management of laboratory activities.

- To monitor and implement effectively Quality Assurance program.
- To implement this manual as well as quality system procedure laid down in the Quality manual.
- Laboratory resource planning/deployment/ utilization to meet the requirements.
- Signing of Patient Reports after verifying the results.
- Reviewing of existing tests/methodologies/equipments.
- To resolve interdepartmental issues in consultation with the Senior Consultant and Heads of divisions.
- Reviewing of functional modalities and direct the implementation of Corrective/Preventive actions when anomalies are observed.
- Preparation and Amendment of policies

7.3 Biochemists: For technical management of Biochemistry and Immunoassays divisions of the department. Has standing deputation of the department to perform administrative responsibilities of Laboratory Incharge in the latter(s)' absence.

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7.3.1 Associate Professor and Assistant Professor of Biochemistry: For technical management of Biochemistry and Immunoassay divisions of the department.

- a. Validating QC of all the machines for all the parameters.
- b. Signing of Patient Reports.
- c. Interaction with the clinicians regarding the abnormal values, sampling errors & other issues.
- d. Verification of Stock register.
- e. Verification of handover registers of technicians.
- f. Monthly verification of stock audit.
- g. Verification of purchase indents sent to the purchase department.
- h. Personal follow up with the purchase department and BME regarding purchase of reagents and maintenance of equipments.
- i. Verification of NABH documentation along with Lab in-charge.

7.2.1 Tutor of Biochemistry: For technical management of Biochemistry and Immunoassays divisions of the department.

- a. Verification of QC of all the machines.
- b. Verification & updating stock register.
- c. Verification of handover book of technicians.
- d. Verification & maintenance of monthly stock audit.
- e. Send the purchase indents every month in the 3rd week, after stock auditing.
- f. Personal follow up with the purchase department and BME regarding purchase of reagents and maintenance of equipments.
- g. Verification of NABH documentation along with Lab in-charge.

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7.3 Laboratory Technicians: Execute Quality Assurance procedures laid down in the Quality Manual.

- a. Collection, transportation, processing and preservation of biological samples and documentation of the same.
- b. To perform various kinds of laboratory investigations as per protocols/guidelines/instructions laid down in the documented procedure sheets/manuals.
- c. Daily/Weekly maintenance of equipments scheduled under preventive maintenance process or as per demands of the situation/instructions of divisional heads.
- d. Calibration of parameters as per approved procedures and protocols.
- e. To supervise housekeeping in the Lab adhering with safety standards as applicable.
- f. To update the NABH files assigned to them.

7.4 Phlebotomist: The phlebotomist represents the laboratory and should uphold the quality standards of Laboratory. He / she should always bear in mind that his conduct and actions on duty towards the patient and Doctor directly reflects the quality assurance standards given by the Laboratory. Principal responsibility includes Patient preparation, specimen collection, specimen storage and specimen dispatch. Additionally an efficient and courteous handling of queries, clear communication about specimen requirements, test schedule, report delivery time must be done in proper steps to minimize confusion and delay of these services

7.5 Computer operator: The computer operator is responsible for entering the test results into the software format containing patient's details after verifying the patient's identification number.

7.6 Staff of dispatch center: Staff of dispatch center shall dispatch the reports after verifying the patient's details in the bill copy brought by the patient/patient's attender and document the same.

7.7 Laboratory Attendants: To carryout daily Housekeeping /waste management activities. To assist Lab technician for the collection, transportation, preservation and disposal of biological samples. To ensure un-interrupted supply of consumables/re-usable as per demand of the work flow. To provide items for reuse after recommended washing, cleaning and drying.



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8.0. DEPARTMENT WORKING HOURS: Each shift duty shall have the following staff on duty.

Sl. No	Designation	Shift timings
1.	Biochemist	9 am to 4 pm
2.	Lab In-charge	9 am to 4 pm
3.	Lab Technician	9 am to 4 pm
4.	Lab Technician	2 pm to 8 pm
5.	Lab Technician	4 pm to next day 9am
6.	Lab Technician	9 pm to next day 9am
7.	Lab Assistant	9 am to 4 pm
8.	Cleaning Staff	9 am to 4 pm

9.0 REFERENCE TO NABH STANDARDS:

S.No	Chapter	Relevant NABH Standard / Objective Element
1.	Access assessment and continuity of care	The organization has a well defined registration and admission process AAC.2. A – E.
2.	Access assessment and continuity of care	Laboratory services are provided as per the scope of services of the organization AAC 6. A – H.
3.	Access assessment and continuity of care	There is an established laboratory quality assurance programme. AAC 7. A – E.
4.	Access assessment and continuity of care	There is an established laboratory safety programme. AAC .8. A – E.
5.	Access assessment and continuity of care	Patient care is continuous and multidisciplinary in nature AAC.13. A – F.



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6.	Patient rights and responsibility	A documented procedure for obtaining patient and / or family's consent exists for informed decision making about their care. PRE .4 A – H.
7.	Hospital infection control	Proper facilities and adequate resources are provided to support the infection control programme HIC.5. A – D.
8.	Hospital infection control	Statutory provisions with regard to Bio medical waste(BMW) management are complied with HIC.8.A – F.
9.	Continuous Quality Improvement	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tool for continual Improvement. CQI.3.
10.	Continuous Quality Improvement	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tool for continual improvement CQI.4.
11.	Responsibility of Management	The service provided by each department are documented ROM.3.

10.0 POLICIES:

10.1 Scope of Services: Laboratory services are provided as per the scope of services of the organization.

10.1.1 Clinical Biochemistry. The Department of Laboratory Medicine of RRMCH & hospital is performing following lab investigations. **(ANNEXURE -I).**

10.1.2. Parameters not analyzed in the laboratory shall be outsourced to Thyrocare Laboratory. **(ANNEXURE II).**

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10.2. General Protocol of Laboratory services:

- a. Samples from both in-patients and out patients collected by phlebotomist following clinician request, shall be bar coded and brought in sample collection box in a safe and secure manner by the attenders to the sample receiving room of Biochemistry laboratory.
- b. Samples along with the request form and bill shall be received and details entered in the OP and IP registers by the sample receiving technician after checking for the patient particulars, labeling, adequacy and integrity of the sample. If any sample has not fulfilled the required criteria, it shall be rejected (policy for rejection criteria) mentioning the reason for rejection in the book brought by the attender and the same is documented in the sample rejection file.
- c. Sample shall be centrifuged and sent to analyzing room for analysis. Parameters which are outsourced shall be preserved and later collected by the personnel of Thyrocare laboratories which shall be documented.
- d. Samples shall be analyzed after daily maintenance of the instruments and when internal quality control is found to be within range. Depending upon the parameters requested by the clinician the sample shall be analyzed in various instruments. All the tests are done as per the protocol of standard test procedures which are available.
- e. After samples are analyzed results shall be noted down by the technician in separate note books kept for individual instruments.
- f. If any critical values are observed, they shall be reported to the concerned department over the phone and documented.
- g. Computer operator shall generate the overall biochemistry report of the particular patient.
- h. The final report cross checked and signed by the technician shall be interpreted and signed by the biochemist before sending it to the dispatch centre.
- i. Signed reports of both in-patient and out-patient reports shall be collected by the concerned attenders from the Dispatch counter and documented.
- j. All the results of the laboratory investigations are available for the physicians or patients as per the time frame according to the laboratory test schedule.



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10.3 Policy for hospital postings

- HOD shall supervise both College & Hospital.
- Teaching staff are regularly posted on 4(four) months rotation to the hospital clinical laboratory.
- One Professor and two Assistant Professors are posted on rotation and one Tutor posted permanently in the clinical laboratory.
- Working hours: 9am-4pm.
- Staff posted to the laboratory attends Academic Sessions (Theory Classes, PG Seminars and Journal club) as and when required in the College.
- Post Graduates are posted on rotation for a period of 6 months.
- On rotation one staff and one post graduate are posted on Sundays and holidays.

10.4 Policy For Holiday And Night Duty Postings

10.4.1 For Faculty:

- Holiday duty roster shall be prepared by the Lab In-charge.
- All the teaching faculty of the Department of Biochemistry shall be posted to do holiday duties between 9am to 1pm on rotation basis.
- Consolidated duty roster of all the three Departments (Biochemistry, Pathology and Microbiology) shall be prepared by the central laboratory in-charge and then signed by HODs of all the three Departments and Medical Superintendent.
- Final duty roster shall be sent to all the three laboratory Departments for execution of the duty and also sent to the Clinical Departments for information.
- In case of emergency, duty shall be exchanged with lab In-charge permission, documented and the same send to the Medical superintendent.

10.4.2 For Technicians

- All technicians of the department of biochemistry shall be posted to do holiday duties on rotation basis in two shifts-9am to 4pm(two technicians) & 4pm to 9am (one technician)
- Two technicians shall be posted to do night duties on rotation basis.
- Duty roster shall be prepared by the senior technician in the last week of every month and shall be approved by lab in charge.
- Duty roster signed by the HOD shall be sent to the Central laboratory In-charge



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- e. Consolidated duty roster of all the three Departments (Biochemistry, Pathology and Microbiology) shall be prepared by the central laboratory in-charge and then signed by HODs of all the three Departments and Medical Superintendent
- f. Final duty roster shall be sent to all the three laboratory Departments for execution of the duty and also sent to the Clinical Departments for information.
- g. In case of emergency, duty shall be exchanged with lab In-charge permission, documented and the same send to the Medical superintendent.

10.5 Induction Policy for new teaching staff

10.5.1 Induction of new teaching staff

- a. Introduction to teaching and non-teaching staff in the department.
- b. The new staff shall work under the supervision of the Lab In-charge.
- c. They shall be oriented regarding the Quality Management System in the laboratory
- d. They shall be oriented to the routine workflow.
- e. The new staff shall receive training on various instruments by the respective application specialists.
- f. After orientation, they will be posted with a senior staff.
- g. The staff shall sign the reports after completion of orientation.

10.5.2 Induction of new technicians

- h. Introduction to teaching and non-teaching staff in the department.
- i. Initially Senior lab technicians shall give orientation program regarding the various instruments, lab quality policies & procedures
- j. Training period shall vary from 1 month to 1½ months depending on the experience of the appointed technician (1 month for experienced & 1½ months for fresher)
- k. They shall be exposed to various operations in the laboratory step wise under the supervision of one for the senior technicians
 - a. Sample processing for 1 week (centrifuge & sample arrangement)



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- l. Semi auto analyzer } 1 week
 - a. Electrolyte analyzer }
- m. OP Sample collection } 1 week
 - a. IP Sample collection }
 - b. Auto analyzer- BECKMAN CULTER AU480 - 1 week
 - c. Auto analyzer- BECKMAN CULTER ACCESS 2 - 1 week
- n. If found satisfactory he/she shall be allowed to conduct routine lab investigations
- o. Then he/she shall be posted to collection center for 1 month
- p. He/she shall be allowed to do night duties & holiday duty after 2 months.
- q. The Training Schedule of the technicians shall be documented.

10.6 Policy To Procure Instrument On Rental Basis

Following criteria shall be considered to select instruments for the Laboratory

1. Sample load
2. Random access capabilities
3. STAT functions
4. Turn- around time
5. Full test menu
6. Availability of service
7. No of hospital/laboratories are using the instrument
8. Type of instrument – open or closed
9. Level of automation
10. Clot/clog detection
11. Auto dilution
12. Operator friendly
13. What does the software do?
14. How will it interact with the lab's LIS?
15. Memory
16. Financial/economy of the instrument



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17. What is the maintenance cost?
18. What quality control (QC) package is included?
19. How easy is the QC to review for techs?
20. What is in development?
21. Will this instrument meet a lab's needs for the next 5 years?

We will go and visit the laboratories using the instrument of interest and enquire about their performance.

10.7. Policy for indenting reagents and consumables

10.7.1 Policy for indenting reagents

- a. Indent is sent every month as per the format provided by the purchase department
- b. This format is filled in the third week of every month after taking a stock audit of the reagents present in the lab.
- c. Number of reagent kits required is calculated by evaluating previous month's consumption.
- d. This list shall be signed by the Laboratory in-charge, HOD and sent to the hospital stores for further processing.
- e. Depending on the requirements of the laboratory, reagent kits shall be indented and brought to the laboratory from the hospital stores, and documented in the "reagent consumable book", checked for expiry date and stored at the temperature recommended by the manufacturer.
- f. The kits with long expiry shall be arranged at the back and near expiry, in the front of the refrigerator/cupboard.
- g. Two technicians shall be assigned to check for day to day reagent requirement, if any reagents are required they shall be taken from the lab main stock and documented.
- h. In the event of excess consumption of the reagents, emergency indent shall be sent to the purchase department
- i. Reagent handover book shall be maintained.



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10.7.2 Policy for indenting consumables other than reagents

- Depending on the monthly requirement, a separate indent shall be made for consumables other than reagents such as tips, centrifuge tubes, Eppendorf tubes, cotton swabs and sample cups etc.
- This list shall be signed by the laboratory in-charge, HOD and sent to the hospital stores for further processing.
- Depending on the requirements of the laboratory, consumables shall be indented and brought to the laboratory from the hospital stores, and documented in the “reagent consumable book”.

10.8. Policy For Temperature Log Monitoring In The Laboratory

- The temperature & humidity of the laboratory analyzing room shall be checked & documented in the temperature log sheet twice daily at 9am & 3pm respectively.
- The temperature of the analyzing room shall be maintained between 15°C - 25°C.
- The humidity of the analyzing room shall be maintained between 40 % - 60 %.
- Temperature of the refrigerators shall be maintained between 2°C – 8 °C & temperature of the freezers shall be maintained below -20°C.
- Temperature of the refrigerators & freezers containing the reagents, calibrators, quality control material & stored patient samples shall be monitored & documented in the temperature log sheet twice a day at 9am & 3pm respectively.

10.9. Equipment Maintenance

10.9.1 Policy For Beckman Coulter Au480 Equipment Maintenance

- Daily maintenance shall be done & documented in the daily maintenance “start of the day” log sheet.
- When indicated in the analyzer, weekly maintenance shall be done with acid or hypochlorite on alternate weeks & the same shall be documented in the weekly maintenance log sheet.



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- c. When indicated in the analyzer, monthly maintenance shall be done & the same shall be documented in the monthly maintenance log sheet.

10.9.2 Policy For Access 2 Equipment Maintenance

- a. Daily maintenance shall be done & documented in the daily maintenance of access 2 maintenance log sheet.
- b. Weekly maintenance shall be done on every Thursday & same shall be documented under weekly maintenance of access 2 maintenance log sheet.
- c. System check shall be done after weekly maintenance & observed for the system check results & same shall be documented in the system check results of access 2 maintenance log sheet.

10.9.3. Policy For Erba XI 640 Equipment Maintenance

- a. Daily maintenance shall be done & documented in the daily maintenance “start of the day” log sheet.
- b. At the end of every day before switching of the analyzer daily maintenance shall be done & documented in the daily maintenance “end of the day” log sheet.
- c. Every Monday, weekly maintenance shall be done & same shall be documented in the weekly maintenance log sheet.

10.9.4. Policy For Aquaplas Rotech Plant Of Beckman Coulter Au480 Maintenance

- a. Everyday, Conductivity shall be checked from the LED display of Aqua plus Rotech water plant half an hour after switching on the instrument & same shall be documented.
- b. Every Monday and Thursday maintenance shall be done according to standard protocol & same shall be documented.



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10.9.5 Policy For Roche Electrolyte Analyser Maintenance

- a. Daily maintenance shall be done & documented in the daily maintenance “start of the day” log sheet.

10.9.6. Robonik Prietest Semi automated Analyzer Maintenance

- a. Daily maintenance shall be done & documented in the daily maintenance “start of the day” log sheet.
- b. Every Monday, weekly maintenance shall be done & same shall be documented in the weekly maintenance log sheet

10.10. Policy For Calibration Of Parameters

Calibration for various laboratory parameters will be done:

- a. As per manufacturer’s instructions.
- b. Following a change in reagent lot.
- c. Following major instrument maintenance.
- d. Following replacement of a critical machine part.
- e. In case of significant shift in control values.

10.11. Policy for IQAS and EQAS

10.11.1 Policy for Internal Quality assurance programme

- a. The laboratory purchases Assayed Internal Quality Control materials from BIORAD for Internal Quality Assurance Programme.
- b. Internal Quality Control is performed for all general chemistry parameters, serum electrolytes, Glycated haemoglobin, Hormones and Vitamins once a day in the morning before processing patient’s sample.
- c. Two levels of control shall be run for each parameter once daily.
 - a. Lyophilized vials of both the levels shall be reconstituted with 5ml of distilled water and 5ml of reconstituted quality control is aliquotted into 10 vials (each 500µl) and kept in the freezer.



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- d. After daily maintenance, one aliquot from both the levels are brought to the room temperature and mixed thoroughly with gentle inversions.
- e. All the above mentioned parameters are analyzed in all the instruments.
- f. If the value obtained is within the range, results are considered satisfactory and patient samples are processed.
- g. If the values fall out of range, the controls are repeated after checking the possible sources of variation and employing corrective measures.
- h. Once satisfactory results are obtained, patient samples are processed.
- i. Same shall be documented daily in internal quality register kept for the individual instruments.

10.11.2. Policy for External Quality assurance programme

- a. The laboratory is enrolled with BIORAD for External Quality Assurance Programme.
- b. All the routine biochemistry parameters, HbA1c, Serum electrolytes, Hormones and Vitamin are included in external quality assurance programme.
- c. Enrollment has to be renewed every year.
- d. Twelve samples (one sample to be processed/month) are sent by the BIORAD mentioning last date to perform the test.
- e. On the day of performing external quality control, lyophilized sample to be processed for that month shall be brought to the room temperature and reconstituted with distilled water.
- f. After daily maintenance and internal quality assurance programme, sample is analyzed for all the routine biochemistry parameters in both general chemistry auto analyzers (Erba EM 640 and Au-480 Beckman Coulter), electrolytes in both the electrolyte analyzers (I –smart and Roche), Hormones and Vitamins in Access 2 Immunoassay analyzer and HbA1C in BioRad D-10.
- g. The values shall be uploaded online in the Biorad EQAS web site (www.qcnet.com) before the last date of that particular month
- h. The statistically analyzed report from BIORAD shall come in the first week of every month which shall provide the result of each analyte in the form of Z score.
- i. Root cause analysis shall be done for the parameters whose Z score is >2



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- j. If the Z score is >2 but <3 and it's for the first time the parameter shall be kept under observation and if the Z score is >3 Proper action shall be taken (inform service engineer of that particular instrument)
- k. Same shall be documented in EQAS file.
- l. Parameters not covered under EQAS shall be covered under Interlaboratory Comparison where samples processed in our lab will be sent to two other NABH/NABL accredited laboratories and their results compared with our results. The same shall be documented.

10.12. Policy For Monitoring CV %

10.12.1. Policy For Monitoring CV % Of Beckman Coulter Au480

Biorad lyphochek assayed chemistry control L1 & L2 for all the parameters shall be done daily.

- a. "Day to Day" QC chart" in the instrument shall be checked for monthly Mean, SD & CV % of all the parameters & same shall be documented.
- b. CV % goal $<5\%$ shall be achieved.
- c. If CV% is $>5\%$, root cause analysis & corrective action shall be taken.

10.12.2. Policy For Monitoring CV % Of Beckman Coulter Access 2

- a. Two levels of Biorad lyphochek immunoassay control (out of 3 levels) shall be done as follows(each combination shall be run for 20 days),
 - 1. L1 & L2
 - 2. L2 & L3
 - 3. L3 & L1
- b. Two levels of QC for T3, T4, TSH shall be done daily. Two levels of QC for FT3, FT4 and Ferritin shall be run only if the patient samples for those parameters are received.
- c. Two levels of QC for FSH, LH, Prolactin. Vitamin B₁₂ & Insulin shall be run twice a week on Tuesday & Friday only if patient samples of that particular parameter are received.
- d. Biorad liquichek speciality immunoassay control L1 & L2 for Vitamin D3 shall be run on every Tuesday & Friday only if patient sample is received.



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- e. Quality control review chart & data in the instrument shall be checked for monthly Mean, SD & CV % of all the parameters & same shall be documented.
- f. CV % goal <10% shall be achieved.
- g. If CV % is >10%, root cause analysis & corrective action shall be taken.

10.12.3. Policy For Monitoring CV % Of Biorad D10

Biorad lyphochek diabetes control L1 & L2 shall be done daily.

- a. Data shall be tabulated in Microsoft excel. Mean SD & CV % shall be calculated.
- b. CV % goal < 3 % shall be achieved.
- c. If CV% is >3 % root cause analysis & corrective action shall be taken

10.12.4. Policy For Monitoring CV % Of Roche Electrolyte Analyser

- a. Biorad lyphochek assayed chemistry control L1 & L2 for all the parameters shall be done daily.
- b. Data shall be tabulated in Microsoft excel. Mean SD & CV % shall be calculated.
- c. CV % goal <5% shall be achieved.
- d. If CV% is >5%, root cause analysis & corrective action shall be taken.

10.12.5. Policy For Monitoring CV % Of Erba XI 640

- a. Biorad lyphochek assayed chemistry control L1 & L2 for all the parameters shall be done daily.
- b. "Tests statistics" in the instrument shall be checked for monthly Mean, SD & CV % of all the parameters & same shall be documented.
- c. CV % goal <5% shall be achieved.
- d. If CV% is >5%, root cause analysis & corrective action shall be taken.



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10.13. Policy For Harmonization Of Test

When there is a change in the lot number of any reagent, one sample processed with old lot reagent shall be reprocessed with the new lot reagent, to check the reproducibility of that parameter. The same shall be documented in the Test Harmonization File.

10.14. Policy For Rejection Of Samples

Samples shall be rejected based on the following criteria.

1. Sample Labeling Rejections

- Unlabelled sample
- Labelled with more than one number/Name
- Requisition & sample labeling mismatch

[Name/age/OP or IP no parameters]

2. Sample Integrity Rejections

- Incorrect vacutainer or preservative that would invalidate results.
- Insufficient quantity of sample for analysis
- Hemolysed samples
- Two samples received with same labeling
- Leaky vacutainers

The concerned staff (Collection centre/wards) shall be informed about the same and shall be documented in the sample rejection file.



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10.15. Policy For Repeating The Tests (Re-Dos)

Testing of a patient's result shall be repeated under the following circumstances.

- When the test value is in the Critical Range.
- If requested by the treating clinician (tests results not correlating with the diagnosis).
- When the test results vary significantly from previous tests results of the patients (routinely done for In-patients).
- Wrong sample ID

10.16. Policy For Reporting Critical Values

A list of all critical parameters will be documented and laboratory staff made aware of the same.

- When a critical value is identified, the sample will be rerun to confirm the test result.
- The critical value will be communicated immediately to the concerned ward by telephone.
- If a response is not received from the ward, the value will be communicated to the Post graduate/Staff on duty, failing which, the Head of Unit will be informed.
- Root cause analysis will be done and corrective action will be taken for tests results not correlating clinically.
- Documentation of all critical values will be done and reviewed on a monthly basis.

10.17. Policy For Handling Reporting Errors

Reporting errors include typing errors, decimal errors, incorrect units and incorrect calculation of results. In the event of a reporting error, following measures will be undertaken.

- Following identification, the correct report will be generated and the erroneous report will be filed in the reporting errors file along with a copy of the amended report.
- Total number of reporting errors will be documented and reviewed on a monthly basis.
- Training will be given to all laboratory staff on identifying and rectifying reporting errors.



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10.18 Policy for Recall of Reports

In the event of a complaint made by the Clinician about the test results, the concerned report shall be recalled and a root cause analysis will be done to address the complaint. The same shall be documented.

10.19. Policy for Outsourcing Investigations

- The institution has signed an MOU with Thyrocare which is renewed every year.
- The investigations that are outside the scope of our services are outsourced to Thyrocare lab.
- A list of outsourced investigations is maintained in the laboratory. The same is periodically reviewed and communicated to all clinical departments.
- Samples sent from the wards and collection centre are received by the clinical biochemistry laboratory staff and dispatched to Thyrocare from the premises after ensuring cold chain is maintained .
- Reports of the test are received by the biochemistry laboratory staff and dispatched to the wards and collection centre after recording the results.
- All the outsourced investigations are documented and a record of the results is maintained.
- Related Files/Registers -Thyrocare register maintained

10.20.1 Policy for Dispatching of Reports

- Printed reports will be verified and signed by Signatory Authority of Biochemistry Department.
- Verified and signed reports will be sent to the Dispatch Center.
- Out- Patient reports will be given to the patient/patient's attender after verifying the bill copy and documentation in the dispatch register.
- In- Patient reports will be given to the hospital attender / patient's attender after verifying the bill copy or the ward book and documentation in the dispatch register.
- In the dispatch register, the name of the person collecting the report will be mentioned in front of patient ID (IP/OP) number, age, sex and the name of investigation.



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10.20.2 Turn Around Time/ Time of Reporting

The time interval between receiving the sample in the laboratory up to the generation of the report.
(Refer to ANNEXURE IV)

10.21. Policy For Laboratory Safety

10.21.1 Policy For Disposal Of Reagent Bottles & Kits

- The reagent bottles in the kit shall be checked for the volume of reagent remaining in the bottle. If found insufficient the remaining dead volume shall be discarded into the sink
- Excess of water shall be flushed into the sink
- Empty bottles shall be discarded into red plastic waste bag for further disposal by the Department of Biomedical waste management
- The bottle/kit contains the date of opening and date of consumption of reagent
- Electrolytes cartridge shall be sent to the stores for further procurement of packs
- The kit cartons shall be disposed in the general waste bin (black cover)
- The kit opened & closed date shall be entered in the kit in use log book (kit details)

10.21.2. Policy For Disposal Of Samples

Vacutainers containing processed samples are refrigerated at 2 – 8°C for minimum of 24 hours after analysis. Then the sample is discarded into the sink connected to the Effluent Treatment Plant which goes to the Sewage Treatment Plant. The sample tubes are discarded in red bag and sent to Biomedical Waste department for further disposal.

10.21.3. Policy For Management Of Needle Stick Injury/Blood Fluid Exposure

- Follow the needle stick/ splash protocol given in Lab safety manual
- Inform to the Lab In-Charge about the incident.
- Report to HICC officer (Hospital Infection Control Committee officer).
- Document the exposure in the register maintained.



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10.21.4. Policy for use of Personal Protective Equipment.

All laboratory staff are supposed to wear Gloves, Masks, Aprons and Caps while handling samples.

10.22. Policy for condemnation

10.22.1 Policy for condemnation of instruments

- a. A letter shall be sent to biochemical engineer to assess the working condition of the instrument.
- b. BME will assess the working condition of the instrument.
- c. After assessing they will categorize the instrument as
 1. Working
 2. To be repaired
 3. To be condemned
- d. Condemned instrument shall be sent to the biomedical department with acknowledgement.

10.22.2 Policy For Disposal Of Old Biochemistry Medical Records

- a. Used OP & IP sample receiving registers shall be retained in the clinical laboratory for a period of one year after which they shall be sent to Medical Records Department (MRD)
- b. Test requisition forms shall be sent to MRD once in 3 months
- c. Reports of outsourced tests which are not collected by the patients shall be retained in the clinical laboratory for a period of one year after which they shall be sent to MRD.

10.23. Policy For Professional Development Activity

10.23.1. Teaching Staff

- a. Faculty members shall undergo training in Quality Management System.
- b. Faculty members shall receive training regarding the principles and usage of the instruments in the Clinical Biochemistry Laboratory by respective application specialists.
- c. The Department shall organize a minimum of one CME / Conference in a year.



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- d. Faculty shall be encouraged to attend CME and Hands on Workshops as a part of professional development activity.
- e. Faculty members shall be encouraged to take up STS projects sponsored for the students.
- f. Faculty members shall be encouraged to apply for Extramural Funded projects.
- g. Relevant documents regarding all the above shall be maintained by the department.

10.23.2. Non -Teaching Staff

- a. Non- teaching staff shall attend minimum of one CME /Hands on workshop per year.
- b. Non -teaching staff shall attend monthly training programme conducted by the department.
- c. All Non- teaching staff shall receive training regarding the principles and usage of the instruments in the clinical Biochemistry laboratory by respective application specialists.
- d. Relevant documents regarding all the above shall be maintained by the department.

10.24. Policy for Research Projects

- a. Procurement of reagent kits, calibrators and control shall be done in consultation with the Department of Biochemistry to ensure compatibility of kits with the machines.
- b. Processing of project samples will be done only after calibration and controls are satisfactory, as is done for patient samples.
- c. Samples will be processed on days when routine sample load is less so that the hospital reports are not delayed due to the project.
- d. A separate register shall be maintained in the clinical laboratory, for the projects.
- e. The lab shall support UG, PG, ICMR projects and analyzing camp samples and registers are maintained for these projects.

10.25. Policy For Yearly Calibration Of The Instrument

Pipettes and thermometers used in the laboratory shall be sent for yearly calibration. A record of calibration report will be maintained in the laboratory.



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11.0 PROCEDURES:

11.1 Sample collection Procedure:

11.1.1 Purpose: To provide guidelines on sample collection.

11.1.2 Scope: Applicable to all laboratory divisions.

11.1.3 Responsibility: The responsibility of Phlebotomist: The phlebotomist shall be qualified and trained personnel. He / she shall always bear in mind that his conduct and actions on duty towards the patient and Doctor directly reflects the quality assurance standards given by the Laboratory. Principal responsibility includes Patient preparation, specimen collection with aseptic precautions.

11.1.4 Labeling the samples: No sample / specimen shall be collected or allowed without proper labeling. The tests requested on the Requisition Form shall be verified before proceeding with the collection.

11.1.4.1 Name of the patient. Age & gender. OP/ IP number. Date. Consultant's name. Investigations required. Clinical history of the patient.

11.1.4.2 The phlebotomist shall check for the following information before sample collection: Specimen requirement and quantity. Special collection instructions like preservatives & sterile containers to be used.

11.1.5 Allotting Lab ID & Labeling: After receiving request form, Check whether the Bill was raised properly for the required tests or not. Enter the Bill number, patient details and test particulars in the Reception Register and allot an individual Lab ID for the specific patient sample. Note down the time of specimen collected / received. Note down the type of patient, i.e., Outpatient or Inpatient. Label the vacutainers and other collection vials with the Lab ID allotted and specimen type. Collect appropriate specimen and quantity so as to avoid redraws and inconvenience to the patient. If the patient require investigations



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with urine and other specimens, label the required container with proper Lab ID and ask the patient to collect the sample in that particular container.

11.1.6 Basic steps for drawing a blood specimen: Sample collection step by step procedure

11.1.6.1 Check and confirm with the patient details given on the requisition form.

Assemble the vacutainers, collection vials, spirit swab, and tourniquet etc, required for phlebotomy. Make the patient to sit comfortably on a chair.

11.1.6.2 Selection and preparation of vein site for blood collection: For most vein puncture procedures on adults, veins located on the arm are used. The median cubital vein is most commonly used.

11.1.6.3 The following conditions shall be avoided while selecting a vein: Vein from area having extensive scarring. Phlebotomy must not be performed on any site of hematoma. Blood shall not be collected from the arms having intravenous line.

11.1.6.4 Locating Veins: To locate veins it is necessary to palpate and trace the path of the vein several times with index finger.

11.1.6.5 Alternate site: Site such as dorsal wrist or hand and ankles or lower extremities may be required for patients with difficult veins.

11.1.6.6 Applying a tourniquet: A tourniquet is used to increase venous filling. This makes the vein more prominent and easier to enter. Wrap the tourniquet around the arm 3 to 4 inches above the vein puncture site. The tourniquet should never be left on the arm for more than 2 minutes, because it prevents blood from flowing freely. After blood has been drawn, the patient should release the fist and the tourniquet is also released and then the needle is withdrawn from the vein with simultaneous application of cotton at the vein puncture site.

11.1.6.7 Cleaning of the vein puncture site: The puncture site must be cleansed to prevent microbiological contamination of the specimen and infection at the



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vein puncture site. A cotton ball shall be soaked in the spirit, excess shall be dripped away. The cleaning shall start from the vein and move out in circular motion towards the outer surface. Once disinfected, this site shall not be touched with bare hands.

11.1.6.8 Preventing Hematoma during vein puncture: The tourniquet shall be released after no more than one minute.

11.1.6.9 After dismantling the needle the blood should be transferred to the n-vac tube containing sodium fluoride and EDTA for Plasma Glucose and Glycated Hemoglobin estimation and to red capped n-vac tube containing clot activator for estimation of serum Renal profile, Lipid profile, Liver function tests, cardiac profile, electrolytes, Uric acid, calcium, magnesium etc.

11.1.6.10 Collection of blood from pediatric patients: Pediatric collections shall be done with the help of scalp vein needle.

11.1.6.11 Procedure to be followed post blood sample collection: A cotton ball is held firmly over the vein puncture site as soon as the needle is removed. After checking that there is no blood flow, the patient is given permission to go.

11.1.6.12 Patient preparation for various tests:

11.1.6.12.1 Fasting blood glucose: Fasting period of 8 – 10 hours required.

11.1.6.12.2 Post prandial blood glucose: Collect sample between 1.5 after completion of meals.

11.1.6.12.3 Lipid profile: 8-10 hours of fasting is required.

11.1.6.12.4 Thyroid Hormone, AFP, CEA & PSA etc - Random blood sample.

11.1.6.12.5 Cortisol: The blood specimens are collected at 08:00 a.m and 04:00 p.m or the time specified by the physician. The



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timing of blood collection has clinical significance and hence must be clearly specified on the vacutainer.

11.1.6.12.1.6 Glucose Tolerance Test: Starting with fasting condition then glucose load given (75gms of glucose in approximately 300ml of water). Then every half an hour blood & urine samples are collected for two hours.

11.1.6.12.1.7 Urine collection for routine Exam: Early morning & mid stream sample.

11.1.6.12.1.8 24 hours urine collection: With preservatives collected in a specific bottle. Patient shall be instructed to collect 24 hour urine sample in a 5 litre clean container containing preservative 10ml of 6N HCl. Eg. The patient shall be asked to empty the bladder at 8 a.m. in the morning. This sample shall be discarded. Thereafter patient shall collect the urine till the next morning 8 a.m. The 8 a.m. morning sample of urine shall be collected. Thus 24 hour urine sample shall be collected.

11.1.6.12.1.9 Collection of body Fluids (Pleural fluid, Ascitic fluid, peritoneal fluid, synovial fluid and cerebrospinal fluid) done by clinicians in their wards/minor OT under strict aseptic precautions.



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11.1.6.13 Containers to be used for estimation of biochemical parameters: Refer to ANNEXURE V

11.1.6.14 Anticoagulants for various investigations: Refer to ANNEXURE VI

11.1.6.15 Transporting samples to the Main Lab: The samples collected in the wards shall be placed in the sample collection box provided. Samples or sample containers shall not be carried without collection boxes. Before sending to the main lab, all the specimens shall be rechecked for proper labeling and Lab ID shall be given. Specimens in the sample collection box shall be handed over in the main lab along with the prescription & the bill.

11.1.6.16 Processing of the blood sample in the biochemistry laboratory: Blood sample received from the collection centre shall be checked for patient particulars and particulars shall be entered in the Main lab register. Samples shall be processed (centrifuged for 1500 rpm for 10-15 minutes) and the serum/plasma separated. Serum shall be observed for the amount and hemolysis before further processing. The samples shall be analyzed in fully automated analyzers depending upon the investigations asked. The outsourced samples shall be checked for patient particular and hemolysis and entered in the Thyrocare register. Thyrocare request forms shall be filled to be sent along with the patient samples. The separated serum samples shall be stored in the refrigerator (at 2-8 degree centigrade) till the thyrocare personnel shall come and collect.

Dispatching Laboratory Reports:

The results are 1st entered in the respective analyzer books. Then they are entered in the main lab register. Computerized lab reports will be generated by the computer operator. The patient's particulars, results are cross checked and



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signed by the technician and the Biochemist before the patient/patient attenders/ward attenders.

11.1.6.17 Turnaround Time: For the time of reporting, Please refer to ANNEXURE IV.. It is the time from the time of sample receipt till the report is ready for dispatching

11.1.6.18 Rejection criteria for unacceptable samples: The samples must be rejected for the following reasons: Insufficient quantity of the sample, If the specimen quality is not acceptable (hemolysed / clotted etc.), incorrect specimen type and test name, if the test is cancelled either on request of the patient or doctor, in case of invalid results got for various technical reasons, (A repeat, fresh sample shall be collected and sent for testing). In the event of unforeseen circumstances like non-availability of kits, failure of test runs, instrument break down, etc, in case if the samples are not collected in clean containers with proper preservatives for urine analysis.

11.2 Critical tests:

- 11.2.1 Purpose:** To ensure immediate reporting of critical values / results to appropriate care providers to enable provision of timely, appropriate treatment to the patient.
- 11.2.2 Scope:** All critical cases.
- 11.2.3 Responsibility:** All laboratory Technicians.
- 11.2.4 Definition:** A critical test is defined as a stat test with critical values/ results or other results that are determined by the laboratory to be critical to the patient's subsequent treatment decisions.
- 11.2.5 Procedure:** All critical results and critical values must be informed immediately to the Consultant or attending physician (Medical officer) or ward in-charge. Documentation of the call including time and date and who received the critical value/result must be made as a permanent part. All shall be recorded in critical report intimation register properly.

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Critical values: Critical Limits For Urgent Clinician Notification (ANNEXUREVII)

11.3 Outsourcing Tests: Purpose: To establish Standard Operating Procedures for Outsourced Laboratory Tests.

11.4 Scope: The tests which are not processed in our lab have been outsourced.(ANNEXURE II)

11.5 Laboratory Quality Assurance Programme:

11.5.1 Purpose: The Quality Assurance manual for clinical laboratory performing clinical biochemistry tests provides the details of quality assurance practices followed in the Laboratory.

11.5.2 Scope: These guidelines, policies and procedures describe quality assurance activities that laboratories shall follow to ensure its competency, quality and integrity of its reports. The scope of the manual extends to the tests performed in the Laboratory Medicine Units – Clinical Biochemistry.

11.5.3 Responsibility: All Laboratory Staff.

11.5.4 Definitions & Abbreviations: As used in these guidelines, the following terms have the meanings specified:

Audit is an inspection used to evaluate, confirm, or verify activities related to quality.

Calibration is a set of operations that establish, under specified conditions, the relationship between values provided by a measuring instrument, measuring system, and a known material or known values.

Control samples or known samples are test materials whose identity, type, or values have been established are used to assess the performance of a laboratory or an individual(s).

Quality assurance is the system of management activities designed to ensure that a process item, or service is of the type and quality needed, this includes monitoring



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activities that are intended to verify whether practices and test results are providing reliable and relevant information. **Quality control** is a mechanism or laboratory activity intended to verify whether test conditions are functioning appropriately to yield reproducible results.

Quality manual is a document stating the quality policy, quality system, and quality practices of an organization. **Validation** is a process by which a procedure is evaluated to determine its efficacy and reliability for analysis.

11.5.5 Procedure:

11.5.5.1 Organizations and Management: Medical Team: consists of HOD, Laboratory in-charge and Biochemist

11.5.5.2 Documentation Requirement: It is important for the hospital to maintain control over the distribution, updating, and storage various documents. This is to make sure that the staff receive and use proper and the latest systems and procedures and related material. An effective document control will result in reduced costs by helping eliminate wasted effort and material due to the use of improper documents. It will also ultimately result in increased business due to customer satisfaction from getting expected services. The following are the four levels of documents introduced as part of Quality Management System and being implemented and controlled: Quality Assurance Manual. Laboratory Safety manual. Standard operating procedures and policies for each tests. Work instructions.

11.5.5.3 Document Approval and Issue: To avoid using documents that are incorrect, inadequate, or unauthorized, it is the hospital's policy that authorized personnel always reviews these documents for adequacy and approves them prior to issue. The pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality



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system are performed, and obsolete documents are promptly removed from all points of issue or use.

11.5.5.4 Sample collection manual: This manual is collection of SOPs, which establishes guidelines for collection of various specimens, based on site of collection of specimen, type of container, identification, Handling and transportation of the specimen. This manual is available in work area and reviewed annually.

11.5.5.5 Standard procedures for all tests: SOPs, which define test performance, reference ranges; specimen acceptability, reagent preparation, QA calculations and reporting of the tests are available in work area and reviewed annually. Required elements include: Step by step performance of the procedure, including test calibrations and interpretation of results. Preparation of solutions, calibrators, controls, reagents and other materials used in testing. Calibration and calibration verification. The reportable range for test results: Quality control procedures. Corrective actions to taken when calibration or control results fail to meet the laboratory's criteria for acceptability. Limitations in the test methodology, including interfering substances. Reference intervals. Imminently life threatening test results (critical values). The system for reporting imminent life threatening results (critical values). Critical results are intimated immediately to the concerned personnel. Procedure manuals may be in hard copy or electronic format (**Ref. Department wise SOPs**).

11.5.5.6 Laboratory safety program: The Laboratory ensures that the appropriate safety techniques are adopted and known to the staff. Laboratory safety manual are available at the work area, and regular staff training is conducted.

11.5.5.7 Facilities: The laboratory is designed to provide appropriate levels of safety, and minimize contamination. Laboratory management shall ensure that: Access



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to the laboratory is controlled and limited. The laboratory follows written procedures for monitoring, cleaning, and decontaminating facilities and equipment. This policy is highlighted clearly in the laboratory safety manual. The laboratory has documented waste management requirements to ensure that appropriate decontamination and disposal measures are in accordance with local/national laws. This policy is described in Laboratory safety manual. The laboratory considers measures to address the following: Back up power sources for power outages to protect evidence from temperature fluctuations, when appropriate. 24 hours emergency notification procedures are advisable. Computer security and backups for data and case documentation records.

11.5.5.8 Quality Management System: The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies evaluates and resolves problems.

a. Pre-analytical system: Test requests and patient identification. Samples are marked with unique identifiers. See sample collection manual. Documentation of sample identity, receipt, storage, and disposition is maintained. Criteria for specimen acceptance: No sample / specimen shall be allowed into the Laboratory without proper Test Request Form (TRF). While receiving the specimens into the laboratory, check for the following information. Each sample must have the corresponding TRF and Bill. Nature of the sample & Quantity of the sample required. Check for the proper labeling and Lab ID allotted. In case of any doubt, the referring doctor may be contacted for further clarification. Separate and distribute the samples to the sections according to the tests required.

Identification of tests required: Note down the test details in the main lab register followed by Lab Work Registers provided in the different analyzer



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sections. Note Lab ID, Name of the patient, Patient type (OP or IP), Ward number if IP and the tests required for the patient. Note down the Time of sample received into the Laboratory.

b. Analytical system: Procedure manuals. **Test systems:** Test systems are selected by the Laboratory. Test systems must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications.

11.5.5.9 Calibration and calibration verification procedures of Equipments: The laboratory uses equipment suitable for the methods employed. The laboratory identifies shall have a documented program for calibration and, when appropriate, monitoring instruments and equipment. The frequency of the calibration is documented for each instrument requiring calibration which is maintained by service engineers of the respective company instruments.

11.5.5.10 Verification and validation of performance specifications: The laboratory compares patient test results for consistency with patient age, sex, diagnosis or pertinent clinical data, and relationship with other test parameters. For each test system, the clinical laboratory has established a control procedure to monitor the accuracy and precision of the complete analytic process. At a minimum, the quality control process will detect: Immediate errors and errors occurring over time. Errors occurring due to test system failure. Environmental condition changes. Operator performance.

11.5.5.11 External Quality Assurance Programme: External quality control materials are used to monitor the accuracy and precision of the test system. The laboratory is enrolled with BIORAD for External Quality Assurance Programme for Biochemistry.



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11.5.5.12 Internal Quality Assurance Programme: For each quantitative procedure, two levels of Biorad quality control material are used (Normal & Pathological), for which values are already known. Calibrators of different lot numbers and concentration are used to calibrate the system.

11.5.5.13 Post – analytic system: Test reporting: The laboratory maintains written procedures for generating and maintaining documentation for tested samples. The laboratory maintains written procedures for the release of tested sample information. The laboratory maintains the following examination documentation: Analyst / technician - generated notes, to include identity of person generating notes. Date and time of analysis completed.

Review of reports: The laboratory follows written procedures for technically reviewing all tested samples information and results. The technical review is conducted by a technically qualified individual other than the preparer of the report, notes, data and other documents under review. Authorized personnel will sign the reports. All the laboratory reports are verified and signed by qualified Biochemist & Lab In-charge. Normal ranges where appropriate are provided. Errors in patient's reports will be corrected in timely fashion.

Complaints about lab investigations: The laboratory has a system in place to ensure that it documents all the complaints and problems reported to the laboratory.

Corrective and Preventive actions: The laboratory follows procedure for corrective action whenever analytical errors and / or proficiency testing discrepancies are detected. The laboratory maintains documentation for the Corrective & Preventive actions

11.5.5.14 Retention period for Specimen, Registers, Reports:

11.5.5.14.1 Storage period of Examined Specimen:

Specimen (plasma/serum/urine/ body fluids)	Duration



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Minimum of 24 hours after analysis

11.5.5.14.2 Storage period for Registers (logs) containing results: 1 year.

11.5.5.14.3 Storage period for uncollected reports: 1 year.

11.5.5.14.4 Storage period for copies of reports of outsourced tests: 1 year.

11.6 Laboratory Safety Programme:

11.6.1 Purpose: To follow good laboratory practices (GLP) to reduce the risk of occupational exposure to infectious agents, hazardous chemicals and to avoid accidents (eg. fire) in the laboratory.

11.6.2 Scope: Applies to all patients who give specimens in the Clinical laboratory.

11.6.3 Responsibility: Head of Department and All lab staff.

11.6.4 Procedure:

11.6.4.1 A. Handling of Specimen:

a. Wearing Gloves: Wear gloves and laboratory coats (Aprons) at all times when handling and processing patient specimen, decontaminating instruments and cleaning. Apply Bandage to open cuts and scratches on the hand and then wear gloves. Wear gloves when performing phlebotomy and handling actual blood specimens. Wash hands immediately after gloves are removed, after a task that involves heavily contaminated matter and before leaving the laboratory. **b. Specimen Transportation:** Always transport specimens to the laboratory in leak proof containers. Do not accept grossly soiled or contaminated specimens. **c. Using syringes and needles:** Use needle-locking syringes or plastic disposable syringe-needle units. Never bend the needles after use, do not recap. Burn the needle with the help of needle destroyer and discard them in the sharps container. Secure blood culture bottles before inserting needles into the bottle (eg., place bottle in support rack). **d. handling test tubes:** Always carry test tubes in the racks provided. Use plastic tubes when possible. Do not use the glass tubes that are broken or damaged. Discard such tubes into the sharps container. **e. Using Centrifuges:** Centrifuge



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tubes must be intact and properly balanced during Centrifugation. Do not place table top centrifuges in the biological safety cabinets. Clean the centrifuge once daily after use, to remove any contaminating material on the inner side of the centrifuge. Do not open lid during centrifugation process. **f. Hand washing:** Frequent hand washing after removing gloves, before leaving the laboratory are absolutely essential. Use non irritating soap for routine washing. Use antiseptic soap or an alcohol based hand disinfectant followed by thorough hand washing for accidental skin contamination.

B. Specimen Transportation: Always transport specimens to the laboratory in leak proof containers. Do not accept grossly soiled or contaminated specimens.

C. Using syringes and needles: Use sterile disposable syringe-needle units. Never bend the needles after use, do not recap. Discard them in the sharps container.

D. handling test tubes: Always carry test tubes in the racks provided. Use plastic tubes when possible. Do not use the glass tubes that are broken or damaged. Discard such tubes into the sharps container.

E. Hand washing: Frequent hand washing after removing gloves, before leaving the laboratory are absolutely essential. Use non irritating liquid soap for routine washing. Use antiseptic soap or an alcohol based hand disinfectant followed by thorough hand washing for accidental skin contamination.

11.6.4.2 Handling Chemicals: Wear appropriate PPE (disposable aprons, gloves and mask etc). when handling hazardous chemicals. Label all reagents with their chemical names and appropriate hazard warnings provided from their Material Safety Data Sheets (MSDS). Keep MSDS for all chemicals either in the laboratory or in the office near by. Store all hazardous chemicals, including chemicals, reagents and dyes, below eye level.

11.6.4.3 Housekeeping and Miscellaneous Safe Practices: Avoid or minimize the activities associated with transmission of infectious agents. Dispose all



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contaminated materials in appropriate color coded & closed bags as per BMW protocol.

11.6.4.4 a. Decontamination: Routine decontamination and cleaning of the work environment is the responsibility of all laboratory workers, particularly of the house keeping staff. To accomplish this work area shall be uncluttered, with clean and unclean materials clearly demarcated and separated. **Procedures for Decontamination: a. Usage of 1% Sodium Hypochlorite solution:** Prepare fresh solution daily. Dispense in wide mouthed large plastic containers. The containers shall be only half full. Place the containers in the designated areas.

b. Decontamination of Work Surfaces: Work surfaces have to be decontaminated at least twice daily, before the work begins and at completion of work. Use a paper towel or a soft cloth soaked with the disinfectant (1% sodium hypochlorite solution). Wipe the work surface going over each area at least twice. Allow to air dry with a minimum contact time of 5 -10 min.

c. Decontamination of Equipments: NOTE: Do not use Alcohol on equipments which are close to open flames (burner). Do not use Sodium hypochlorite on metal parts because they may cause rusting. Do not use Aldehyde based disinfectants as general surface disinfectants.

d. Cleaning of Spills: The staff cleaning the spill shall ensure that they use the appropriate PPE (disposable aprons, gloves and mask etc). Use disposable absorbent pads to wipe off the liquid in the spillage and discard the absorbent in yellow plastic bag. Cover the entire spillage area with appropriate disinfectant (Sodium Hypochlorite). Leave the area for 20 minutes after 20 minutes clean the area with absorbent paper again cover with disinfectant and the wipe off. Wash hands with soap and water.

11.6.4.5 Disposal of Waste: Proper waste disposal and management of biohazardous wastes is essential to limit the risk of infections to the health care workers.



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1. Segregation: Segregation of wastes generated in the laboratory is the responsibility of every laboratory worker. The house keeping staff are responsible for ensuring that every section of the laboratory has disposal containers with all the color coded bags according to Biomedical Waste Management Protocol. The color code has to be strictly followed while the wastes are segregated: Further processing of these wastes will be handled by Maridi Eco Industry Pvt. Ltd.

Laboratory Areas: The laboratory shall have designated areas for laboratory work and access to such areas shall be limited to the laboratory employees. **1.**

Visitors in laboratory areas: Children under 12 years of age shall not be permitted into laboratory. Each laboratory supervisor is responsible for the safety of adult visitors to the laboratory. **2. Hazard warning signs and labels:**

The following four symbols may be used by the laboratory to communicate the extent of risk in the laboratory. **NOTICE** - states a policy related to safety of personnel or property but not a physical hazard. **CAUTION** - indicates a potentially hazardous situation, which may result in minor or moderate injury. **WARNING** - indicates a potentially hazardous situation, which may result in death or serious injury. **DANGER** - indicates an imminently hazardous situation that if not avoided, will result in death or serious injury.

11.6.5 Laboratory Accidents: Though the laboratory provides all facilities to avoid accidents, it is inevitable that a few accidents may occur over a period of time. The following section provides details of the management of such laboratory accidents:

11.6.5.1 Needle stick injuries (including other sharps): Wash the area immediately under running tap water. Inform Phlebotomist and Technical manager about the accident. The hospitals' policy of Post exposure prophylaxis will have to be followed and the appropriate prophylaxis instituted as early as possible. All incidents shall be documented



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properly for further management. Patient shall be assessed for any communicable disease like HIV/AIDS, Hepatitis B & C etc.

11.6.5.2 Eye wash station: There shall be at least one eyewash facility per laboratory. Laboratory workers exposed to dangerous chemicals or infectious materials shall immediately use the eye wash to flush out the material. Hold the eyelids open while using the eye wash and let the water spray of for an extended period of time (15 minutes). Report about the incident to the Ophthalmologist.

11.6.5.3 Body shower station: There shall be at least one body shower station facility per laboratory. Laboratory workers exposed to (splashes of large volumes) of infectious materials shall immediately use the shower facility for a minimum of 15 min. A mild disinfectant solution must be used to clean the area most exposed to infectious material. Report the incident to the laboratory in charge.

11.6.5.4 Incident report: While it may not be possible to alert the supervisor about the Laboratory accident immediately, the laboratory worker should ensure that the supervisor is informed about the incident at the earliest. The supervisor is duly advised to prepare a report of the incident, using the incident report work sheet and the HOD has to be informed. The laboratory In charge will have to ensure that the appropriate treatment has been followed.

11.6.5.5 Fire safety: Small bench-top fires are more common than large fires in labs. Labs, especially those using solvents in large quantities have a high potential for flash fires, explosion, rapid spread of fire and high toxicity of products of combustion.

11.6.5.5.1 Prevention: Plan work. Majority of lab fires have resulted from mental or procedural errors or carelessness. Keep work area uncluttered and clean. Observe proper safety practices. Store solvents properly. Keep inflammable reagents in explosion proof cabinets. Wear proper clothing and personal protective equipment. Avoid working alone, whenever possible. Attend the training



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organized by the organization for use of emergency equipment (fire extinguisher.) when needed.

11.6.5.5.2 Emergency: Know what to do - go by the emergency plan of the lab planned during the training sessions. **Know where the things are** - be aware of the closest fire extinguisher, hospital emergency services / maintenance department telephone number, emergency shower, first aid kit and exit(s).

11.6.5.5.3 Fire Procedure: Notify - other occupants of the immediate space. **Evacuate**- the immediate area of the fire if necessary. **If safe to do so**- attempt to extinguish.

11.6.5.5.4 Fire Extinguishers: (Note: an extinguisher is a first aid tool, do not expect it to control a big fire). **To use a portable extinguisher remember the acronym P.A.S.S.**

11.6.5.5.4.1 Pull the pin.

11.6.5.5.4.2 Aim extinguisher nozzle at the base of the flames.

11.6.5.5.4.3 Squeeze trigger while holding the extinguisher upright

11.6.5.5.4.4 Sweep the extinguisher from side to side, covering the area of the fire.

11.6.6 Training: Training regarding fire safety is provided periodically to staff is necessary.

12.0 QUALITY OBJECTIVES:

12.1 To ensure compliance of the turn-around-time for all tests.

12.2 To ensure timely communication and documentation of the critical test values.

12.3 To ensure minimum reporting errors.

12.4 To ensure minimum re-dos of tests.

12.5 To ensure compliance of test results with the patient diagnosis.



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12.6 To ensure compliance with the quality assurance programme.

12.7 To ensure compliance with safety programme.

12.8 To ensure compliance with the biomedical waste management techniques.

13.0 Quality Indicators:

S.No	Indicator	Numerator	Denominator	Standardization factor
1	Number reporting errors per 1000 investigations	Number of reporting errors	Number of tests performed	1000
2	Percentage of Re-dos	Number of Re-dos	Number of tests performed	100
3	Percentage of adherence to safety precautions by employees working in diagnostics	Number of employees adhering to safety precautions	Number of employees sampled	100

Data Information:

13.1 All the quality indicators are monitored at appropriate interval as defined in the policy.

13.2 The report shall be submitted to the Quality department or NABH coordinator.

13.3 Improvements on the quality care indicator shall be discussed in the Quality Assurance Committee.

13.4 Appropriate corrective and preventive actions shall be taken and the documentation done of the same.



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ANNEXURES

ANNEXURE I - List of Investigations done in Clinical Biochemistry Laboratory

ROUTINE CHEMISTRY INVESTIGATIONS	SPECIAL INVESTIGATIONS	Calculated values	Investigations done with other body fluids
Blood Urea	Total T4	S. Globulin	24hrs urinary micro protein
Serum Creatinine	TSH	A:G ratio	24hrs urinary micro albumin
S. Uric Acid	Free T3	VLDL	24hrs urinary creatinine
S. Total Bilirubin	Free T4	TIBC	24hrs urinary micro albumin- creatinine ratio
S. Direct Bilirubin	FSH	% Transferrin	Urinary calcium
S.G.O.T	LH		CSF analysis
S.G.P.T	Prolactin		Pleural fluid analysis
S. Total Protein	Vitamin B12		Synovial fluid analysis
S. Albumin	Vitamin D		Ascitic fluid analysis
T. Cholesterol	Ferritin		
LDL	Serum iron		
HDL	UIBC		
Triglycerides	Insulin		
S. Sodium	OGCT		
S. Potassium			
S Chloride			
S. Calcium			
S. Phosphorus			
S. Magnesium			
S. Amylase			
S. Lipase			
HBA ₁ C			
CK NAC			
CK MB			
LDH			
Pseudocholinesterase			
ADA			



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UIBC			
Iron			

No.	PROFILES
1	LIVER FUNCTION TEST (LFT) S.Total Bilirubin, S.Direct Bilirubin, SGOT, SGPT, Alkaline Phosphatase, Total Protein, Albumin, Globulin, A/G Ratio
2	RENAL FUNCTION TEST(RFT) Blood Urea, S.Creatinine, S.Uric Acid
3	LIPID PROFILE T.cholesterol, HDL, LDL,VLDL, Triglycerides
4	CARDIAC PROFILE SGOT, LDH, CK Nac, CK MB
5	IRON PROFILE UIBC, Serum Iron, Ferritin, TIBC, %Transferrin
5	THYROID PROFILE T ₃ , T ₄ , TSH, FT ₃ , FT ₄
6	FERTILITY PROFILE FSH, LH, Prolactin



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ANNEXURE III – List of Outsourced Investigations with Turn-Around Time

Parameter	Turn- Around Time
Homocysteine	30 Hours from time of receiving the sample
Total and Free Testosterone	
DHEAS	
PSA	
Anti – TPO	
G6- PD	
cANCA ,p ANCA	
CORTISOL	
CA-19-9	
CA-125	
CEA	
APLA PROFILE	
ALPHA FETOPROTEIN	
SERUM ELECTROPHORESIS	
FOLIC ACID	
PTH	
PROGESTERONE	
ANTI-THYROGLOBIN	
ESTRADIOL	
β-HCG	



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ANNEXURE IV – Turn Around Time for Parameters processed in the laboratory

INVESTIGATIONS	TIME OF REPORTING	DAY OF REPORTING
BIOCHEMISTRY (individual test)	2hrs from the time of receiving the sample in the lab	Same day
Profiles (LFT, RFT, Lipid profile)	2 to 4 hrs from the time of receiving the sample in the lab	Same day
TFT	24 hours from the time of receiving the sample in the lab	Next day
Vit B12, Vit D3,FSH, LH, PROLACTIN,INSULIN	24 hr to 72 hr from time of receiving the sample in the lab	Wednesday & Saturday after 11:am
Emergency investigations	Within 1 hr from time of receiving the sample in the lab	Same day

ANNEXURE V - Containers to be used for estimation of biochemical parameters

Specimen	Type Of Containers to be used



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Cerebro Spinal Fluid	Clean screw cap plastic container
Ascitic Fluid	Clean screw cap plastic container
Pleural Fluid	Clean screw cap plastic container
Synovial Fluid	Clean screw cap plastic container
Peritoneal Fluid	Clean screw cap plastic container
Bronco alveolar lavages	Clean screw cap plastic container
Urine	Clean screw cap plastic container
Blood	n-vac tubes

ANNEXURE VI - Anticoagulants for various investigations

Investigations	Specimen type
Biochemical investigations :	
Blood glucose	Sodium fluoride with EDTA containing non vacutainer tubes (Grey cap n-vac tube)
Hemoglobin A1c	EDTA containing non-vacutainer tubes (Purple cap n-vac tube)
All other tests including Hormones and vitamins	Blood in non-vacutainer tubes containing clot activators for serum (Red cap n-vac tube)
Out sourced lab investigations: Hormones & Tumor markers	Blood in non-vacutainer tubes containing clot activators for serum (Red cap n-vac tube)



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ANNEXURE VII – Critical Values

Pediatrics

PLEASE NOTE: To inform the clinician when the values fall below lower limit and above upper limit indicate below

SLNO	TEST	LOWER LIMIT	UPPER LIMIT	UNITS
1	Serum Glucose	46	445	mg/dl
	Serum Glucose (New Born)	30	325	mg/dl
2	Serum Potassium (New Born)	2.8	7.8	mEq/L
3	Serum Total Bilirubin(New Born)	--	15	mg/dl
4	Serum Calcium	6.5	12.7	mg/dl
5	Serum Creatinine	--	3.8	mg/dl
6	Serum Urea	--	118	mg/dl
7	Serum Albumin	1.7	6.8	gm/dl

ADULTS

PLEASE NOTE: To inform the clinician when the values fall below lower limit and above upper limit indicate below

SLNO	TEST	LOWER LIMIT	UPPER LIMIT	UNITS
1	Serum Glucose	40	450	mg/dl
2	Serum Potassium	2.8	6.2	mEq/L
3	Serum Calcium	6.0	13.0	mg/dl
4	Serum Sodium	120	160	mEq/L
5	Serum Chloride	80	120	mEq/L
6	Serum Urea	--	171	mg/dl
7	Serum Creatinine	--	5	mg/dl
8	Serum Uric acid	--	13	mg/dl
9	CSF Glucose	40	200	mg/dl

REFERENCE : TIETZ textbook of clinical chemistry & 80 × 2.14 molecular diagnostics fourth edition.



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ANNEXURE VIII - Registers maintained in the laboratory

All the below mentioned records (registers and files) shall be maintained in the Laboratory Services unit

Sl.No.	Name of the Register	Sl. No.	Name of the Register
1.	In-Patient Register	5.	Teaching-Staff Attendance Register
2.	Out-Patient Register	6.	Non-Teaching Staff Attendance Register
3.	Outsourcing Register (Thyrocare)	7.	DMLT/CMLT Students Attendance Register
4.	Immunoassay Register	8.	BPT Students Attendance Register
5.	Leave Book	9.	Pg Postings Register
6.	Hb A1c Register	10.	Project Register

ANNEXURE IX -List Of Files In Clinical Biochemistry Laboratory

SLNO	CONTENT	SLNO	CONTENT
1.	NABH Lab Manual	11.	SAMPLE REJECTION REGISTER
2.	NABH accreditation guide book	12.	SAMPLE STORAGE & DISCARD REGISTER
3.	NABH minutes of meeting file	13.	EQUIPMENT HISTORY
4.	NABH CIRCULAR	14.	SOP's of Analyser a. ERBA b. BECKMAN AU 480 c. BECKMAN ACCESS 2 d. BIORAD D10
5.	POLICY FILE	15.	IQ,PQ,OQ FOR ANALYSERS
6.	Redo/repeat (QI 1)	16.	Equipment Calibration Certificate
7.	REPORTING ERROR (QI 2)	17.	Equipment breakdown /maintenance record
8.	IQAC (QI 3)	18.	Kit log in use a. Accucare



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			b. I smart & roche c. Erba xl 640 d. Beckman access 2 e. Beckman au 480 f. Biorad D10 g. Biorad QC
9.	INTERNAL AUDIT FOR MONITORING TAT	19.	Equipment maintenance log a. ERBA b. BECKMAN AU 480 c. BECKMAN ACCESS 2 d. Aquaplus water plant Daily & Weekly
10.	CRITICAL VALUE REPORT	20.	INTERNAL QUALITY CONTROL & CALIBRATION FILE a. ERBA b. BECKMAN AU 480 c. BECKMAN ACCESS 2 d. BIORAD D10



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SLNO	CONTENT	SLNO	CONTENT
21.	CV % a. ERBA XL 640 b. BECKMAN AU 480 c. BECKMAN ACCESS 2 d. ELECTROLYTE ANALYSER e. BIORAD D10	31.	NEEDLE STICK BLOOD & BODY FLUID EXPLOSURE
22.	BIORAD EQAS	32.	HEPATITIS B VACCINATION FILE
23.	EQAS CERTIFICATE	33.	HIRA
24.	INTRA & INTER LABORATORY COMPARISON	34.	MSDS
25.	HARMONIZATION OF TEST	35.	TECHNICIAN ENDORSEMENT & TRAINING CERTIFICATE
26.	TEMPERATURE LOG FILE-ROOM	36.	POLICY FOR RESEARCH FILE
27.	TEMPERATURE LOG FILE-FRIDGE	37.	DISPOSAL OF OLD BIOCHEMISTRY RECORDS
28.	NABH TRAINING	38.	FUTURE PLANS OF THE LABORATORY
29.	HAZARD MANAGEMENT FILE		
30.	SPILL MANAGEMENT		



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ANNEXURE X - List of Equipments available in Clinical Biochemistry Laboratory

Sl. No.	Name of the Instrument	Serial No	COMPANY/ manufacturer
1	ERBA XL640 Fully automated Analyzer	XL640 640101	Transasia
2	AU 480 Beckman Coulter Chemistry Fully automated analyzer	2017030966	Beckman Coulter
3	Robonik Prietest Semi automated analyzer	AT 1251214RBK	Robonik
4	Roche 9180 Fully automated Electrolyte analyzer	13091	Roche
5	I Smart - 30 Fully automated Electrolyte analyzer	50773	I sense
6	ELISA Micro plate Reader and Micro plate Washer	451203015FSE	Tulip group
7	Access-2 Beckman Coulter immunoassay automated Analyzer	570020	Beckman Coulter
8	Centrifuge	20991 1475	Remi
9	Biorad D-10	DJ6E039104	Biorad
10	Refrigerator	VAP243/2010(2)	Videocon
11	Refrigerator	180613CT	Biocare
12	Refrigerator	RT37K3993SLHL2016	Samsung

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ANNEXURE XI Signatory Authority

(For signing biochemistry lab reports)

Faculty with one of the following qualification is eligible for signing biochemistry lab reports

1. M.D. (Biochemistry)
2. DNB is equivalent to M.D./M.S. in the respective disciplines.
3. Ph.D. (Medical Biochemistry) with M.Sc. (Medical Biochemistry)
4. M.Sc. in Medical Biochemistry with 5 years' experience or M.Sc. in Biochemistry with 7 years experience in Clinical Biochemistry laboratory
5. M.B.B.S with 3 years of experience in Medical Laboratory

ANNEXURE XII List of Technicians

SI No	NAME OF THE TECHNICIANS	DATE OF JOINING	TOTAL EXPERIENCE
1.	Mr. Madhu.R.S.	15/07/2004	14 Years
2.	Mr. Anandgowda.H.S.	03/02/2005	13 Years
3.	Ms. Shashikala.G.	25/09/2008	10 Years
4.	Mr. Krishna.D.	04/11/2009	09 Years
5.	Mr. Shivarajkumar.G.	07/03/2013	05 Years
6.	Ms. Manjula.M	25/10/2013	05 Years
7.	Mrs. Gangamma.S.	24/10/2013	05 Years



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8	Ms. Ashwini K	26/12/2013	05 Years
9	Ms. Shruthi.K.P.	20/01/2014	04 Years
10	Ms. Vinutha Sequeira.	20/01/2014	04 Years
11	Mrs. Tejaswini.M.P	10/02/2014	04 Years
12	Mr. Chethan.E	16/12/2015	03 Years
13	Ms. Shanthamma R	21/10/2016	02 Years
14	Miss Ranjitha	01/08/2017	1 Year
15	Miss Hema Bai	15/12/2017	1 Year
16	Mr Morigeri Kotresha	06/12/2018	1 Month
17	Miss Samreen Khanum	06/12/2018	1 Month
18	Miss Saranya	17/12/2018	1 Month

ANNEXURE XIII - List of Computer Operators

SI No	NAME OF THE COMPUTER OPERATORS	DATE OF JOINING	TOTAL EXPERIENCE
1.	Mr. Arun C.J	24/02/2014	5 years
2.	Mrs. Nagarathna	06/03/2018	8 months
3.	Ms. Suchithra	10/12/2018	1 week

ANNEXURE XIV -List of Attenders

SI No	NAME OF THE ATTENDERS	DATE OF JOINING	TOTAL EXPERIENCE
1.	Miss. Sujatha (report dispatch)	03/04/2017	1 year 6 months
2.	Mrs. Shanthamma	05/06/2011	7 years 5 months
3.	Mrs. Thangamma	22/07/2015	3 years 4 months

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Service Name :	DEPARTMENTAL MANUAL Dept of Blood Bank NABH/RRMCH/DM/Blood Bank/01
Date Created :	28/01/2019
Approved By :	Additional Medical Director Name : Dr. Signature :
Issued By :	Medical Superintendent Name : Dr. Govindaraju K.M Signature :
Responsibility of Updating	Head of the Department Name : Dr. Latha.V Signature :

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AMENDMENT SHEET

Sl.No	Section No. & Page No.	Details of the Amendment	Reasons	Signature of the preparator ry	Signature of the approval authority
1	Page 10	Competency Matrix	Resignation / New recruitment of staff		
2	Page 75	Blood grouping by Gel Matrix system	Up gradation		
3	Page 102	Cross Matching by Gel Matrix system	Up gradation		
4	Page 30	New Equipment (BP Apparatus & Stethoscope	Added		
5	Page 143	Procedure for accepting returned blood	Up gradation		

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Sl.no.	Particulars	Page No.
1.0	Introduction	02
	Vision & Mision Statement	03
	Quality objective of the department	04
	Scope	05
2.0	Abbreviation	05
3.0	Roles and Responsibilities	06
4.0	Departmental Hierarchy	06
5.0	Competency matrix	07
6.0	Roles & Responsibilities	08
7.0	Staffing pattern	14
8.0	References to NABH Standards	15
	Conditions where Blood & Blood products are used	16
	Quality Indicators	23
	In – House training for the year 2015	24
	Files maintained in Blood Bank	25
	Register/Record maintained in Blood Bank	26
	Blood Bank equipments	27

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9.0	Detailed Procedure	31

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CONTENTS

1.0. INTRODUCTION:

Blood Transfusion services is the vital part of any health care system. Increasing Advancement in the field of Transfusion Medicine has necessitated enforcing measures to ensure quality of Blood and its products. Blood safety & transfusion safety depends upon the co-ordinated linkage of many processes from Donor selection to Transfusion.

Rajarajeswari Medical college & Hospital Blood Bank run by Moogambigai Charitable trust was established in October 2004, bearing license No: KTK 28C/173/2004.Started off with whole Blood service & license was renewed in 2011.Processing of Blood Components commenced in Dec 2011.Licence was valid up to Oct 20th 2014.We got a new licence bearing license No. **KTK28C/273/2014** due to change of premises on June 2014. License is **valid upto June 2019**.

All activities related to the transfusion of Blood / Blood components are in accordance to the Drugs and Cosmetics Act 1945 issued by Government of India, NACO guidelines. Blood transfusion is often a life saving procedure. The objective of our blood transfusion service is to deliver effective, safe, specific blood / blood components to the right patient at the right time, meeting patients need.

This manual outlines the functioning system of Blood Bank & the guidelines of good manufacturing practices followed in donor selection/collection, pre-transfusion testing procedures, component preparation, screening of TTD, Quality control up to post transfusion monitoring of patients.

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VISION AND MISSION STATEMENT

1. **Vision:** We shall be the most efficient Blood Bank/ Department of Transfusion Medicine in India, operating as an efficient centre of excellent services with compassion and respect and adhering to the highest standard of good manufacturing practices, serving the needy patients and the common man.
2. **Mission:** To be recognized as a supplier of safe blood and blood components and to ensure that no one suffers for want of blood or blood components in our hospital and in Karnataka.
 - (1) To help in providing holistic health care to all.

To provide excellent opportunities for Medical Education and Research

Quality objective of the Department:

We Rajarajeswari Medical College and Hospital Blood Bank, at Bangalore, catering with modern Blood Bank with Blood Component Separation Unit and with License No. KTK/28C-273 /2014 will follow all the standard procedures to procure and dispense safe blood on time.

- (1) We are committed for continuous improvement of our blood transfusion services with strict adherence to ethical standards.
- (2) We are also committed to provide safe, appropriate and good quality blood and blood components round the clock to all patients as per the Quality Standards and latest development in the field of Transfusion Medicine, ensuring the availability of blood products to any patient in our hospital and in our state during emergency and disaster.
- (3) Our aim is to collect blood from voluntary blood donors and to achieve 100% VBD.

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(4) To provide rational use of blood components and to give training to all Clinicians regarding the same.

(5) Continuous education, research and training to all the Blood Bank staff and resident doctors.

(6) To be updated and to know the latest developments in Transfusion Medicine

SCOPE:

Our Blood Bank provides the following services:

1. ABO grouping and typing.
2. Antibody detection (Cold Agglutination Test)
3. Antibody titer (Rh, anti A, anti B)
4. Coomb's Cross-match
5. Cross-match (routine)
6. Direct Coomb's test
7. Indirect Coomb's test
8. Therapeutic Phlebotomy
9. Whole blood
10. Phlebotomy (Blood Donation/Blood Collection)
11. Blood Component -
 - (a) Packed Cells
 - (b) Platelet Concentrate
 - (c) Fresh Frozen plasma
 - (d) Cryoprecipitate
12. TTD Screening (For donors)

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2.0. ABBREVIATIONS:

Rh: Rhesus factor

CME: Continuous Medical Education

TTD: Transfusion Transmitting Diseases

DCT: Direct coombs test

ICT: Indirect Coombs test

PRBC: Packed Red Blood Cells

WB: Whole Blood

FFP: Fresh Frozen Plasma

PRC: Platelet Rich Concentrate

CPP: Cryo Poor Plasma

3.0. RESPONSIBILITY

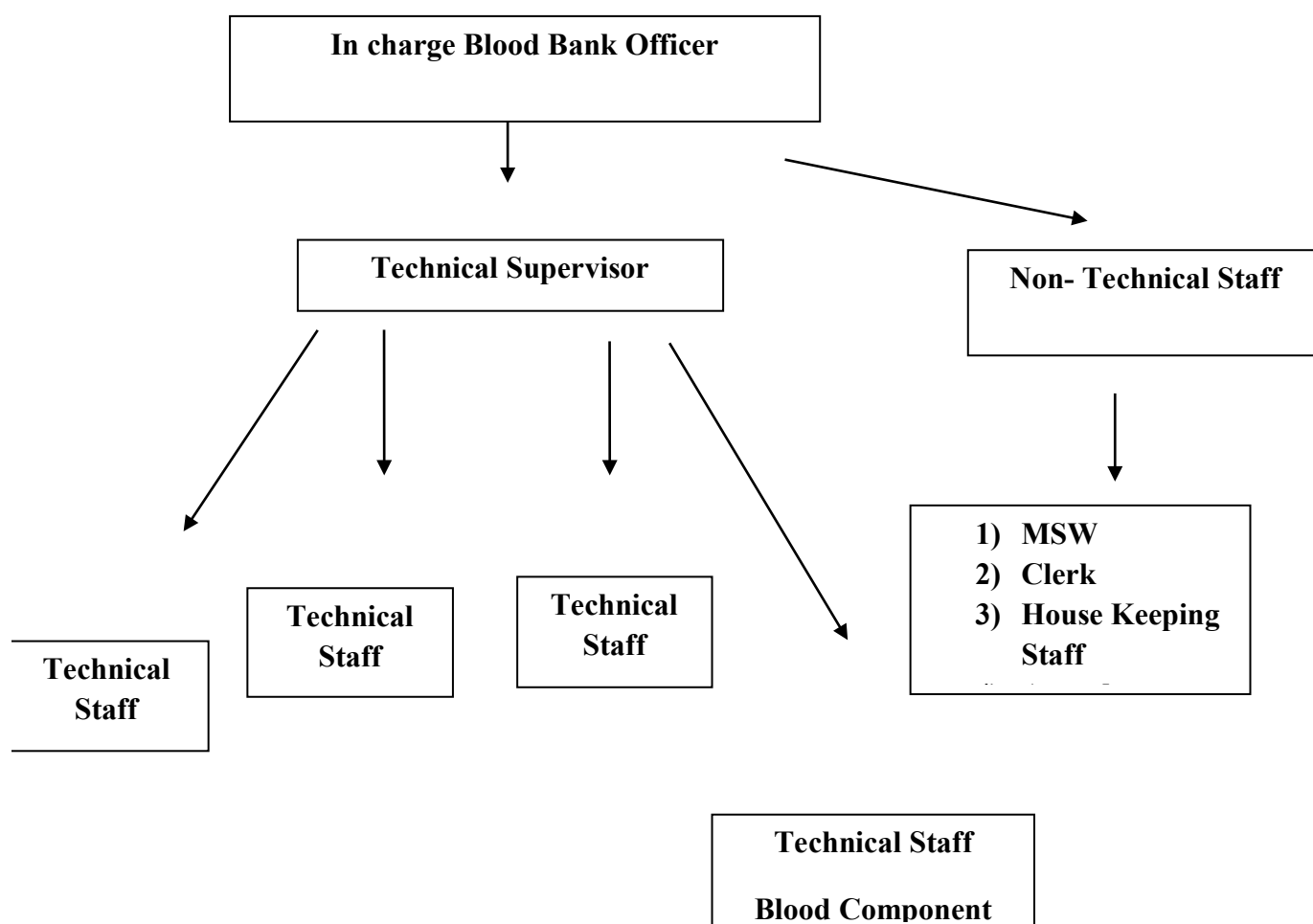
5.1 HOD

5.2 Technicians

5.3 Phlebotimist

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4.0 HIERARCHY



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5.0 COMPETENCY MATRIX:

SL. No.	Name of the staff	Designation	Educational Qualification	Experience		
				RRMCH	Previous	Total
1.	Dr.Latha.V	Blood Bank Officer	MBBS, DCP	14 yrs 8 months	----	14 yrs 8 months
2.	Dr.Jyothi.A. Raj	Blood Bank Officer	MBBS, MD	13 years 7 months	----	13 years 7 months
3.	Mr.Shivakumar.N	Technician Supervisor	JOC	13 years 7 months	10yrs(lab)	13 years 7 months
4.	Mr. Ramalingaiah.S	Technical Supervisor	DMLT	1 year 7 months	10 year 6 months	1 year 7 months
5.	Ms. Manjula.S	Technician	DMLT	7 years 11 months	6yrs(lab)	3yrs 2 months
6.	Mr. Siddappa.H	Technician	JOC	4 Years	11 years (lab)	4 years
7.	Mr. Shivakumarswamy .G	Technician	DMLT	1 year 11months	1 year 6months	1 year 11months
8.	Mr. Manjappa .L.G	Technician	DMLT	6 months	6 months	6 months
9.	Ms.Renukamma.R.N	Staff nurse	GNM	9 yrs 2 months	---	9 yrs 2 months
10.	Mrs.Rashmi .M	Staff nurse	GNM	2 years	3 year	2 years
11.	Ms. Santhiya .M	Staff nurse	BSC	1year 1month	6 months	1 year 1 month
12.	Mrs. Shobha.N	Attender	Matriculation	4 year	----	4 year
13.	Ms. Divya .S.M	Computer operator	B.A	10 month	----	10 month

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6.0. Roles & Responsibilities

6.1 In charge Blood Bank Officer/Medical officer:

The Officer in charge

- Will have direct supervision of all problems in Blood Bank & will monitor all the work areas of the Blood bank ie, Donor area, Red Cell Serology, Transfusion Transmissible Infection screening & component preparation & separation & component storage.
- Will monitor Blood donation procedure, including therapeutic phlebotomy and manage donor adverse reaction.
- Will monitor Issue of blood and blood components from the Blood Bank.
- Will check & sign various files & registers like - daily stock, TTI Test results, Blood grouping and Cross matching reports, Blood donor forms & all the registers maintained in the Blood bank.
- Will check for regular calibration of equipments.
- Will attend Transfusion Committee meeting and address any issues regarding the Blood Bank.
- Will attend CMEs conducted by ISBTI, ISTM & other training Programme so as to keep update with recent changes/ trends in the Blood Bank.
- Will be responsible for checking the quality control of various reagents/methodology used in immune haematology.
- Will be responsible to perform investigations for Transfusion reaction.
- Will be responsible for medical examination of Blood Donors before blood donation.
- Ensure adequate stock position of each Blood group including negative blood groups for inpatients.
- Will check & monitor the indents & supplies of consumables & kits.

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- Will check & sign temperature graphs of all equipments, ELISA reports of TTI diseases such as HIV, HBsAg, HCV, syphilis & malaria.
- Daily stock of blood & blood components are up dated and sent by mail to the drug control department
- Monthly blood bank statistics are sent to drug controller's office, KSAPS,DAPCU
- Will provide training to the Technicians.
- Take classes for students- 3rd 4th & 5th term MBBS, DMLT, MLT, Interns and post graduates posted in blood bank & monitor their regularity during their postings.
- Will report to the administrator, Dean, Medical superintendent, HOD, pathology regarding any issues & requirements of Blood bank.
- Will write all the correspondence of Blood Bank.
- Will check the duties of Technical supervisor, Technicians, clerk, social worker, nurse and housekeeping staff of Blood Bank.
- Will prepare all the SOPs according to WHO, NABH and NABB guidelines.
- Will prepare Quality Manual and Quality Policy for NABH.
- To organize events such as World Blood Donors' day and National voluntary Blood Donation Day.
- To give talks to various UG medical students, PG medical students, students of Allied Health Sciences, Nursing students regarding blood donation.
- Daily check the various serological procedures, screening tests and preparation of blood components.
- To co-ordinate and conduct the Blood Transfusion Committee meeting last monday of every month.
- To check and sign the CIMS monthly statistical report.
- To check if monthly Quality Control of 1% of all blood components is done.
- To clarify and answer the queries of clinicians whenever required
- Over all will be responsible for smooth functioning of Blood Bank at all times.

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6.2. Technical Supervisor:

Routine work - Blood grouping , Cross matching , DCT , ICT, Donor bleeding , component separation , cancellation of blood units reserved for patients (> 48 hrs) & entry into Blood stock

- Daily and monthly QC maintenance
- On 2nd of every month – monthly statistics must be sent to Drug Controller office, DAPCU, KSAPS,
- EQUAS & IQUAS
- Staff record maintenance
- Donor motivation
- In house camps
- Break down, calibration of equipments & follow up, purchase of new equipments
- To update the Blood Bank Public stock online daily by 10a.m
- To attend and arrange for the Blood Transfusion Committee meeting and note down the minutes of the meeting.
- To provide monthly statistics to the offices of the Drugs controller, NACO, Dapcu, DHO, by the 3rd of every month and send them to the concerned offices.
- Maintenance of incident report
- Maintenance of transfusion reaction forms (a complete work up)
- Stock (consumables) maintenance and indenting (General store indent, Purchase indent and donor refreshment indent).
- Maintenance of all files & registers & other documents pertaining to blood bank.

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6.3. Technicians:

- To bleed the donors
- To do the serological procedures such as blood grouping, cross matching, coomb's test, & antibody screening.
- Daily QC - Maintenance
- Daily Temperature recording with signature of the technician.
- Pooled cell preparation
- Preparation of 5% red cell suspension
- Preparation of Copper Sulphate solution
- To prepare the blood components
- To maintain the documents such as Donor Entry register, Donor and patients Grouping, Cross matching, Coomb's test register, master register, Issue register, Discard register, screening register, components separation register, blood stock register.
- To issue the blood & blood components.
- To maintain the following files such as Donor file, daily blood stock, donor deferral file, blood bank camps file, blood bank license file and file of meetings conducted.
- To do shift duties during day and night on rotation and report for the duties in time.
- To attend the phone calls regarding enquiries about availability of patient reports, blood and blood components.
- To attend the blood donation camps on rotation
- Daily preparation of 1% Sodium Hypo chloride solution
- Blood stock arrangement & maintenance
- Daily entry of Consumables stock
- To ensure only tested units [ELISA] are issued

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ELISA /Rapid- Testing for HIV I & II, HBsAg, HCV, screening test for Syphilis & Malaria & filing of the reports with signature of the technician

- Break down and maintenance & cleaning of equipments at regular intervals.
- Regular checking & recording of the temperature of the various equipment provided with the temperature recorder with signature of the technician on duty.
- Daily Consumables stock Verification & indenting
- Discarding of TTD positive units as per bio-medical waste management
- After testing the units, units must be shifted to the Refrigerator meant for screened units.

Post Graduates postings in Blood Bank

- To take the history and to examine the donor for fitness to donate blood.
- To do serological procedure such as Blood grouping, cross matching, coomb's test under supervision and report it to the Blood bank In charge.
- To find out the clinical details of the serological discrepant cases such as the presence of atypical antibodies, positive coomb's test during Blood transfusion reaction.
- To observe and then perform TTI screening under supervision and report it to the Blood Bank In charge.
- To perform Phlebotomy initially under supervision of the Technical staff and then perform independently. To also examine and monitor the donors during Phlebotomy procedure.
- To observe component preparation.
- To attend the Blood donation camps.

Medico Social worker

- To organize the Blood Donation Camps.
- Filling the Donor Questionnaire forms.
- Educating the donor regarding blood donation.

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- If any blood group/component (which is deficient) if required, inform the people regarding its need.
- Donor entry in Donor Register form (sometimes) sometimes receiving the sample.
- Filling up of voluntary blood donors appreciation certificates and donor Cards.
- Attending to the reception counter and phone calls.
- Entering cross matching reports in serology laboratory

6.4. Staff Nurse:

- Bleeding donors & blood grouping
- Donor register maintain
- Filing of Donor form
- Juice stock Maintenance
- Emergency Drug register & indenting emergency drug

Clerical staff in Blood Bank

- To take daily stock of Blood and blood components and mail it daily to Asst Drugs Controller office.
- To prepare full statistics (previous days donors, issue, discard blood and daily stock and sent it to Administrator's and Medical Superintendent's office.
- Maintaining the office files.
- Typing the reports, correspondence and communication letters.
- Preparing monthly statistics and sending to DAPCU, KSAPS, Drug controller office, Bangalore and mailing to DAPCU office.
- Monthly statistics of Blood units and components, tests performed and donors to administrator and Medical Superintendent's office.
- Attending to the reception counter and attending the phone calls.

6.5. Lab attender:

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- Maintain cleanliness of the entire premises of the blood bank.
- Washing & Cleaning of tubes, glassware, slides etc.
- Disposal of bio – medical wastes as per waste management norms.
- To submit daily stock, leave forms, indent book, donor certificates, official letters to the Administrator's office.
- To get Medical store indent, purchase indent, general store indent and donor refreshment.
- To do Xerox (official documents etc) for Blood Bank.

7.0. STAFFING PATTERN:

Sl. No	Designation	Working Hours	Shift Timings	Number Of Staffs
1.	Blood Bank Officer	7 hours	9 am to 4 pm	2
2.	Technical Supervisor	7 hours	9 am to 4 pm	2
3.	Staff Nurse	7 hours	9 am to 4 pm	3
4.	Technicians	7 hours	9 am to 4 pm 2 pm to 8 pm 8 pm to 9 am	5
5.	Attenders	7 hours	9 am to 4 pm	1
6.	Clerical Staff	7 hours	9 am to 4 pm	1

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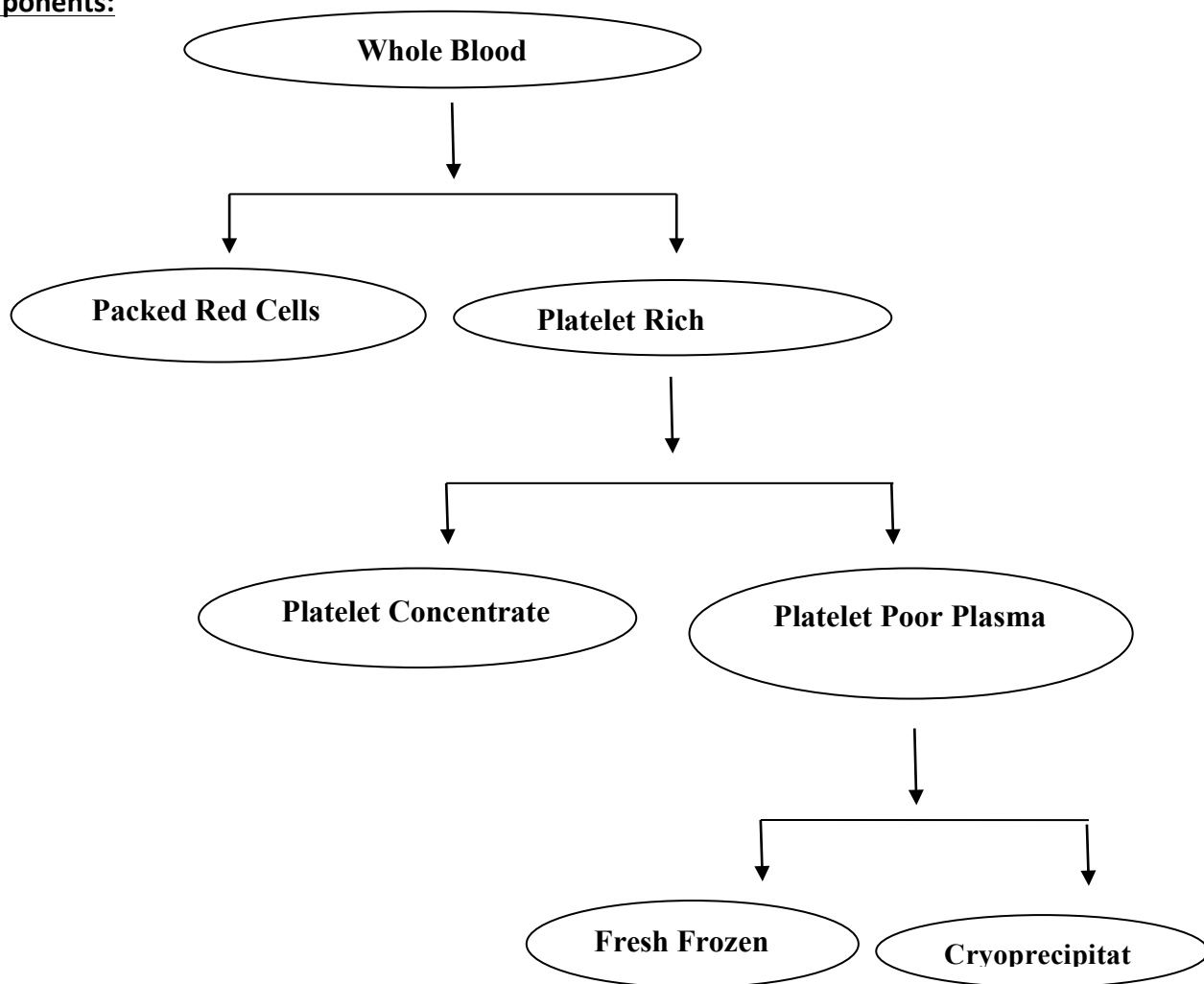
8.0. REFERENCE TO NABH STANDARDS:

Sl.No	Chapter	Relevant NABH Standard / Objective Element
1.	Continuous Quality Improvement	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tool for continual improvement. CQI.3.
2.	Responsibility of Management	The services provided by each department are documented. ROM.2.
3.	Care of Patients	Documented policies and procedures define rational use of blood and blood products. COP.7
4.	Patient Rights and Education	A documented procedure for obtaining patient and/or families consent exists for informed decision making. COP.4

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CONDITIONS WHERE BLOOD AND BLOOD PRODUCTS ARE USED

Blood Components:



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I. CONDITIONS WHERE WHOLE BLOOD IS USED:

- The main Indication of Whole Blood is to provide both oxygen carrying capacity and increase in blood volume in an actively bleeding patient with blood loss greater than 25%.
- Exchange Transfusions (Blood should be less than 5 days old)
- Patients needing red cell transfusions where red cell concentrates or supervisions are not available.

II. CONDITIONS WHERE PACKED RED CELLS ARE USED:

- To raise the Red Cell Mass in very severe, symptomatic Anemia as in cases of b Thalassemia major, sickle cell Anemia, Aplastic anemia etc... (1 Unit of Packed Red Cells has a Hematocrit of 55-65% & raise Hb concentration of recipient by 1 gm/dl)
- In chronic Blood Loss
- **Red Cells (Leukocyte Depleted)** are used to prevent HLA – Immunization before Transplantation.
 - Also used to prevent febrile Non Hemolytic Transfusion Reaction
 - Prevention of Cytomegalovirus Transmission in individual at risk.
 - Multiparous women
 - Multitransfuse patients like thalassemia.
 - Leukemia, Aplastic Anemia.

Leuko reduced red cells are not indicated

- To prevent transfusion related GVHD.
- **Washed Red Cells:** are used to prevent severe allergic reactions to the donor's plasma proteins.
 - Patients having recurrent attacks febrile non – Hemolytic transfusion reactions (FNHTRs) & urticaril reactions.

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- **Frozen and Thawed Red Cells (Stored up to 10 years):**

Indications

- The provision of rare blood lacking common antigens for patients with corresponding antibodies.
- Autologous units of patients with multiple red cell allo antibodies stored for future surgery.
- IgA deficient patient with antibodies IgA.

- **Irradiated Blood Components:** are used to prevent graft versus Host Disease (AVHD) in Immuno suppressed patients.
- The main indications for transfusion of irradiated blood components are :
 - Patients with congenital immune – deficiency syndrome.
 - Bone marrow transplant recipients.
 - Peripheral blood progenitor cell transplant patients.
 - Patients with haematologic malignancies.

III. **CONDITIONS WHERE PLATELETS CONCENTRATES ARE USED:**

a) **Prophylactic Indications:**

- Platelets are indicated prophylactically for patients who have platelet count $\leq 20,000 \mu\text{l}$ to prevent bleeding
- To prevent severe bleeding due to Thrombocytopenia in Patients with Bone Marrow failure (as in Acute leukemia, Aplastic Anemia) or Bone Marrow suppression (as in Irradiation or Myelo-toxic Drugs).
- Patients with disorders of platelet function who require a surgery or who develop serious hemorrhage.

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- In patients with acquired defects of platelet function (as in Multiple Myeloma, paraproteinemia or uremia)
- In patients undergoing surgery, bleeding may occur if platelet count is <70-80,000/ μ l.

Note: Prophylactic platelet Transfusion are not recommended in patients with platelet consumption disorders such as ITP (Idiopathic Thrombocytopenic purpura) and TTP (Thrombotic Thrombocytopenic Purpura).

b) Therapeutic Indications:

- Platelet count <5000/ μ l regardless of clinical condition.
- Platelet count is 5000-10,000/ μ l, if there is increased risk of bleeding due to hematological malignancies, sepsis, severe Aplastic anemia or patient undergoing bone marrow transplant.
- Platelet count is 10,000-20,000/ μ l, if thrombocytopenic bleeding is present.
- Chemotherapy for malignancy (decreased production), if platelet count $\leq$ 20,000/ μ l
- DIC (increased destruction), if platelet count $\leq$ 50,000/ μ l
- In major surgeries if the platelet count is <70-80,000/ μ l
- After Cardiopulmonary bypass.
- To treat Dilutional Thrombocytopenia (massive transfusion) if the Patients is bleeding and the platelet count is <50,000/ μ l
- In Thrombocytopenic patients with micro vascular bleeding (E.g. Oozing from the surgical incision, bleeding from the mucous membrane ,Bleeding from the venepuncture site,ecchymoses)

IV. CONDITIONS WHERE GRANULOCYTES ARE USED:

- In cases of severe persistent Neutropenia. (Absolute Neutrophils count is 500 cells/cumm) over 2-3 weeks.
- Septicaemia not responding to antibiotics. Infections in patients undergoing chemo/radio therapy for neoplastic diseases.

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- In cases of abnormal granulocyte function with persistent infection. Eg. Chronic Granulomatous Diseases and Leucocyte Adhesion deficiency.
- To combat infection in Neonatal sepsis.

Note: Granulocyte Transfusions are generally not indicated as the patients are administered **growth factors** instead, so as to stimulate Myelopoiesis.

V. CONDITIONS WHERE FRESH FROZEN PLASMA (FFP) IS USED:

- Actively bleeding & multiple factor coagulation factor deficiency in
 - Liver diseases
 - DIC (Disseminated Intravascular Coagulation) if the patient is bleeding.
 - Coagulopathy in massive transfusion.
 - As a replacement fluid for plasma exchange procedures. Egs. In TTP (Thrombotic Thrombocytopenic Purpura).
- Deficiency of factors II, VII, IX & X : It is due to the absence of vitamin K or the use of drugs such as coumarin, like warfarin sodium & dicumarol that interfere with vitamin K metabolism. Administration of vitamin K is preferred to FFP in order to correct Vitamin K deficiency or coumarin over dose. Because several hours are required for vitamin K effectiveness, signs of hemorrhage may require transfusion of FFP in emergency.
- Anti thrombin Deficiency.
- For reversal of the effect of oral Anticoagulation's therapy associated with serious bleeding.
- To replace clotting factors during massive transfusion.
- FFP is used as a replacement fluid for plasma exchange procedures – Egs, in TTP.
- Congenital or acquired coagulation factor deficiency.

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Contraindications for the use of fresh frozen plasma

- Blood volume expander
- Hypoproteinaemia
- Source of immunoglobulins
- When the prothrombin time is <18 seconds

VI. CONDITIONS WHERE CRYOPRECIPITATE (ANTIHEMOPHILIC FACTOR) IS USED:

- Most often used to correct HYPOFIBRINOGENEMIA which leads to bleeding, particularly in Massive obstetric hemorrhage which leads to profound Hypofibrinogenemia.
- For congenital/acquired fibrinogen deficiency.
- To treat Hemophilia A, Von willebrand disease, Factor XIII deficiency when specific concentrates are not available.
- Acquired Factor VIII deficiency (e.g. DIC, massive transfusion)

Quality Indicators:

The following Quality Indicators are applicable to the Blood Bank.

- (1) % of Transfusion Reactions
- (2) % of Wastages of Blood and Blood Products
- (3) % of Blood Components Usage
- (4) Turnaround time for issue of Blood and Blood Components

These Quality Indicators are calculated and evaluated once in a month in the Blood Bank.

INDICATOR	DATA COLLECTED FOR ANALYSIS
% of Transfusion Reactions	Report on analysis of Transfusion

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% of Component usage	Report on analysis of Component usage
TAT(turn around time) for emergency Issues	Report of analysis on time taken for Issue of Blood Components during emergency

IN –HOUSE TRAINING FOR THE YEAR 2015

1) Orientation to Blood Bank & Blood banking Techniques	}	New Technicians - March
2) ELISA trouble shooting aspects		
3) Handling of Mercury Spills		-May
4) Automation in blood banking		- June
5) Column Agglutination technology		–July

FILES MAINTAINED IN OUR BLOOD BANK

1. Blood Bank License file
2. Blood Bank License renewal file
3. Donor Questionnaire Forms file
4. Post Transfusion report forms file
5. Transfusion reaction file
6. Donor reaction file
7. Elisa report forms file
8. Culture report file
9. Quality control report file
10. Equipment maintenance file
11. Reliance FFP file
12. KSAPS file

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13. Drug controller's office correspondence file
14. QC St. Johns Hospital file (fibrinogen & factor VIII)
15. Staff duty roster file
16. Technician records file
17. Daily QC file
18. Donor deferral file
19. Daily stock file
20. Blood Request forms file
21. KSAPS file
22. Temperature charts & graph file
23. SIMS AND CIMS file
24. Blood Bag- certificate of Analysis Report
25. Equipment Calibration reports
26. Invoice & bills
27. Correspondence – Internal

REGISTER / RECORD MAINTAINED IN BLOOD BANK

For daily functioning of the blood bank following registers are maintained

1. Master Register (details of both donor& patient) [RRMCH/BB/REGISTER – 5]
2. Donor Register [[RRMCH/BB/REGISTER – 6]
3. Issue Register (RRMCH/BB/REGISTER – 1]
4. Cross Matching Register [RRMCH/BB/REGISTER – 4]
5. Screening (TTD) Register [RRMCH/BB/REGISTER – 2]
6. Blood Grouping Register [RRMCH/BB/REGISTER – 10]
7. Patient Blood Grouping Register [RRMCH/BB/REGISTER – 8]
8. Blood Components Register [RRMCH/BB/REGISTER – 9]
9. Daily Blood Stock Register [RRMCH/BB/REGISTER – 7]

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10. Transfusion Reaction Register [RRMCH/BB/REGISTER -11]
11. Emergency Drug List [RRMCH/BB/FILE -74]
12. Staff Medical Record [RRMCH/BB/FILE -67]
14. Register for Furniture
16. Hospital Transfusion Committee Record [RRMCH/BB/FILE -74]
17. Discard Register [RRMCH/BB/REGISTER – 3]
18. Records of SOP [RRMCH/BB/FILE -40]
19. Donors Adverse Reactions [RRMCH/BB/REGISTER – 11]
20. Record for Daily Quality Control [RRMCH/BB/FILE – 59]
21. Record for Donor Deferral [RRMCH/BB/FILE – 95]
22. EQUAS – Record [RRMCH/BB/FILE -24]
23. Register for Equipment Calibration [RRMCH/BB/FILE – 58]
24. Records of Monthly QC for WB, PRBC, Platelets & FFP
- 25 .Record For Blood Bank Monthly Statistics (KSAPS/
26. DRUG CONTROLLERS OFFICE) [RRMCH/BB/FILE – 45]
27. Blood & Blood Components brought from other blood
Bank [RRMCH/BB/REGISTER – 12]
28. Invoices/ Bills and receipts [RRMCH/BB/FILE -51]
29. Voluntary blood donor list & rare blood group register

BLOOD BANK EQUIPMENTS

Sl.No	List of Instruments	Manufactured	Catalogue No	Sl.No	Quantity
1	Blood collection monitor	1. Terumo Penpol 2. Terumo Penpol 3. Terumo Penpol	1. D601 2. D601	1. 12061154 2. 12061156	3 No
2	Dielectric tube	Med sealer	MS-20		2 No

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	sealer				
3	Blood Bank refrigerator for storing tested and untested blood with thermograph and alarm	Remi Equipments Pvt Ltd	1.BR 280 SR 1/40 2.BR-70SR 11/10 with stabilizer	1. BDI-3087 2. BDI-3086 3. BDI-1669	3 No
4	Ultra Low freezer-80C Plasma freezer with stabilizer	Remi Equipments Pvt Ltd	PDV 90D, 11/10 TSBO2, 5/10	BDI-1684 S) VS 05	1 No
5	Quick freezer - 40C plasma freezer with stabilizer	Remi Equipments Pvt Ltd	RPFV-130, 11/10 S) VS 02	BDI - 1670 SB 2248	1 No
6	Platelet Agitator with stabilizer	Remi Equipments Pvt Ltd	P1-105 VS 03, 11/10	RIS-541 SBI1623	1 No
7	Thawing bath with stabilizer	Remi Equipments Pvt Ltd	CB-704, 12/10 VS-03	1HC-1609 SB-1621	1 No
8	Plasma Extractor	Remi Equipments Pvt Ltd	4R4414	1209177	1 No
09	Refrigerated centrifuge with stabilizer	Remi Equipments Pvt Ltd	KBM 70 plus 12/10 VS-06	VCCE-2912 TSB-02	1 No

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10	Laminar flow	Alpha Linear			1 No
11	Electronic weighing machine	AXPERT		10g-5kg	1 No
12	Micro plate ELISA reader	Tulip Group	451114015FSE		1 No
13	Micro plate ELISA washer	Tulip group	591118011E3AZ		1 No
14	Microscope	1. Adelta Optec: Binocular 2. Olympus (Ch2Oi):Binocular			2 No
15	Domestic Refrigerator	1. Electrolux 2. Videocon	Md.No.VAP 243/2	180liters 235 liters	2 No
16	VDRL Shaker	Remi Equipments	RS 12E 9/03	IXCM 1428	1 No
17	Hot air oven	Techno Scientific Product			1 No
18	Incubator with digital thermo control	Techno scientific product			1 No
19	Autoclave	Single drum			1 No
20	BP apparatus	1. Diamond-7 2. Life line -1 3. Elkometer-1	160 Oct-10 120 Oct 10 206952	00587 49419	9 No
21	Weighing device for	Docble Braun			3 No

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	blood bags				
22	Donor Weighing scale	Tanita	HA622	871222	2 No
23	Oxygen Cylinder	B type			1 No
24	Air conditioner	1. Panasonic-3 2. Intello air-1 3. I general-1 4. LG Buss -1 5. Sanyo-1			7 No
25	Stethoscope	1.Poiner 2.Life line	Silver CE		5 No
26	Pipettes various size	100-1000µl 5-50µl 50µl 1000µl 10-100 µl 10 µl 25 µl	2 2 1 1 1 1 1		9 No
27	Insulated container for transporting blood				6 No
28	Thermometer	1. Hvcer-1 → 2. BIOCRAFT-2 →			6 No

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		1. Clinical-1 2. Digital-1 3. Room temp-1 4. Dial Thermo-3			
29	Centrifuge	Remi Equipments Pvt Ltd		Remi R8C-1 (16buckets) Remi(6 Buckets) Remi(6Buckets)	3 No
30	UPS	On line - 1 Wep-2	3 KVA 600VAECO		3 No
31	Printer	HP LaserJet	P1007		1 No
32	Computer Keyboard CPU	Zenith Pleomax/Samsung corporation zenith			1 No
33	Electric Stove	HRC, Hakso Electro control			1 No
34	Hemocue				1 No
35	Gel matrix Centrifuge	Matrix			1 No
36	Gel matrix Warmer	Matrix			1 No

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LIST OF INSTRUMENTS, MATERIALS, REAGENTS AND EMERGENCY DRUGS

Equipments

- Tube sealer
- Blood collection monitor
- Blood bank refrigerator
- Platelet incubator
- Calibrated refrigerated centrifuge
- Microscope
- Refrigerator to store samples & reagents
- Deep freezer
- Table top centrifuge
- Incubator
- Plasma expresser
- Thawing bath
- Electronic weighing scale
- ELISA Washer & reader

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- Dry bath

Reagents

- Anti D (IgM)
- 0.9% saline
- Distilled water
- Group O pooled cells/ antibody screening reagent red blood cells
- 22% bovine albumin
- Antihuman globulin reagent (anti-IgG + anti C3d)
- IgG sensitized control cells
- Anti sera [Anti A, Anti B, Anti AB, Anti D, Anti A1 (Lectin), Anti H(Lectins)]
- Group A,B & O pooled cells
- Copper sulphate working solution
- HIV ELISA kits
- HCV ELISA kits
- HBsAg ELISA kits

Glassware

- Serum tubes
- Pasteur pipettes
- Glass slides
- Pilot tubes: Plain and EDTA
- Heparinized capillaries
- Micropipettes and disposable tips
- Sticks
- 20ml test tubes

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- 5ml pipettes

Oral medication

- Analgesic & Antipyretic tablets
- Calcium & vitamin tablets
- Electrolyte replacement fluid
- Glucose powder

Injections

- Adrenaline
- Tropine
- Avil
- Perinorm
- Deriphylline
- Diclofenac
- Hydrocortisone
- Ondesteron
- Pyrolate
- Dextrose 25%

Antiseptic

- Betadine
- Hydrogen peroxide
- 70% Alcohol
- Thrombophob ointment

Miscellaneous

- Bandaid
- Micropore

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- Absorbent tissue
- First aid tray
- Blood collection bags
- Discard jar with 1% sodium hypochlorite
- Artery forceps, scissors
- Adhesive tapes
- Donor cot
- Biosafety cabinet
- Blood lancet
- Reagent kit
- Bandaid
- Disposable syringes and needles 22g
- Clinical thermometer
- Weighing scale
- Electronic weighing scale
- Sphygmomanometer
- Oxygen cylinder
- Infusion set
- Paper bag
- Test tube racks
- Ice packs
- Insulated carry box
- Timer
- Disposable gloves
- Small funnel
- Whattman No. 1 filter paper
- 5ml plastic vial with screw cap

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- Measuring jar

9.1 CRITERIA FOR DONOR SELECTION

Scope & Application

This SOP describes the criteria for a donor to be accepted for blood donation, for ensuring safety of donor as well as recipient. The purpose of donor selection is to identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently.

Responsibility of Blood Bank Staffs:-

The Medical Officer is responsible for determining the suitability of donor for blood donation. He/She should confirm that the criteria are fulfilled after evaluation of health history questionnaire & medical examination including the results of pre donation screening tests. To ensure that blood donation does not cause any harm either to the donor nor the recipients.

Donor selection and screening process has four major aspects:-

1. Registration, consent of the donor, and demographic information like donor's full name, father/husband's name, date of birth/age, male/female, residential/office address with phone number.
2. Medical history.
 - Accept only voluntary/replacement, non-remunerated blood donors.

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- No person shall donate blood and no blood bank shall draw from a person more than once in 3 months.
- Donor must be in good health and mentally alert and physically fit.
- Donor must **not be** a person having multiple sex partners and drug addicts.
- Donor must be free from any disease transmissible by blood transfusion, which can as far as determined by history and medical/physical examination of the donor.
- The arm/forearm of the donor must be free from skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics.
- Defer the donors for the conditions for a period mentioned below.

CONDITIONS	PERIOD OF DEFERMENT
Abortion	6 months
History of blood transfusion	6 months
Minor Surgery	3 months after recovery
Major surgery	6 months after recovery
Typhoid fever	12 months after recovery
History of malaria duly treated	3 months (endemic) 3 years (non endemic)
Tattoo	6 months
Breast feeding	
Immunization	15 days
Rabies vaccination	1 year
Hepatitis in family or close contact	12 months

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Hepatitis immune globulin	12 months
Tooth extraction /Dental Manipulation	3 days
Dental procedure under anesthesia	1 month
Influenza/URTI	1 week after treatment
High BP controlled with medicine	Acceptable if BP is normal
Tuberculosis	5 years after cessation of symptoms & treatment

Vaccination & Inoculation

1.No waiting period before donation if symptoms free

Inoculation with toxoid or a killed viral/bacterial vaccine

Tetanus

Typhoid

Paratyphoid

Cholera

Prophylactic Hepatitis B

Rabies as prophylactic

2. Four weeks deferral from time of vaccination

Anti – tetanus serum

Anti – venom serum

Anti – diphtheria serum

Anti – gas gangrene serum

Rubella (German measles)

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3. Twelve months deferral from time of vaccination

Anti – rabies vaccination as a result of animal bite

HBIG (Hepatitis B immune globin)

Gamma globin

Medication

If a donor is taking some medicines it may not be in his/her own interest to donate blood & may also effect the patient who would receive the blood.

Medicines

Accepted/Deferred

• Oral contraceptives	Accepted
• Analgesics	Accepted
• Vitamins	Accepted
• Mild sedatives & tranquilisers	Accepted
• Salicylates (aspirin) taken in Last three days	Not accepted if blood be used for preparing platelets
• Isotretinoin (accutane) used for acne	Defer for 1 month after the last donation
• Finasteride (e.g. Proscar) used to Treat benign prostate hyperplasia	Defer for 1 month after the last dose
• Oral anti – Diabetic drugs with no Vascular complication	
• Diabetics on insulin	Defer while taking the Drug
• Antibiotics (Oral)	Defer for 3 days & till symptoms free
• Antibiotics (injection)	Defer for 4 days & till

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- Cortisone symptoms free/after the last donation
Defer for 7 days after the last dose
- Medicine to treat Hypercholesterolemia Accepted

Donors following medicines are permanently rejected

Anti – arrhythmics	Immunosuppressive
Anticonvulsions	Pituitary growth hormones of human Origin
Anticoagulants	Sedatives or tranquilisers in high doses
Antithyroid drugs	Vasodilators
Cytotoxic drugs	Etretinate (e.g. Tegison) to treat psoriasis. It is teratogenic
Digitalis	vasodilators
Dilantin	Drugs for Parkinson's disease.

Defer the donor permanently if suffering from following conditions.

1. Cancer
2. Cardio vascular diseases (myocardial infarction, coronary artery disease, Angina pectoris, Rheumatic heart disease) permanently defer.
3. Heart disease
4. Abnormal bleeding tendencies
5. Unexplained weight loss
6. Diabetes-controlled on insulin
7. Hepatitis B infection

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8. Chronic nephritis
9. Signs and symptoms suggestive of AIDS
9. Liver disease
10. Tuberculosis
11. Polycythemia
12. Asthma
13. Epilepsy
14. Leprosy
15. Schizophrenia
16. Endocrine disorders
17. IV drug addicts
18. Homosexuals and Heterosexuals
19. High risk group donors for HIV infection.

3. Physical examination.

General Appearance: Donor should look well built & nourished. A donor may be deferred if he appears ill, under the influence of drugs & alcohol or do not appear to be providing proper answers to medical history.

- Donor must fulfill the following requirements

Age	18 - 60 yrs
Weight	>45kg for 350ml & 60kg/> for 450ml collection
Temperature (oral)	37.5°C (+/-0.2°C) Should not exceed 37.5°C

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Pulse	60 – 100 beats/minute
Blood pressure	Systolic 100 – 180mmHg Diastolic 50 – 100mmHg

Donation Interval

The interval between the donation of a unit of blood should be at least 12 weeks except in unusual circumstances. Whole blood donation must be deferred for at least 72 hours after plasma or platelet apheresis.

Donor Skin

The skin at the venepuncture site should be free of any lesion or scar of needle pricks indicative of addiction to narcotics or frequent blood donation as in the case of blood sellers.

Systematic examination

Clinically heart, lungs & abdomen should be normal. Liver & spleen should not be palpable.

Informed consent:

Provide information regarding:

- Need for blood
- Need for voluntary donation
- Regarding transfusion transmissible infections
- Need for questionnaire & honest answers
- Safety of blood donation
- How the donated blood is processed & used
- Screening Tests carried out on donated blood.

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- This gives the donor an opportunity to give his/her consent if they feel they are safe donors. Request the donors to sign on the donor questionnaire and donor register indicating that he is donating voluntarily & giving consent to carry out screening tests for transfusion transmitted diseases including HIV 1 & 2 .

4. Laboratory tests

- Hemoglobin should not be less than 12.5g/dl and is estimated by Hemacue.
- Donor is screened for ABO & Rh by slide method. (Refer SOP No. for procedure)

The medical examination and assessment of the donor suitability is done as per Blood Donor Form.

DOCUMENTATION

Enter all details in the donor questionnaire form & donor register

9.2.PREPARATION OF PHLEBOTOMY SITE

Scope & Application

Cases of transmission of bacterial infection in blood are rare, but when they occur they can be fatal. Hence careful preparation of the skin at the site of blood collection before venipuncture is very important.

Responsibility

The phlebotomist collecting the blood unit from the donor is responsible for preparation of phlebotomy site.

Materials Required

- Sterilizing tray
- Absolute alcohol/demethylated spirit

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- 10% Povidone Iodine
- Cotton Swabs
- Tourniquet

Method of Preparation of Phlebotomy Site

- Phlebotomist should wash his/her hand with soap before attending the donor.
- Make the donor lie down with a pillow under the head.
- Apply blood pressure cuff; inflate to 50-60mmHg and select a prominent firm vein that is free of any skin lesion.
- Clean 4-5cm area starting at the site of puncture and moving outward in a concentric spiral way with alcohol.
- Apply 10% Povidone Iodine Solution (Betadine or tincture of Iodine) at the site of Venipuncture. Allow it to dry.
- Then clean with Methylated spirit or alcohol, allow the solution to dry. Never touch the site prepared for venipuncture.
- If the puncture site is touched, repeat the skin preparation procedure.
- On checking the used swab, if it is physically soiled or contaminated take a new swab and repeat skin preparation procedure.
- Dispose off used swabs into the bin as per Bio medical waste protocol. Allow the skin to dry. Do not wipe the area with the cotton wool, fan or blow on it.

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9.3. BLOOD COLLECTION

Selection of Bags

Scope & responsibility

According to the components to be prepared from the blood unit & the weight of the donor, the blood bags are selected for blood collection.

Responsibility

The technician or phlebotomist in the donor area co-ordinates with the components room for deciding the type of blood bags to be used. The medical officer is consulted in case of difficulty in making a decision or to optimize the availability of components.

Select the bag as per the following chart

DONOR WEIGHT	COMPONENTS	BAGS/VOLUME	
>55Kg	PRBC+FFP+PLT	Triple	450ml
>55Kg	PRBC+Cryo+CPP	Triple	450ml
>55Kg	PRBC+FFP	Double	450ml
45-55Kg	PRBC+FFP	Double	350ml

PRBC: Packed Red Blood Cells // FFP: Fresh Frozen Plasma // PLT: Platelets
// Cryo: Cryoprecipitate

- Check the bag visually - Each blood collection bag should be properly inspected for any leakage, defect and clarity of anti – coagulant solution.
- In case of puncture or discolouration, do not use
- Check the expiry date of the bag

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- The date of collection and Expiry should be written on the label of bag.
- The blood collection bags and pilot tubes should be identified by specific donor registration number, so that it can be traced back to the donor and also to the recipient.
- Use single bag when:-
 1. Components are not to be separated from that unit.
 2. When autologous blood is collected for patients e.g: elective surgery
 3. Therapeutic phlebotomy is being performed on a patient.

Documentation

Enter the following details in the register meant for blood bags stock

- Type of the bag
- Batch no.
- Date of manufacture
- Date of Expiry

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9.4. BLOOD COLLECTION

Scope & Application

This describes a procedure for blood collection from the donor, using an aseptic method. Blood is collected in a sterile closed system bag with a single venepuncture. Successful venepuncture results not only in safe collection of a full unit of blood suitable for separation of components with good quality yields, but also contributes to the comfort & satisfaction of the donors thus encouraging re-attendance

Responsibility

The Phlebotomist or Doctor is responsible for blood collection from the donor after the donor screening details, checking the unit number labels & preparing the phlebotomy site.

Materials Required

- Cotton Swabs
- Tourniquet
- Pilot Tubes
- Oxygen Cylinder with accessories
- Gloves
- Blood Collecting Bags
- Tubing Stripper
- Needle Destroyer
- Blood Collection Monitor
- Adhesive tapes
- Comfortable Donor Couch/Hospital Cot
- Tube Sealer
- Discard jar with 10% Sodium Hypochlorite Solution

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- Crash Cartz with Emergency Drugs

Method of Phlebotomy:-

- Prepare the site for phlebotomy as per SOP No 3
- Select a bag for blood collection as per SOP No 4.
- Identify the donor by name. Identify the donor by specific donor registration number.
- Enter the bag number, blood group, date of collection and expiry on the blood bag.
- Donation number on the blood bag, donor form and the pilot tube should be same.
- Place the blood bag on blood collection monitor; ensure it is below the level of the arm and set the monitor for required volume of blood (350/450).

Uncover the sterile needle and perform vein puncture by a bold single prick to ensure smooth flow of blood and secure on the arm with adhesive tapes.

- Once blood enters the bag tubing press the blood collection monitor “Start” switch.
- Advice the donor to gently squeeze the hand roller to improve blood flow and observe the donor throughout the phlebotomy.
- If the venipuncture is not successful do not make further attempt in the same arm, if donor agrees & suitable vein is found, Second attempt can be done on the other arm.
- The flow of blood should be uninterrupted and constantly mixed with the anticoagulant, otherwise will not be suitable for components preparation.
- After the programmed volume of blood is collected, the monitor automatically clamps the tubing.

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- Deflate and remove the cuff, place a sterile swab and apply light pressure and withdraw the needle from the donor's vein & flex the arm.
- Ask the donor to lie down with the arm in the flexed position for 10 minutes.
- Seal the blood bags tubing with tube sealer and collect blood from the tubing so that blood flows directly into the pre-labelled pilot tubes.
- Burn the needle of the bag using Needle destroyer & discard the tubing with the burnt needle in a container containing Sodium Hypochlorite solution.
- Strip blood bag tubing ,starting at seal ,pushing blood into the bag. Invert bag several times then allow tubing to refill with anti coagulated blood from the bag.
- Seal the tubing attached to the bag into 3-4 segments with the tube sealer such that each segment has the tube segment number.
- Blood bags to be refrigerated at 2°-8°C. For platelets, bags to be kept at 20-24C; Platelets/Plasma to be separated within 6hrs.
- Apply band aid to the site and offer refreshments with a certificate of appreciation. Ensure the donor does not leave the blood bank without the consent of technician/nursing staff.
- **Difficulty with Blood Flow** – May be due to spasm vein/reduced cuff pressure/occlusion of the lumen of the needle by vein wall/by the valve within the vein.
 - * Reassure the donor & check the cuff pressure.
 - * Do little positioning & adjustment of the needle.
 - * Avoid excessive manipulation as it can result in haematoma & discomfort to the donor.

Processing of Donor Blood

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The general considerations in processing donor blood are:

1. The blood unit number of donation on the blood bag, pilot tube and donor record should be rechecked prior to processing.
2. ABO group is determined by tube test - forward & reverse grouping. Blood must not be released for use until the discrepancies, if any, are resolved.
3. Rh group must be tested for Rh(D) only with anti D serum. Rh(D) negative units must be tested for weak Rh(D) i.e, Du by anti human globulin (AHG) serum. Units those are Rh (D) negative and Du positive must be labeled Rh (D) positive and those which are Rh(D) negative and Du negative must be labeled Rh(D) negative.
4. Donor blood is tested for unexpected antibodies by saline, albumin/enzyme and anti-human globulin tests with pooled 3 fresh O group red cells.

5. Screening Tests for Transfusion transmitted diseases:

- a. Hepatitis B surface antigen & anti HCV by ELISA method.
- b. Test for anti HIV 1 & 2 by ELISA
- c. Test for Syphilis – by Rapid Plasma Reagin (RPR)
- d. Test for malarial parasites – by rapid malaria test

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9.5. POST DONATION CARE & ADVICE

SCOPE & APPLICATION

In order to avoid any untoward reaction/ incident during the procedure of donation. Also, in case any reaction happens, it should be dealt with immediately and effectively.

RESPONSIBILITY

Blood bank technical supervisor / Staff nurse

- To prevent adverse reactions like giddiness ask the donor not to get up from the cot/chair for 10 mins even if he feels perfectly all right.
- Observe for another 10minutes in the refreshment area.
- Inspect the venipuncture site before the donor leaves the room. Apply an adhesive tape only after oozing stops. If there is persistent oozing at the site of puncture, apply pressure with a dry, sterile cotton swab. If there is hematoma apply Thrombophob ointment gently over the area after 5minutes. Inform the donor about the expected change in skin color. If the pain persists, ask him/her to apply ice.
- Instruct the donor to drink adequate fluid in the day and avoid strenuous activities.

Advice

- Drink more fluids than usual in next 4 hours. Do not remain hungry.
- Do not smoke for half an hour.
- Do not take alcoholic drinks for at least 6 hours.
- If there is bleeding from phlebotomy site, raise the arm and apply pressure.
- If there is feeling of faintness or dizziness, either lie down or sit with head between knees. If symptoms persist, ask for help, return to the blood bank or consult a doctor.

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- Remove the band-aid after 5-6 hours.
- If there is any discoloration of the skin, it will gradually decrease within 10days of donation.
- You may resume work soon after donation however you are cautioned that if you are working in a hazard occupation like construction or at a height or operating heavy duty machines; dizziness may occur, if you return to work immediately.
- In case of emergency the donor is instructed to contact the blood bank personnel.
- It is important to make note of any adverse reactions in the donor register so that due care can be taken at the next donation.

9.6. PREOPERATIVE AUTOLOGOUS DONATION

Scope & Application

Pre operative autologous blood donation feasible for patients likely to require transfusions during elective surgeries scheduled to take place within 35-42 days especially for patients under going major ortho procedures(joint replacement, vascular surgery, cardiac/thoracic surgery radical prostactomy, plastic & reconstructive surgery, major abdominal surgery splenectomy) & in OBG conditions especially females with multiple antibodies, antibody to high frequency antigens. Not recommended for procedures that are unlikely to require transfusion/that seldom require transfusion such as cholecystectomy, herniorrhaphy, vaginal hysterectomy, and uncomplicated obstetric delivery.

Eligibility for pre-deposit autologous donation

Guidelines for selection criteria of the patient - donor autologous donation is prepared in consultation with patient- donor's physician/surgeon & blood bank officer:

- 1.The acceptable Hemoglobin concentration of the donor should be 11g/dl and HCT 33%.

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2.Age : There is no upper or lower limit of age. Paediatric patients undergoing elective surgery can benefit from autologous blood.

3. Weight & volume of Blood Withdrawn: Donors weighing 60kg or more can donate 450ml of blood, donor weighing less than 60kg can donate proportionately smaller volume of blood but not more than 8-9ml/kg body weight. In pediatric patient of 8 years the weight should be 27kg & not more than 10% of the patient's blood volume should be drawn at each phlebotomy.

4. Frequency of donation: Donations are often scheduled weekly (4 days interval) unit can be collected every 5-7 days (not more than 1 unit every 3 days) with the last donation performed 72 hours or more before the operation.

5. Oral iron (32mg of Ferrous sulphate 3 times a day is given) to accelerate the restoration of hemoglobin to pre-donation level. Use of Erythropoietin along with oral iron is the most effective way to enhance the chances of successful pre-donation program but it is expensive.

Requirements/ Arrangements of Autologous blood collection

1. A successful autologous program requires co-operation & proper communication among all the patient's treating physicians & Blood Bank Staff.

2. Responsibility for the health & safety of the patient during the collection procedure rests with the Blood bank Officer & during the transfusion process responsibility rests with the patient's physician & Blood Bank Officer.

3. Written advice for pre-operative autologous donation is required by the treating physician (which may be a simple prescription form or in the patient's file).

4. CONSENT for autologous donation that they have been informed and understand the risks & advantages of autologous donation.

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5. A number is assigned to each unit drawn from the patient, and is written on the bag & also in the donor-patient record. The patient-donor name, date of collection will be mentioned on the blood bag.

6. Blood collection is done by the blood bank staff at blood bank collection room/ patient's bedside (refer SOP No.04 for Phlebotomy). If any difficulties are encountered, the Medical Officer will be informed.

7. Each autologous unit must be labeled autologous donor and voluntary donor. In addition a special label, "For Autologous use only" is required.

8. Autologous blood units should be stored in a separate shelf of the refrigerator.

Use of autologous donation as Homologous use

The unused unit of pre-operative autologous donation is not used as homologous use because of donor-patient's associated illness & medication. The unused units will be discarded as per SOP No.

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Lab testing

1. ABO blood group & Rh typing is done.

2. All screening tests are carried out on autologous blood units. The rationale behind screening tests is to protect the technical staff

a. The first unit of blood requires the screening tests & if found any test positive, a Bio-Hazard label must be applied to the units & the patient's physician must be informed.

Documentation

Separate register for autologous donation is maintained. The details required to be documented in the register are patient-donor name, IP No., blood unit No, date of collection, the diagnosis & the

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amount of blood collected. The blood group & Rh typing, results of regular screening tests & cross matching details should also be mentioned in the register .

9.7. THERAPEUTIC PHLEBOTOMY

Scope & Application

Therapeutic Phlebotomy is the therapeutic procedures offered to patients with medical condition where regular removal of blood is beneficial. Therapeutic phlebotomy may be used to treat the following medical conditions:

Haemochromatosis, Polycythemia, RubraVera, Porphyria Cutanea tarda & other conditions such as secondary Polycythemia, Sickle cell disease.

Responsibility

The referring doctor is ultimately responsible for clinical management & will review the ongoing need for phlebotomy. Blood Bank is responsible for therapeutic collection & for ensuring patient safety during the procedure. Blood bank has the right to refuse phlebotomy if there is concern for patient safety.

Blood Bank guidelines for Therapeutic phlebotomy

1. The patient's concerned staff must first discuss and inform the Blood Bank Officer/Blood bank staff the need for Therapeutic Phlebotomy.
2. The concerned treating doctor should mention the indication for phlebotomy in the patient's file.
3. The requisition for therapeutic phlebotomy and blood investigations reports like Hb% & PCV must accompany the file.

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4. Patient is examined for eligibility for phlebotomy either by the Blood Bank Officer/ the treating doctor.

5. Therapeutic phlebotomy is the same procedure that people undergo voluntarily at the blood bank as in SOP 03.

6. The procedure is done by blood bank staff at the patient's bedside.

7. Before the procedure, the time of phlebotomy to be confirmed so that the blood bank staffs are available for the procedure.

8. The procedure should be explained to the patient & the consent has to be taken.

9. The patient should be accompanied by the nursing staff, referring doctor or his representatives during the procedure.

10. The blood bag is not used for other patients but discarded by autoclaving.

11. Patient is kept for observation for 15 minutes post phlebotomy & recovery will be assessed & monitored.

12. The patient is advised to take more liquids following the procedure, so as to prevent dehydration.

Documentation

The blood request form for therapeutic phlebotomy is filed in the therapeutic phlebotomy file.

The details required to be documented in the register are Patient's name, age, sex, IP No, Indication for therapeutic phlebotomy & Investigations done such as Hb, HCT, Date & time of phlebotomy & quantity of blood collected.

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9.8. MANAGEMENT OF ADVERSE REACTION IN DONORS

Scope & Application

Any adverse reaction in the immediate post – donation period requires to be attended to.

Responsibility

The Medical Officer in attendance is responsible for managing the adverse reaction in the donor.

Donor reactions are rare but do occur at times either during/after donations but they are usually harmless. Personnel in the phlebotomy area must be trained to recognize these reactions and provide necessary/initial treatment.

In general if adverse reaction occurs,

- Deflate the tourniquet and withdraw the needle from the donor's vein at the first sign of a reaction, put a sterile swab and apply pressure at the site.
- Call for assistance from other personnel or the medical officer, if needed.
- If possible, remove the donor to an area where she/he can be attended to in privacy.

Symptoms	Action taken
1. Nervousness (before/during donation)	Usually recovers after donation is over
2. Giddiness/Syncope (vasovagal syndrome) Sweating, weakness, pallor,	Raise feet and lower head end. Loosen tight clothing (belt, tie etc) Ensure adequate airway.

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loss of consciousness, convulsion, skin-cold, fall in BP, Thready pulse	Check pulse and blood pressure. Apply cold compresses to forehead and back. Administer inhalation of spirit of ammonia if needed. The donor must respond by coughing which will elevate the blood pressure. Continuously check the blood pressure, pulse and respiration until donor recovers.
3. Bradycardia and hypotension	Administer IV normal saline or dextrose saline infusions if hypotension is prolonged. Administer injection Atropine 1ml IM, if bradycardia continues for more than 20 minutes.
4. Convulsion	Keep the head tilted to side; prevent the tongue bite; keep the airway patent by inserting a tongue blade or gauze between the teeth.
5. Nausea/Vomiting	Ask the donor to breath slowly & deeply. Usually this provides relief. If the donor feels nauseous, turn the donor head to side to avoid aspiration of vomit. If vomiting is severe, inject Stemetil/Perinorm. Usually subsides on its own
6. Tetany/Muscular spasm/twitching	These are usually due to hyperventilation in an apprehensive donor. Ask the donor to breath in a paper bag, which provides prompt relief. Do not give oxygen.
7. Haematoma	Deflate the pressure cuff immediately. Ask the donor to open the fist and withdraw the needle from the vein. Place 3 or 4 sterile gauze pieces

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	or cotton swabs over the haematoma and apply digital pressure for 5-10 min with the donors arm held above the heart level. Advise the donor to apply ice if there is pain & inform about the expected change in colour
8. Eczematous reaction of the skin around venipuncture site	Apply steroid ointment.
9. Delayed Syncope	These may occur as late as 30minutes to 1hr after donation, usually after the donor has left blood bank. Permanently defer any donor who gives history of such attack more than twice.

- The nature and treatment of all adverse reactions should be noted in donor's record/form.
- Keep a record of stocks of medicines & materials required, especially the expiry date of medicines.

9.9. TRACEABILITY OF BAGS

SCOPE AND APPLICATION

To label the blood bags and pilot tubes after verification of donor details in order to accurately relate the blood product to the donor. The unit number label is the unique identifier for the donor and all the blood components separated from the unit collected from the donor.

RESPONSIBILITY

It is the responsibility of the phlebotomist collecting the blood units to ensure proper labeling and recording of the requisite details.

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PROCEDURE

- Give each donor a unique number and once his blood is collected, identify by that number only.
- Do not write donor's name on his/her blood bag or sample tube. This maintains the donor's confidentiality.
- Number the primary bag and all the satellite bags in case of multiple bags and pilot tubes.
- Verify the donor's identity by tallying with the name on the master registration card.
- Cross check the number on the bag, pilot tubes and master registration card to ensure identity. Record the entry in the donor register using the same number.
- Transcribe this number on all records henceforth for storage, testing and distribution.
- While issuing the unit, use the same number on issue record.

DOCUMENTATION

Make sure that the number is written clearly on all records and there are no transcription errors, as this number will trace any product to the donor of the blood and vice versa in case of requirement.

9.10 ESTIMATION OF HEMOGLOBIN BY HEMOCUE 301

Principle: The system sodium deoxycholate haemolyses the erythrocytes & hemoglobin is released. Sodium nitrite converts Hb to methaemoglobin which, together with sodium azide, gives azidemethaemoglobin. The absorbance of whole blood at a Hb/HbO₂ in the analyzer is measured at two wavelengths (506nm & 880nm) in order to compensate for turbidity in the sample.

Specification: The hemocue 301+ is a system used for the determination of total amount of haemoglobin in whole blood. The systems consist of a special/designed analyzer with microcuvette containing dry reagents. The microcuvette serves as a pipette and as a measuring

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microcuvette. No dilution is required. The haemoglobin measurement takes place in the analyzer, which follows the progress of the reaction until the end point has been reached. The system is factory calibrated against the haemoglobincyanide (HiCN) method, the international reference method for the determination of the haemoglobin concentration in blood.

Sample: Capillary, venous, or arterial blood may be used.

Appropriate anticoagulant in solid form i.e., EDTA, Heparin/fluoride are recommended in order to avoid a dilution effect.

Materials required:

- Hemocue Hb 301+ analyzer with main adopter
- Lancet
- Spirit Cotton
- Tissue paper
- Hemocue HB 301 Microcuvette

Procedure:

1. Switch on the analyzer.(Hemocue Hb 301+)
2. Pull the cuvette holder out to its loading position.
3. Press and hold the left button until the display is activated.
4. After 10 seconds the display will show three dashes --- & the hemocue symbol (Hb). This indicates that the analyzer is ready to use.
5. If the sample was to be taken directly from the finger, make sure the donors hand is warm & relaxed. Use only the middle or ring finger for sampling. Avoid finger with rings on.
6. Clean the finger tip with spirit swab and allow drying.

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7. Using your thumb, lightly press the finger from the top of the knuckle towards the tip to stimulate blood flow towards the sampling point. For the best flow and the least pain, sample at the side of the finger tip, not the centre.
8. Lightly pressing towards the finger tip, prick the finger using a lancet. Discard the lancet in a puncture proof container.
9. Wipe away the first 2 drops of blood.
10. If necessary, Re-apply light pressure towards the finger tip until another drop of blood appears. Avoid milking of the finger.
11. Make sure the third drop of blood is big enough to fill the microcuvette completely. Do not refill a partially filled microcuvette.
12. Wipe any excess blood on the outside of the microcuvette tip.
13. There should not be any air bubbles, discard the microcuvette if any bubbles are present and obtain another specimen .Gently wipe out the surface by using tissue paper.
14. Place the filled microcuvette in the horizontal position in the cuvette holder and close it.
15. The Hemoglobin (Hgb) value will be displayed in grams/dL after approximately 30-50 seconds. After 15-50 seconds the haemoglobin will be displayed.
16. Record the result before removing the microcuvette from the instrument.
17. Remove the microcuvette and discard in the sharps container.

If the test has to be done from the pilot sample

1. Take a clean glass slide, Place a drop of blood with the help of micropipette.
2. Fill the microcuvette in one continuous process.
3. Continue the process from the above no. 12 onwards.

Interpretation

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If the Hb% is more than 12.5g/dl accept the donor for blood donation.

If the Hb% is less than 12.5g/dl defer the donor for blood donation.

Quality Control:

The Hemocue Hb 301+ analyzer has an interval electronic "SELF TEST".

Every time the analyzer is turned on, it will automatically verify the performance of the electronic unit of the analyzer. This test is performed every second hour if the analyzer remains switched on.

9.11. PREPARATON OF 5 % POOLED RED CELL SUSPENSION

Scope & Application

This procedure applies to all testing that requires red cell suspension preparation.

Responsibility

It is the responsibility of every technician performing a given test to prepare the appropriate red cell suspension. Every morning, the shift duty technician must prepare A, B & O red cell suspension for the day's use.

Method

Principle:

The ratio of serum to red cells may dramatically affect the sensitivity of agglutination tests. Consistent preparation of 5% red cell suspension is critical to any agglutination test.

- Label tube as A, B and O.
- Add 100μltr of red cells 3 each from A group sample into the A labeled tube.

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- Add 100µltr of red cells 3 each from B group sample into the B labeled tube.
- Add 100µltr of red cells 3 each from O group sample into the O labeled tube.
- Fill the tube $\frac{3}{4}$ with 0.9% saline to resuspend the cells.
- Centrifuge the 3 tubes for at least 2 to 3 minutes at 3000rpm. Decant the supernatant fluid.
- Repeat the washing 3 times.
- Remove any debris or fibrin with the pipette.
- Label another 3 test tubes as A cells, B cells and O cells and add 1900 µltr of saline into each tube.
- Add the above washed A red cell concentrate of 100µltr into Test tube labeled as A cells.
- Add the above washed B red cell concentrate of 100µltr into Test tube labeled as B cells.
- Add the above washed O red cell concentrate of 100µltr into Test tube labeled as O cells.

Or

(Add 1 drop of red cell concentrate to 19 drops of normal saline to get tomato red color suspension)

- Test the pooled cells prepared using the antisera (anti A, B, AB and D) in use.

Proceed to use the same procedure to prepare 5% red cell suspension of a particular donor or patient sample for grouping and cross matching, Coomb's test, Quality control of antisera.

Limitations

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Hemolysis of the red cells from improper washing may result in false results. A cell suspension that is too heavy or too light may produce false positive or false negative results

Documentation

- Enter the donor unit numbers from which pooled cell prepared in the register.
- Record the results of testing with the Antisera in use.
- Enter the manufacturer's name & batch number of the antiseras.

Serological grading of agglutination

- (4+) + + + +** : Complete agglutination into one or two large clumps.
- (3+) + + +** : Numerous large clumps clearly visible to the naked eye with clear background.
- (2+) + +** : Granularity just visible to the naked eye; medium-sized clumps and unagglutinated corpuscles seen under the microscope (with clear background)
- (1+) +** : Tiny clumps; numerous unagglutinated corpuscles. (Clumps of 8 to 10 corpuscles under microscope) with turbid back ground
- (W)** : A definite but weak reaction in which there is a uniform distribution of very small clumps of 4 to 6 corpuscles under microscope. Turbid background.
- ?** : Uneven distribution of corpuscles with no definite clumps.

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Negative : All corpuscles separate and evenly distributed; confirmed under microscope.

NOTE: Partial or complete haemolysis is a Positive Reaction

9.12. BLOOD GROUPING

SCOPE & APPLICATION

To determine the correct ABO group of an individual and to ensure the reliability of the result. This procedure describes the method of detection of ABO antigens on the red cell and the reciprocal antibodies in the serum (Land Steiner's Law). It provides guidance for the use of blood grouping reagents (antisera & standard red cells) in order to detect weak variants, acquired antigens, Bombay (Oh) blood group and irregular red cell antibodies.

RESPONSIBILITY

It is the responsibility of the technician/supervisor in the red cell serology laboratory to perform the ABO grouping of donors and patients. One technician performs red cell testing and the other serum testing. The results are checked by the supervisor. If a discrepancy is encountered in cell and serum grouping, all tests should be repeated by the same technician using anti A1 and anti H lectins if required. If the discrepancy persists, the sample should be handed over to the advanced red cell serology laboratory for further workup. It is the responsibility of all staff performing the ABO grouping to ensure that quality controlled reagents and proper cell concentration are used.

Principle:

ABO system is the only system in which there is a reciprocal relationship between the antigen on the red cells and the naturally occurring antibodies in the serum. Routine grouping of donors and patients must therefore include both RBC and serum tests, each serving as check on the other.

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The procedure is based on the principle of agglutination of antigen positive red cells in the presence of antibody directed towards the antigen

ABO Grouping

1. Routine ABO grouping must include both cell & serum testing as each test serves as a check on the other.
2. ABO grouping test should be done at room temperature or lower; testing at 37 C weakens reactions.
3. Controls should always be run with respect to ABO grouping.
4. Tubes, slides or microplates should be labeled properly. One should not rely on the coloured dyes to identify the reagent antiserum.
5. Serum should always be added before adding cells & examine each tube after serum has been added to ensure that none has been missed.
6. Tubes or slides should be clean & dry.
7. Optical aid should be used to examine reactions that appear reactions (no agglutination) by the naked eye.
8. Results should be recorded immediately after observation.
9. Hemolysis is interpreted as positive result.

Techniques

Blood Sample

1. Clearly labeled samples of blood in sterile plain tubes are best for ABO & Rh tests. The sample can be stored at 4 C & should be tested within 48 hours. No sign of haemolysis should be there.
2. If serum has not completely separated or become clear, centrifuge the blood sample at 1000 – 3000rpm for 3 mins.
3. One or two milliliters of serum is pipette into a pre-labelled tube (identification double checked) for serum grouping & other tests.

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4. Take about 1ml of cells into pre-labelled tube (identification double checked) & add 0.9% normal saline & mix. Wash the cells thrice with normal saline & make 2-5% cell suspension in normal saline.

ABO Typing Techniques

The ABO type techniques are :

1. Slide test
2. Tube technique
3. Microplate technique
4. DiaMed ID microtyping system (Gel System)
5. Glass Microbeads method

Slide testing

Slide method is used for emergency ABO typing for preliminary screening of prospective blood donor, in outdoor camps and in rechecking the blood group prior to issue of blood for transfusion.

Method

- The blood present in the capillary tube after assessment of hemoglobin can be used for blood grouping.
- Take 2 slides. Place 2 drops of blood separately on the 1st slide and 1 drop on the 3rd slide.
- Add one drop of Anti A, Anti B on each drop of blood respectively on 1st slide.
- Add 1 drop of Anti D to the blood drop on 2nd slide.
- Mix the cells and antiserum with a clean stick. Spread each mixture evenly on the slide over an area of 2cm.
- Rotate the slide gently and leave for 2 minutes at room temperature, rotate again gently and look for agglutination.

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Interpretation

- Agglutination in Anti A : A group
- Agglutination in Anti B : B group
- Agglutination in Anti A&B : AB group
- No agglutination in A&B : O group
- Agglutination in Anti D : Rh Positive
- No Agglutination in Anti D : Rh Negative.

Enter the blood group in donor form/record.

9.13. MATRIX GEL SYSTEM BLOOD GROUPING

Sample Preparation for Forward Grouping

Prepare a 5% re cell suspension in Matrix TM Diluent 2 (LISS) as follows:

1. Dispense 0.5mL (500µL) of Matrix TM Diluent 2 (LISS) into a clean & labeled test tube.
2. Add 25 µL packed cells & mix gently.

Sample Preparation for Reverse Grouping

Use serum or plasma from sample. Preferably blood samples should be collected in citrate, EDTA or CPDA. For known cells prepare ABO cells as per following procedure:

1. Take fresh pooled A, B, O cells, and wash at least 3 times with Normal saline.
2. With washed cells make 0.8% cell suspension in 1 ml Matrix TM Diluent 2 by adding 10 µL packed re cells.

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Test procedure

1. Observe the card for appearance of gel and label the card with patient's details and remove the foil seal in instructed manner.
2. Add 50 µL of the patient's serum or plasma to both microtubes 5 & 6.
3. Incubate the cards for 10 mins at room temperature (18-25°C).
4. Pipette 10-15µL of the 5% patient's red cell suspension to microtubes 1-4 (A, B, D & Ctrl).
5. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10 mins).
6. Read the reaction.

Octopus Complete Blood Grouping

Sample preparation for forward grouping

Prepare a 5% red cell suspension in Matrix TM Diluent 2 LISS as follows:

1. Dispense 0.5 mL (500µL) of Matrix TM Diluent 2LISS into a clean & labeled test tube.
2. Add 25µL packed cells & mix gently.

Sample Preparation For Reverse Grouping

Use serum or plasma from sample. Preferably blood samples should be collected in citrate, EDTA or CPDA. For known cells prepare ABO cells as per following procedure:

3. Take fresh pooled A, B, O cells, and wash at least 3 times with Normal saline.
4. With washed cells make 0.8% cell suspension in 1 ml Matrix TM Diluent 2 by adding 10 µL packed re cells.

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Test procedure

1. Observe the card for appearance of gel and label the card with patient's details and remove the foil seal in instructed manner.
2. Add 50 µL of the **patient's serum of plasma** to the above **microtubes 6, 7 & 8.**
3. Pipette 10-15µL of the 5% **patient's red cell** suspension to microtubes 1-4 (A, B, D & Ctrl).
4. Incubate the cards for 10 mins at room temperature (18-25°C).
5. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10 mins).
6. Read the reaction.

Octopus Forward and Reverse Grouping with Subgrouping

Sample preparation for forward grouping

Prepare a 0.8% red cell suspension in Matrix TM Diluent 2 LISS as follows:

1. Dispense 1mL of Matrix TM Diluent 2 LISS into a clean & labeled test tube.
2. Add 10µL packed cells & mix gently.

Sample Preparation For Reverse Grouping

Use serum or plasma from sample. Preferably blood samples should be collected in citrate, EDTA or CPDA. For known cells prepare ABO cells as per following procedure:

1. Take fresh pooled A & B cells, and wash at least 3 times with Normal saline.
2. With washed cells make 0.8% cell suspension in 1 ml Matrix TM Diluent -2 by adding 10 µL packed re cells.

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Test procedure

1. Observe the card for appearance of gel and label the card with patient's details and remove the foil seal in instructed manner.
2. Add 50 µL of the **patient's serum of plasma** to the above **microtubes 7 & 8**.
3. Pipette 10-15µL of the 0.8% **patient's red cell** suspension to microtubes 1-6 (A, B, D, Ctrl, A1 & H).
4. Add 25 µL of LYOPAP to microtubes 5 & 6 (A1 & H).
5. Incubate the cards for 10 mins at room temperature (18-25°C).
6. Centrifuge the cards in Matrix [™] card centrifuge for 1 cycle (10 mins).
7. Read the reaction.

9.14. ABO TESTING BY TUBE METHOD

(FORWARD AND REVERSE GROUPING)

Scope & Application

To determine the correct ABO group of an individual & ensure the reliability of the result. This procedure describes the method of detection of ABO antigens on the red cell & the reciprocal antibodies in the Serum (Landsteiner's Law).It provides guidance for the use of blood grouping reagents (antisera & standard red cells) in order to detect weak variants, acquired antigens, Bombay(Oh) blood group & irregular red cell antibodies.

Responsibility

It is responsibility of the technician/supervisor in the red cell serology laboratory to perform the ABO grouping of donors & patients. One technician performs red cell testing & the other serum testing. The results are checked by the supervisor.

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If a discrepancy is encountered in the cell & serum grouping, all tests should be repeated by the same technician using anti A1 & anti H1 lectins if required. If the discrepancy persists, the sample should be handed over to the advanced red cell serology laboratory for further workup. It is the responsibility of all staff performing the ABO grouping to ensure that quality controlled reagents & proper cell concentrations are used.

ABO grouping must include both cell and serum testing as each test serves as a check on the other. ABO grouping test should be done at room temperature or lower as testing at 37 C weakens reactions. Controls should be done once a day. Tubes should be clean and labeled appropriately. Centrifugation of tubes enhances antigen antibody reaction. Weaker antigen and antibody can be detected. Serum should always be added before adding cells.

Method: Forward grouping (RBC testing)

- Label tubes with donor/patient and test identification.
- Prepare 5% cell suspension for cells being tested.
- Place two drops of anti-A, anti-B, anti AB, anti A1 and anti-H reagent in the appropriately labeled tubes.
- Add to each tube one drop of 5% red cell suspension of blood to be tested.
- Mix the contents of the tubes gently and incubate at room temperature for 15 minutes.
- Centrifuge at 1000rpm for 1 minute.
- Gently resuspend the red cell button & examine for agglutination against a well lighted background.
- When no agglutination is seen macroscopically, examine the contents under microscope.

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Reverse grouping (Serum group testing)

- Label tubes with donor/patient and test identification.
- Add 2 drops of test serum in all tubes in the corresponding tubes.
- Prepare 5% cells for testing of A,B and O groups by pooling 3 samples of each group.
- Add 1 drop of 5% pooled A red cell suspension in tube labeled Ac.
- Add 1 drop of 5% pooled B red cell suspension in tube labeled Bc.
- Add 1 drop of 5% pooled O red cell suspension in tube labeled Oc.
- Mix the contents of the tubes gently and incubate the test tube for minimum 15 minutes at room temperature.
- Centrifuge all tubes at 1000rpm for 1 minute.
- Gently resuspend the red cell button & examine for agglutination.

Interpretation

- Compare the reaction of agglutination according to the **serological grading agglutination** chart.
- Agglutination in any tube of RBC tests and agglutination or hemolysis in serum constitutes a positive test results. The expected agglutination reactions for positive tests are 3+ to 4+.
- A smooth suspension of RBC's after resuspension of RBC button is a negative test result. All negative results must be verified under microscope. Cells must be separate without any clumping.
- The interpretation of ABO group is as follows.

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Interpretation

Cell group	Rh	Serum group	Du	ABO Group Rh
Antisera		Pooled Red Cells		type
-A -B -AB -A1 -H	-D	Ac Bc Oc		
+ 0 + + W	+	0 + or H 0	0	A1 Pos
+ 0 + 0 +3	+	0 + or H 0	0	A2 Pos
+ + + + W	0	0 0 0	Neg	A1 B Neg
+ + + 0 +3	0	0 0 0	Neg	A2 B Neg
0 + + 0 W	+	+ or H 0 0	0	B Pos
0 0 0 0 +4	+	+ or H + or H 0	0	O Pos
0 0 0 0 0		+ or H + or H+ +or H		Oh (Bombay)

Grading Degree Of Agglutination

- +4 Single clump of agglutination with no free cells
- +3 Three or four individual clumps with no free cells
- +2 Many fairly large clumps with many free cells
- +1 Free granular appearance visually, but definite small clumps (10-15 cells) per power field

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W 2 to 3 cells sticking together per low power field, uneven distribution.

O All cells are free

+H Haemolysis (partial or total) must be interpreted as positive

W – Weak

+Agglutination

H-Haemolysis

O – no agglutination

Resolve any discrepancy between cell & serums typing tests before the patient or donor's blood groups is interpreted and record the results immediately.

DOCUMENTATION

- Enter the results of donor grouping in the donor grouping register.
- Enter the results of patients grouping in the patient grouping register, blood group requisition form, serial case number register.

9.15. ABO SUB GROUPING

SCOPE AND APPLICATION:

Blood group A and AB have been divided into subgroups. A1, A2, A1B, A2B depending upon the reaction with anti A1 lectin. This is derived from dolichous biflorus or anti human A1. About 80% of group A & AB belong to sub group A1 & A1B i.e., they react with Anti A1 lectin. While 20% belong to A2 & A2B i.e., they fail to react with anti A1 lectin. The individual with sub group A2 & A2B can have anti-A1 antibodies in their serum. Sub groups of blood group 'B' are Bm, Bx. are rare and non-significant. Bombay blood group: (Oh) discovered in 1952 by Bhende, Bhatia, and Deshpande, in Bombay. The red cell of Bombay group has no A, B & H antigen but contains all antibodies- anti-A, anti-B and anti-H.

RESPONSIBILITY

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It is the responsibility of the technician/supervisor in the red cell serology laboratory to perform the ABO sub grouping of donors and patients by using anti-A1 and anti-H lectin. It is the responsibility of all staff performing the ABO sub grouping to ensure that quality controlled reagents and proper cell concentration are used.

PROCEDURE:

Along with the ABO grouping, sub grouping also should be done.

Testing

1. Label tubes with donor/patient and test identification.
2. Prepare 5% cell suspension for cells being tested.
3. Place one drop of anti-A1, and anti-H lectin, reagent in the appropriately labeled tubes.
4. Add to each tube one drop of a 5% cell suspension of the red cells to be tested.
5. Mix the contents of the tubes gently and incubate at room temperature for 5 minutes.
6. Centrifuge at 1000 rpm for 1 minute.
7. Gently resuspend the red cell button and examine for agglutination.
8. Record the agglutination according to the grading chart.

Interpretation:

CELL GROUPING of A1 and A2 phenotype					
Anti -A	Anti-B	Anti-AB	Anti-A1	Anti-H	GROUP
++++	Negative	+++	+++	0 /weak+	A1

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++++	Negative	+++	0	+++	A2
++++	++++	++++	++++	O/H	A1B
++++	++++	++++	Negative	++++	A2B
SERUM (REVERSE) GROUPING					
A1 cells	B cells	O cells			GROUP
Negative	+++	Negative			A1
Neg/++	+++	Negative			A2
Negative	Negative	Negative			A1B
O/H	Negative	Negative			A2B

+ to +4 = agglutination of increasing strength

H = Haemolysis

O = No agglutination

BOMBAY PHENOTYPE							
Anti – A	Anti-B	Anti- AB	Anti- A1	Anti- H	A1 cells	B cells	O cells
0	0	0	0	0	+++	+++	+++

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DOCUMENTATION

- Enter the results of donor grouping in the donor grouping register.
- Enter the results of patients grouping in the patient grouping register, blood group requisition form, serial case number register.

9.16. Rh D TYPING

Scope & Application

This Standard Operating Procedure (SOP) provides the method to be followed to determine the Rh D type of an individual and ensure the reliability of the result. This procedure describes the method for detection of D antigen on the red cells. It provides guidance for the use of anti D blood grouping reagents.

Responsibility

It is the responsibility of the technician/supervisor in the red cell serology laboratory to perform the D typing of donors & patients using one monoclonal & one bivalent reagent. If a discrepancy is encountered between the two batches of anti D, the test should be repeated by the same technician. If the discrepancy persists, the sample should be handed over to the advanced red cell serology laboratory for further work up. If results of D typing of a blood donor are negative, the technician should proceed with D typing procedure. It is responsibility of all staff performing the D typing ensure that quality controlled reagents & proper cell concentration are used.

Principle:

Testing with anti-D is necessary to determine if red blood cells possess or lack D blood group antigen. Absence of agglutination is a negative test result, which indicates that the D antigen is not demonstrable. Agglutination of red blood cells with an anti-D reagent is a positive test result, which indicates the presence of the D antigen on the red blood cells.

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Other than A and B antigens, RhD is the most important red cell antigen in transfusion practice. Monoclonal anti D(IgM) reagents requires no potentiators and agglutinate most D positive red cells and used for testing of Rh typing but sometimes may fail to agglutinate red cells of some partial/weak-D antigen thus adding polyclonal(IgM+IgG) anti-D will provide a clear reaction even to some partial/weak-D and is now routinely used.

Method (Tube method)

- Label tubes with unit and test identification.
- Prepare 5% cell suspension for testing in accordance with the preparation of cell suspension procedure.
- Add one drop of reagent anti-D to the test tubes.
- Add one drop of red cell suspension to the same test tube.
- Mix well and keep it at room temperature for 15 minutes.
- Centrifuge the tube at 1000rpm for 1 minute.
- Gently resuspend the red cell button and examine for agglutination.

Interpretation

- Agglutination of red cell in the presence of anti-D is a positive test result and indicates the presence of D antigen.
- A smooth suspension of RBCs after resuspending of the button is a negative test result.
- All negative results must be verified under microscope. Cells must appear separate without any agglutination.

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- Proceed with weak D (Du) typing using indirect anti-globulin test.

Discrepancies

- Persons with auto antibodies or abnormal serum protein.
- Cord red blood cells heavily sensitized with anti-D.

Grade and record the results in Blood grouping register

CELL TYPING ANTI-D IgM	INTERPRETATION OF Rh D TYPE
C	Positive
-	Negative
-	?*
C	?*

C = Visible Clumps

In case of Rh negative **blood donor** proceed with weak D (Du) TYPING using indirect anti-globulin technique.

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9.17. TEST FOR WEAKER VARIANT OF D (Du TYPING)

A weaker variant of D-antigen is termed as Du. Du red cells are agglutinated by some anti-D sera and not by others, but mostly these react by the AHG technique and is done as a confirmatory and mandatory test in all negative blood groups in transfusion medicine.

Method

- Label three test tubes as Test (T), Negative (N), and Positive (P).
- Prepare 5% red cell suspension of the blood to be tested and place 2 drops of suspension in tube T and N.
- Prepare 5% Rh Positive red cell suspension and place two drops of suspension in tube P.
- Add one drop of Anti-D (IgM) to tubes T and P.
- Add one drop of Bovine Albumin 22% to tube N.
- Mix the contents of all tubes and incubate all three tubes at 37°C for 30 minutes.
- Add 2 drops of AHG (antihuman globulin) or Coombs sera to all three tubes.
- Mix well and centrifuge all three tubes at 1000rpm for one minute.
- After centrifugation shake the tubes and look for agglutination by both macroscopically and microscopically.

Interpretation

Test (T)	Negative (N)	Positive (P)	Results
+	0	+	Rh+ve Du type
0	0	+	Rh-ve
+	0	0	Invalid

+ indicates agglutination and 0 indicates No agglutination

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1. When agglutination appears in the 'test' tube and not in the 'control' the red cells are of Du variant and should be classified as **Rh Du Positive**.
2. If there is no agglutination in both 'test' and 'control' tubes the red cells should be classified as **Rh Negative**.
3. If agglutination seen in both tubes, then the test is invalid.

Documentation

- Enter the result of donor grouping in the donor grouping register and
- Enter the results of patients grouping in the patient grouping register, blood group requisition form.

Treat Du Positive person as Rh positive as a donor but Rh negative as a recipient.

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9.18. MATRIX GEL SYSTEM WEAK D (DU) TEST

Sample Preparation for Weak D (Du) Test.

Prepare a 0.8% red cell suspension in Matrix TM Diluent 2 (LISS) as follows:

1. Dispense 1mL (1000μL) of Matrix TM Diluent 2 (LISS) into a clean & labeled test tube.
2. Add 10μL packed cells & mix gently.

Test Procedure

Weak D (Du) Test by Indirect Coombs Test (IAT)

1. Observe the card for appearance of gel and label with Patient's details and remove the foil seal in instructed manner.
2. Pipette 50μL of patient's red cell suspension (0.8%) into labeled microtube.
3. Add 25μL of Matrix TM Anti-D IgG to the above microtubes.
4. Incubate at 37°C for 15 minutes in Matrix TM Card Warmer.
5. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10mins).
6. Read the reaction.

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9.19. TEST FOR HAEMOLYSIN

SCOPE & APPLICATION

Presence of haemolysins should be regarded as unsafe for transfusion to recipients of other groups.

RESPONSIBILITY

The technician from the red cell serology laboratory is responsible to check for haemolysins & label accordingly before issue of blood/component.

PROCEDURE:

1. Take 10% red cell suspension of A1, B and O blood group in 0.9% of NaCl.
2. Take three test tubes and label them as A, B, O respectively. Add one volume of fresh donor serum to each tube.
3. Add one volume of prepared 10% A1 cell suspension to the first tube.
Similarly B cell suspension to the second tube. Using O cells may be done as negative control in the third tube.
4. If the serum is more than 24 hours old, add one volume of fresh O group serum free of lysins to each tube as a source of complement.
5. Mix the contents of each tube, incubate at 37°C for 1 hour, and examine the supernatant liquids for haemolysis.

Serum giving a positive result in this test is further examined as follows:

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6. Dilute one volume of the serum with three volumes of 0.9% NaCl(1:3 dilution) and mix one volume of the diluted serum with one volume of fresh O group serum free of lysins and one volume of 10% cell suspension of A1 B cells. (which ever lysed in the first test)
7. At the same time in two further tubes take 1:1 diluted (in 0.9% NaCl) fresh O group serum free of lysins.
8. To one of these tubes add one volume of prepared 10% A1 cell suspension. Similarly B cell suspension to the other tube.
9. Mix the contents. Incubate at 37°C for 1 hour and examine the Supernatant liquids for haemolysis. No haemolysis should be seen in any of the tubes.
10. Group O blood samples whose sera show the presence of haemolysins should be regarded as unsafe for transfusion to recipients of other groups and must be labelled accordingly.

DOCUMENTATION:

Haemolysin test for donor blood is entered in blood reverse grouping register. And patient blood testing result is entered in a separate register.

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9.20. ANTIBODY SCREENING

Scope & Application

This procedure applies to all testing requires antibody screening, including donor units, patient's pre – transfusion blood grouping & prenatal specimens.

Responsibility

It is the responsibility of the technician/supervisor in the red cell serology laboratory to perform the antibody screen using proper cell concentrations. One technician performs all tests & another checks it. If any unexpected blood group antibody is detected, inform the staff of Advanced Red Cell Serology for further investigations.

METHOD

Principle:

The antibody screen test is used in the detection of unexpected blood group antibodies. In this test, pooled O cells or the antibody-screening reagent red blood cells are combined with serum under investigation.

The addition of a potentiating medium enzyme / albumin helps to promote the interaction of red cells and antibodies allowing antibody/antigen reactions to occur. Positive reactions (haemolysis or agglutination) in any tests indicate the presence of allo antibody or auto antibody in the serum.

Method

- Label tubes with donor/patient and test identification
- Add two drops of test serum to each tube
- To the tube add 1 drop of 2 – 5% pooled O red cell suspension

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- Add 1 drop of 22% bovine albumin to the test tubes.
- Add 1 drop of 5% pooled O red cell suspension to tubes labeled 'IAT'. *(1:1, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256, 1:512 dilutions)
- Mix the contents of the tubes gently and incubate for 15 minutes at 37°C
- Either enzyme or albumin or coomb's method may be followed for detection of incomplete antibodies

TEST	INCUBATION TEMPERATURE	IDEAL INCUBATION TIME
Saline	Room temperature	1 hour
Albumin	37°C	45 minutes
IAT	37°C	1 hour

IAT – Indirect antiglobulin test

- Follow manufacturer's directions when using commercial reagents.

Results

- Centrifuge the tube at 1000rpm for 1 minute
- Examine for haemolysis.
- Gently resuspend the red cell button and examine for agglutination.
- Examine all visually negative tests microscopically.
- Grade and record tests results immediately.
- Proceed to perform antiglobulin phase of the indirect antiglobulin test on tubes labeled IAT.
- Wash cells 3 times with saline. Decant completely after last wash.

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- Add 2 drops antihuman globulin reagent to the dry cell button.
- Mix well and centrifuge at 1000rpm for 1 minute.
- Read and record results.
- Add 1drop IgG sensitized cells to all negative results. This shows a positive agglutination.

Interpretation

- Haemolysis or agglutination in test may indicate the presence of an unexpected antibody.
- The absence of agglutination and haemolysis in the test is a negative test result.
- After addition of IgG-sensitized cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.
- If IgG-sensitized cells added to confirm the activity of the anti-IgG show only weak or no agglutination after centrifugation, the test is invalid and must be repeated.

Limitations

If tests with all reagent red cells are reactive, the possibility of spontaneous agglutination must be considered. A control of cells washed 3 to 4 times added to 2 drops of saline must be non reactive.

DOCUMENTATION

Results of donor unit antibody screen are entered in the donor grouping register. Results of patients antibody screen are entered in the patient antibody screening register. All records are

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initialed by the technician who has performed the test and by the technician who has checked the results.

9.21. COOMBS CONTROL CELLS (IgG Sensitized cells)

Scope & Application

Coombs Control Cells are IgG sensitized red cells, used in antiglobulin test.

Responsibility

It is the responsibility of every technician performing a given test to prepare Coombs Control Cells every morning for the day's use.

Only Rh +ve red cells of O group are used and manually coated with Polyclonal IgG with a known dilution and this reagent is used as positive control in testing of DAT & IAT.

Method

- Wash O Rh (D) positive cells 3 times in saline.
- Take 0.5ml of washed packed cells in a test tube.
- Add 2-3 drops of Anti D.

Note : IgG Anti D serum is diluted with normal saline such that it coats the red cells but does not agglutinate them.

- If there is agglutination, the procedure is repeated by taking more diluted Anti D serum.
- If there is no agglutination, wash the cells 3 times with normal saline & then make 5% suspension in saline.
- Add 2 drops of AHG serum to 1 drop of 5% cell suspension.
- Mix gently & centrifuge the tube at 1000rpm for 1 minute.
- Cells should show 2% agglutination.

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- IgG sensitized red cells are called Coomb's control cells which are now ready for use in the Anti globulin tests.
 - Coombs control cells should be freshly prepared for testing of DAT & IAT.
- Enter the date and time of preparation on the tube.

9.22. MATRIX GEL SYSTEM DIRECT & INDIRECT COOMBS TEST

Sample Preparation for Direct & Indirect Coombs Test

Prepare a 0.8% red cell suspension in Matrix TM Diluent 2 (LISS) as follows:

1. Dispense 1mL (1000μL) of Matrix TM Diluent 2 (LISS) into a clean & labeled test tube.
2. Add 10μL packed cells & mix gently.

Test Procedure

Indirect Coombs Test (IAT)

1. Observe the card for appearance of gel and label with Patient's details and remove the foil seal in instructed manner.
2. Pipette 50μL of suspension of fresh, pooled "O" cells into labeled microtube.
3. Add 25μL of the patient's serum/plasma to the microtubes.
4. Incubate at 37°C for 15 minutes in Matrix TM card Warmer.
5. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10mins).
6. Read the reaction.

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Direct Coombs Test (DAT)

1. Observe the card for appearance of gel and label with Patient's details and remove the foil seal in instructed manner.
2. Pipette 50µL of Patient's red cell suspension into labeled microtube.
3. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10 mins).
4. Read the reaction.

9.23. INDIRECT ANTIHUMAN GLOBULIN TEST (IAT)

Scope & Application

To detect the presence of incomplete antibodies (IgG) /complement binding antibodies in the serum after coating on red cells in vitro. The test is done to determine the presence of sensitization of red cells with IgG and/or complement in vitro which are detected in conditions like presence of atypical antibodies in serum, detecting red cell antigens like Kidd, Duffy, Kell etc., and for compatibility testing in transfusion medicine. Serum should be fresh for detecting complement binding antibodies.

Responsibility

It is the responsibility of the technologist of serology laboratory.

Method

- Label 3 test tubes Test (T), Negative (N) and Positive (P).
- Add 2 drops 5% O positive washed red cells suspension to each tube.
- Add 2 drops of to be tested serum to tube T.
- Add 2 drops of Bovine Albumin to tube N.
- Add 2 drops of IgG sensitized cells to tube P.
- Mix and incubate at 37°C for 60 minutes.

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- Centrifuge at 1000rpm for 1 minute, agglutination at this stage indicates presence of saline reacting antibodies.
- If no agglutination wash the red cells in all tubes with normal saline 3 times and decant after last wash. Incomplete washing may give false negative results.
- Add 2 drops of AHG serum to all the test tubes.
- Mix and centrifuge all the tubes at 1000rpm for 1 minute immediately.
- Gently shake the tube to dislodge the button immediately examine for agglutination microscopically. Record the result.
- If test is negative add 1 drop of IgG coated red cells, Mix, centrifuge at 1000 rpm for 1 minute look for agglutination. If negative result obtained at this stage the test is invalid and whole test has to be repeated.
- The positive control should give 2+ reaction.

Interpretation

Test (T)	Negative (N)	Positive (P)	Results
+	0	+	IAT +ve
0	0	+	IAT –ve
+	0	0	Invalid

+ indicates agglutination and 0 indicates No agglutination

Enter the results in Coombs register for IAT/DAT.

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9.24. DIRECT ANTIHUMAN GLOBULIN TEST (DAT)

Scope & Application

To demonstrate the coating (sensitization of red cells in vivo with immune antibodies IgG & or complement components C3b & C3d may occur in conditions like hemolytic disease of newborn, autoimmune hemolytic anemia, drug induced hemolytic anemia, hemolytic transfusion reaction and for detection of atypical antibodies on patient/donor red cells. Blood sample should be fresh and test should be done immediately.

Responsibility

Technicians on duty

Method

- Label 3 test tubes as Test (T), Negative (N) and Positive (P).
- Add 2 drops of 5% red cells suspension of blood to be tested to tube T and N.
- Add 2 drops of 5% IgG sensitized cells to tube P.
- Add 2 drops of AHG to tube T and P.
- Add 2 drops of Bovine Albumin to tube N.
- Mix, and centrifuge all tubes at 1000rpm for 1 minute immediately.
- Gently shake the tube to dislodge the cells button & see for agglutination. Record the results.
- If test is negative add 1 drop of IgG coated red cells, Mix, centrifuge at 1000 rpm for 1 minute and look for agglutination. If negative result obtained at this stage the test is invalid and whole test has to be repeated.

Interpretation

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Test (T)	Negative (N)	Positive (P)	Results
+	0	+	DAT +ve
0	0	+	DAT –ve
+	0	0	Invalid

+ indicates agglutination and **0** indicates No agglutination

IAT (ICT) and DAT (DCT) is **positive** when agglutination is observed either/after incubation at room temperature and immediate after spin.

DOCUMENTATION:

After investigation the results should be recorded in the register along with Sl. No., Date, Patient name, age, sex, hospital name/IP No., ward/bed No., and Doctor -In-charge.

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9.25. MATRIX GEL SYSTEM COMPATIBILITY TESTING (CROSS MATCHING)

Sample Preparation for Coombs Test

Prepare a 0.8% red cell suspension in Matrix TM Diluent 2 (LISS) as follows:

1. Dispense 1mL (1000µL) of Matrix TM Diluent 2 (LISS) into a clean & labeled test tube.
2. Add 10µL packed cells & mix gently.

Test Procedure

Major Coombs Crossmatch

1. Observe the card for appearance of gel and label with Recipient and Donor's details and remove the foil seal in instructed manner.
2. Pipette 50 µL of Donor's red cell suspension (0.8%) into labeled microtube.
3. For auto control (if to be included) add 50 µL 0.8% recipient's red cell suspension.
4. Add 25 µL of the recipients' serum/plasma to all microtubes.
5. Incubate at 37°C for 15 minutes in Matrix TM card Warmer.
6. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10mins).
7. Read the reaction.

Minor Coombs Crossmatch

1. Observe the card for appearance of gel and label with recipient and Donor's details and remove the foil seal in instructed manner.
2. Pipette 50µL of recipient's red cell suspension (0.8%) into labeled microtube.
3. Add 25µL of donor's serum/plasma.
4. Incubate at 37°C for 15 minutes in Matrix TM card Warmer.
5. Centrifuge the cards in Matrix TM card centrifuge for 1 cycle (10 mins).
6. Read the reaction.

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9.26. COMPATIBILITY TESTING (Cross matching)

Scope & Application

To ensure that the donor blood when transfused into the recipient will not result in any predictable adverse reaction.

Responsibility

Technicians on duty

Compatibility testing or pretransfusion testing is to select blood components that will have acceptable survival when transfused and will not cause harm to the recipient. Normally group specific blood is selected. Compatibility testing is done to ensure safe transfusion therapy.

Method

Saline technique: It is designed to detect compatibility of IgM antibody in patients' serum against antigens on donor red cells.

Principle:

The major cross-match is used to detect unexpected blood group antibodies in patient's serum against antigens on donor cells. Positive reaction in any test indicates incompatibility.

Saline cross - match

- Label 2 test tubes as Major (P) and Minor (D)
- Add 2 drops of patient serum in tube P.

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- Add 2 drops of donor serum in tube D.
- Add 2 drops of patients washed 5% red cell suspension in tube D.
- Add 2 drops of donors washed 5% red cell suspension in tube P.
- Mix, and incubate for 45 minutes at room temperature.
- Centrifuge at 1000rpm for 1 min.
- Gently resuspend red cell button and examine for agglutination & hemolysis.

Interpretation

- Examine all visually negative reactions under microscope
- Absence of hemolysis or agglutination in all tests indicates compatibility.
- If negative, continue next step of cross matching by AHG method.
- Hemolysis or agglutination in any tests indicates incompatibility and should be checked for discrepancies.

Limitations:

The saline / enzyme cross match will not:

1. Detect error in Rh typing
2. Prevent isoimmunisation of the recipient
3. Ensure normal red blood cell survival.
4. Detect some weakly reactive antibodies.

DOCUMENTATION

Enter results in cross-match register and compatibility report form. All records are initialed by technician who performed the test and the technician who has checked the results.

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9.27. ANTI GLOBULIN CROSS MATCH

SCOPE & APPLICATION

This procedure applies to compatibility testing of all multi-transfused patients and transfusion recipients who currently demonstrate or have a history of clinically significant antibodies.

RESPONSIBILITY

It is the responsibility of the technician in the cross match facility of the red cell serology laboratory to perform the anti-globulin cross match using quality controlled reagents and proper cell concentrations. One technician performs the tests and another checks it. If any unexpected blood group antibody is detected, further working is suggested.

Procedure

Principle:

The cross match through the anti-globulin phase permits detection of clinically significant incompatibilities caused by incomplete antibodies that sensitize cells at 37°C, but do not directly cause agglutination

Antihuman globulin technique: The majority of incomplete antibodies is IgG and is detected by AHG test and is mandatorily done as routine compatibility testing.

- Label 2 test tubes as Major (P) and Minor (D)
- Add 2 drops of patient serum in tube P.
- Add 2 drops of donor serum in tube D.
- Add 2 drops of patients washed 5% red cell suspension in tube D.
- Add 2 drops of donors washed 5% red cell suspension in tube P.
- Incubate for 45 minutes at 37°C.

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- Centrifuge at 1000rpm for 1 min. Check for hemolysis/agglutination.
- If there is no hemolysis/agglutination wash the cells three times with normal saline.
- Perform IAT test
 - Add 2 drops of AHG to the washed cells.
 - Centrifuge at 1000rpm for 1 minute and look for agglutination.
- Microscopic absence of agglutination denotes compatibility.
- Add 1 drop of IgG sensitized cells to all negative test tubes.
- Centrifuge and check for agglutination, absence of agglutination makes the test invalid. After the addition of IgG-sensitized control cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative Antiglobulin test is valid.

Interpretation:

1. Hemolysis or agglutination indicates the presence of a serologically incompatible cross-match. This result is interpreted as incompatible.
2. Absence of agglutination and hemolysis is a negative test result and indicates a serologically compatible cross match. This result is interpreted as Compatible. If the IgG-sensitized control cells added to confirm the activity of the polyspecific reagent show only weak or no agglutination the test is invalid and must be repeated.
3. Limitations:

The anti-globulin cross-match will not:

- i) Detect error in Rh typing.
- ii) Prevent isoimmunisation of the recipient.
- iii) Ensure normal red blood cell survival.
- iv) Detect some weakly reactive antibodies.

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DOCUMENTATION

Enter all results on the transfusion record register. Enter only the results of compatible units in the blood compatibility form. The technician who performed the test and the one who checked the results sign all records.

9.28. EMERGENCY CROSS MATCHING

- The Medical Officer/Sister in charge from respective wards/OT/ICU/CCU calls for the requirement of respective blood components.
- Receive the completely labeled sample with completely filled Blood Request Form in the Blood Bank.
- Mention “Emergency” on the Blood Request Form to ease the identification process.
- Check the Patient’s sample for ABO & Rh grouping by slide method.

Cross matching can be done as follows:

- Take a clean tube & add 4 drops of patient’s serum & 4 drops of 10% donor cells suspension.
 - Mix & incubate at 37 C for 15 minutes
 - After incubation centrifuge for 1 minute at 1000PRM
 - Put a drop on a slide & look for microscopic agglutination
 - If negative, then wash the remaining cells with normal saline & decant the supernatant fluid
 - Add 1 drop of AHG & look for microscopic agglutination
- Enter the details in the Cross match register
 - Label the components & issue the same after entering the details in the issue register.

Interpretation

- Agglutination indicates incompatibility

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- No agglutination indicates compatibility

Dire emergency with no lead time

- Get the request form from the treating medical officer & issue of “O” Rh negative blood without cross matching
- After issuing do a routine cross matching by conventional tube method

9.29. SPECIAL TESTS

Auto antibodies test:

- Separate serum from clotted sample and wash the red cells 3 times with saline.
- Prepare a 5% red cell suspension of the blood to be tested.
- Take equal volume of 5% red cell suspension and serum in a tube.
- Mix and incubate at room temperature for 1 hour.
- After 1 hour centrifuge at 1000rpm for 1 minute and read the result by resuspending the red cell button.
- Negative result should be confirmed microscopically.
- Agglutination indicates presence of auto antibodies.

Warm antibodies test:

- Prepare 5% red cell suspension of pooled cells of O group.
- Add equal volumes of 5% pooled O cell suspension and patients serum.
- Mix and incubate at 37°C for 1 hour.
- Centrifuge for 1 minute at 500rpm.
- Resuspend the red cell button and look for agglutination microscopically.
- Both positive and negative controls are necessary. Rh antibody coated cells are used as positive control and saline suspension of unsensitized donor cells are negative control.

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- Agglutination indicates presence of warm antibodies.

Cold antibodies test:

- Prepare 5% suspension of pooled O cells.
- Take equal volumes of 5% pooled O cell suspension and patients serum in a test tube.
- Keep the tube after thorough in the refrigerator at 3-4°C for 1 hour.
- Centrifuge at 500rpm for 1 minute.
- Resuspend the red cell button and look for agglutination microscopically.
- Both positive and negative controls are necessary. Rh antibody coated cells are used as positive control and saline suspension of unsensitized donor cells are negative control.
- Agglutination indicates presence of cold antibodies.

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9.30. BLOOD COMPONENT PREPARATION & THEIR USES

Scope & Application

For judicious use of blood it is necessary to use the components as per the need rather than using whole blood. From the whole blood collected in double bags, packed cells & FFP or F-VIII deficient plasma are separated. From triple bags, packed cells, FFP & platelets or packed cells, FVIII deficient plasma & cryoprecipitate are separated. When the plasma frozen at -80° C is thawed at 4° C, a cryoglobulin remains as a precipitate which is called cryoprecipitate. It contains mainly F-VIII & fibrinogen.

Responsibility

It is the responsibility of the component room technician to separate components from whole blood collected in multiple bags.

A blood donor donates whole blood from which components are prepared, which when used separately or in combination, meets most patients transfusion need and keep the risk of transfusion to minimum. The ability to separate various components from whole blood is desirable for following reasons:-

- Separation of blood into components allows optimal survival of each constituent.
- Component preparation allows transfusing only specific blood component that the patient requires which avoids the use of unnecessary components, which could be contraindicated in patients.
- By blood component, several patients can be treated with the blood from one donor, making optimal use of every unit of donated blood.

Preparation of blood components is possible due to

- Multiple plastic pack system

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- Refrigerated centrifuge
- Different specific gravity of cellular components

Red cell Sp.Gr.	1.08 to 1.09
Platelet Sp.Gr.	1.03 to 1.04
Plasma Sp.Gr.	1.02 to 1.03
- Due to different Sp.Gr. of cellular components, they can be separated by centrifugation at different centrifugal force in g for different time.

Method

Centrifuges used for separation are calibrated to produce highest product in the shortest time at lowest possible spin so as to cause the least trauma to each product and at the same time maintain optimal temperature for component viability. Correct speed, time and temperature must be programmed and maintained as they are the most crucial factors in component preparation.

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9.31. Preparation of Packed cells and FFP/Cryo poor plasma using double bags.

Packed Red Blood Cells are prepared by removing most of the plasma from a unit of whole blood. Red cells have higher Specific gravity than plasma and settles due to gravitational sedimentation.

- Keep the units vertical on the laminar flow table for 30-45 minutes (process all units within 6hrs of blood collection)
- Keep the bags on the weighing machine and balance them with rubber disc.
- Keep the equally balanced bags diagonally opposite in the refrigerated centrifuge ensuring that the position of the bags in buckets is parallel to the direction of the spin otherwise excessive eccentric loads placed on rotor of centrifuge causes irregular wear and tear, eventually leading to breakage of the blood bag.
- Observe for any abnormal vibration till the required speed is attained, if there is any, stop the centrifuge and check the weight of the cups.
- After centrifugation at 2500rpm for 7 minutes at 2-6°C, gently remove the bags from the bucket and place them on the expresser stand under the bio safety cabinet. Break the integral seal of the tube connecting it to the satellite bags manually and express the supernatant plasma into the satellite bag. Leave 50-60ml of plasma with the red cells in the primary bag and this component is Packed Red Blood Cells.
- Label the plasma in the satellite bag, as Fresh Frozen Plasma (FFP), if separated within 6hrs of collection and stored immediately at -80°C.
- If plasma is separated after 6 hrs of collection label as Cryo Poor Plasma (CPP) and stored below -30°C.

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9.32. Preparation of packed cells, platelet concentrate and FFP using triple bags with or without additive solutions.

- Process the blood bag collected within 6hrs.
- Keep the bags on the bio safety cabinet for 30-45minutes.
- Balance the bags using rubber disc.
- Keep equally balanced bags diagonally opposite each other in the refrigerated centrifuge.
- Position the bags in bucket parallel to the direction of the spin. Centrifuge the bags at 1500rpm for 10 minutes at 22°C in refrigerated centrifuge.
- Keep the bag in the plasma expresser in the bio safety cabinet. Break the seal of the tubing connecting to the satellite bag, and express the plasma into the satellite bag leaving 50-60ml plasma along with the red cells. If the bag with additive solution is used, remove all plasma in satellite bag before clamping. Remove the clamp of the bag containing additive solution and let the additive solution solely pass into the primary bag containing red cells.
- Mix the contents thoroughly and seal the tubing and detach the bags.
- Keep the primary bags containing packed cells with additive solution in quarantine storage in the blood bank refrigerator kept in the component room.
- Take it into inventory after the testing is over.
- Spin the satellite bag containing platelet rich plasma (PRP) and connecting bag from which additive solution was emptied, at 22°C in refrigerated centrifuge at 2600rpm for 10 minutes after balancing.
- Place the bag containing PRP on the expresser stand.
- Express the plasma into the empty bag leaving 50-60ml plasma along with the platelets.

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- Seal the tubing and cut the tubing of the plasma bag short to avoid breakage during frozen stage.
- A small segment of tube containing platelet (about 8cm along) is prepared after mixing of the bag content as when requested by quality control laboratory.
- Leave the platelet concentrates on the bio safety cabinet for 30 minutes. Mix the contents of the bag manually before transferring the units to quarantine storage in the incubator at 22°C on the lower shelf.
- After the required test results are available place the platelet concentrates on the agitator in the upper shelf for use.
- Keep the plasma bag in the quarantine storage in the deep freezer kept in the component room and transfer to deep freezer in issue area when the test are completed.

Saline Washed red Cells

Undertake the washing unit only after the compatibility test and screening test is over.

- Connect the bag with a sterile 0.9% saline bottle using a transfer set under laminar flow.
- All aseptic precautions should be taken.
- Introduce approximately 200ml of saline into the packed cell bag and mix thoroughly.
- The proposed blood unit is balanced in the centrifuge bucket with another empty bucket. The buckets are centrifuged as per program (high speed)
- Transfer the supernatant saline with some plasma into a transfer bag using the expresser under laminar flow.
- Disconnect the transfer bag, seal and discard.

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- Repeat the washing with saline 2 more times exactly in the same manner as described above.
- In the end keep 25-30ml saline with the red cells in the bag.
- Seal the final thrice washed red cell unit.
- Weigh the bag and record details in the register.
- Store the washed packed cell unit at 2-6°C and use within 24hrs of washing.
- Use the blood only for the patient for which requested, if not used discard after 24hrs with standard disposal protocol.

9.33. Preparation of Cryoprecipitate

- The basic material is platelet poor fresh frozen plasma. The plasma must be free of red cells. Use the plasma frozen at -80°C preferably within a day or two of freezing.
- Keep the segment of the bags for potential cryo-preparation longer.
- Keep the frozen plasma bags in the blood bank refrigerator maintaining the temperature at 2-6°C. When the plasma is thawed, place the bags on weighing scale and balance.
- Keep the equally balanced bags diagonally opposite to each other in the refrigerated centrifuge.
- Spin the buckets at 2500rpm for 7minutes at 4°C in refrigerated centrifuge.
- Place the plasma bags on expresser and separate plasma into the satellite bag leaving approximately 15-25ml as cryoprecipitate suspension in the original bag.
- Seal tubing and separate F-VIII deficient plasma. Store the bag with Cryoprecipitate at -30°C or lower and bag with Cryo poor plasma in the second satellite bag is stored at -20°C or below.

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- Both the bags are kept in quarantine till the tests are completed.
- Place them in deep freezer and issue after test results are available and are found to be negative for infectious parameters.

9.34.WHOLE BLOOD (cpd – Adenine – 1)

Description : Whole blood contains $450 \pm 45\text{ml}$ or $350 \pm 35\text{ml}$ of donor blood +anticoagulant solution

- 450ml donor blood & 350ml of whole blood
- 63ml anticoagulant – preservative solution for 450ml blood collection & 49ml of anti coagulant – preservative solution for 350ml blood collection
- Whole Blood has Hemoglobin approximately 12g/ml
- Haematocrit 35% - 45%
- Stored blood has no functional platelets
- No labile coagulation factor (V & VIII)
- Minimum of 70% of transfused red cells should survive in the recipient's circulation 24 hours after transfusion.

Unit of issue 1 donation, also referred to as a “unit or pack”

Infection risk

- Not sterilized, so capable of transmitting any agent Present in cells or plasma which has not been detected By routine screening for transfusion – transmissible Infections, including HIV – 1 & HIV – 2, hepatitis B & C ,Other hepatitis viruses, syphilis, malaria & chagas Disease.

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Storage

- Upto 35 days between +2°C & +6°C in approved Blood Bank refrigerator, fitted with a temperature chart & alarm.
- Transfusion should be started within 30 minutes of removal from refrigerator.

Indications

- There is no single clinical condition requiring whole blood transfusion may be indicated in massive blood loss resulting in shock (trauma or major surgeries).
- Exchange Transfusion
- Patients needing red cell transfusions where red cell concentrates or suspensions are not available

Contraindications Risk of volume overload in patient with:

- Chronic anaemia
- Incipient cardiac failure

Administration

- Must be ABO & RhD compatible with the recipient
- Never add medication to a unit of Blood
- Complete transfusion within 4 hours of commencement

9.35.Red Cell Concentrate (“packed red blood cells”,)

Description : Packed red cells are concentrated source of red blood cells that remain in a small amount of plasma upon removal of supernatant plasma after centrifugation.

- CPDA – 1 whole blood with 200-250ml plasma from 450ml whole blood or 150-175ml of plasma from a unit of 350ml whole blood.
- Haemoglobin approximately 20g/100ml (not less than 45 per unit)

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- Haematocrit 55% - 75%

Unit of Issue : 1 donation

Storage Same as whole blood

Indications

- Any condition requiring replacement of oxygen carrying capacity like severe anemia. Elderly & young patients with circulatory overload surgeries and etc.
- One unit red cells raises Hb concentration in an average-sized adult (70kg) by 1g/dl and Hematocrit by 3%.
- Use with crystalloid replacement fluids or colloid solution in acute blood loss

Contraindications

- Well compensated anemic patients such as chronic renal failure.
- Nutritional anemia such as iron deficiency or pernicious anemia responsive to iron, folic acid, recombinant erythropoietin etc. unless patient shows of decompensation (need for increased oxygen-carrying capacity).
- To correct protein & coagulation factors deficiency
- Preoperative transfusion to raise Hb above 10g/dl
- To enhance general well being, promote wound healing, prevent infection, expand blood volume when oxygen-carrying capacity is adequate.

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Administration

- Same as whole blood
- To improve transfusion flow, normal saline (50 – 100ml) may be added using a Y – pattern infusion set.

9.36. Saline washed Red cell suspension

Description

- 150 – 200ml red cells with minimal residual plasma to which +20 to 50ml normal saline been added
- Haemoglobin approximately 15g/100ml (not less than 45g per unit)
- Haematocrit 50% - 70%

Unit of issue 1 donation

Infection risk same as whole blood

Indications same as red cell concentration

Contraindications Not advised for exchange transfusion of neonates. The red cell are washed & suspended in normal saline.

Administration

- To be administer within 24 hours of preparation of saline washed red cells.
- Better flow rates are achieved than with red cell concentration or whole blood

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9.37. Platelet Concentrates (Prepared from whole blood donations)

Description : Single donor unit in a volume of 50 – 60ml of plasma should contain:

- At least 55×10^9 platelets

Unit of Issue

May be supplied as either:

- Single donor unit : platelets prepared from one donation
- Pooled unit : platelets prepared from 4 to 6 donor units “pooled” into one pack to contain an adult dose of at least 240×10^9 platelets

Storage

- Upto 5 days at $20^{\circ}\text{C} - 24^{\circ}\text{C}$ (with agitation) do not store at 2°C to 6°C
- Longer storage increases the risk of bacterial proliferation & septicemia in the recipient

Indications

- Treatment of Bleeding due to:
 - Thrombocytopenia due to decreased production eg. Aplastic anaemia
 - Platelet function defects
- Prevention of bleeding due to thrombocytopenia such as in bone marrow failure
- Platelet count $< 5000/\mu\text{l}$ regardless of clinical condition
- Massive transfusion (platelet dilution) if platelet count $\leq 50,000/\mu\text{l}$
- DIC (increased destruction) if platelet count is $\leq 50,000/\mu\text{l}$

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- Chemotherapy for malignancy (decreased product) if platelet is $\leq 20,000/\mu\text{l}$

Contraindications

- Not generally indicated for prophylaxis of bleeding in surgical patients, unless known to have significant pre – operative platelet deficiency
- Not indicated in :
 - Idiopathic autoimmune thrombocytopenic
 - (ITP)
 - Thrombotic thrombocytopenia purpura (TTP)
 - Untreated disseminated intravascular coagulation (DIC)
 - Thrombocytopenia associated with septicaemia, until treatment has commenced or incases of hyperplenism

Dosage

- 1 unit of platelet concentration / 10 kg body weight
- In an adult of 70kg each unit of RDP will raise platelet count by $5 - 10 \times 10^9/\text{L}$ (5000 – 10,000/ μL)
- Increment will be less if there is:
 - Splenomegaly
 - Disseminated intravascular coagulation (DIC)
 - Septicaemia
 - High fever, infection

Administration

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- After pooling, platelet concentrates should be infused as soon as possible, generally within 4 hours, because of the risk of bacterial proliferation
- Must not be refrigerated before infusion as this reduces platelet function
- 4-6 units of platelet concentrates (which may be supplied pooled) should be infused through a fresh standard blood administration set
- Special platelet infusion sets are not required
- Should be infused over a period of about 30 minutes
- Give platelet concentrates that are ABO compatible, whenever possible.

Complication

- Febrile non haemolytic & allergic urticarial reactions are not uncommon especially in patients receiving multiple transfusions.
- Infections transmitted by platelets transfusions are similar to those associated with other blood products. But unusual fatal complication of platelet transfusion is infusion of bacteria that have proliferated in concentrates stored at 20⁰ C - 24⁰ C.
- The efficiency of platelet transfusion can be assessed either by doing platelet count at 1 hour & 24 hours after transfusion or by clinical assessment of the patient.

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- Post transfusion of patients coagulation parameters like PT, APTI or fibrinogen/specific factor assay are important for monitoring the effectiveness of FFP.

9.38. Fresh Frozen Plasma

Description

- Pack containing the plasma separated from one whole blood donation within 6 hours of collection & then rapidly frozen to -25°C or colder. FFP contains albumin & immunoglobulin & all coagulation factors including Labile factor V & Factor VIII

Unit of Issue

- Usual volume of pack is 200-300ml
- One ml of plasma contains one international unit of each coagulation factors

Storage

- At -25°C or colder for upto 1 year
- Before use, should be thawed in circulating water bath at 30°C to 37°C , & higher temperatures will destroy clotting factors & proteins.
- Thawed plasma should be transfused as soon as possible, or within 12 hours, if stored at $2 - 4^{\circ}\text{C}$

Indications

- Multiple coagulation factor deficiencies eg. DIC, liver diseases, vitamin K deficiencies & dilutional coagulopathy due to massive transfusion

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- Reversal of Warfarin effect

Contra indications for use of FFP

- Blood volume expander
- Hypoproteinemia
- Source of Immunoglobulins
- When prothrombin time is less than 18 seconds

Precautions

- Acute allergic reaction are not uncommon, especially with rapid infusions
- Severe life – threatening anaphylactic reactions occasionally occur
- Hypovolaemia alone is not an indication for use

Dosage

- The accepted dose of FFP is 12-15ml/kg.

Administration

- Must normally be ABO compatible to avoid risk of Haemolysis in recipient
- No compatibility testing required. But ABO compatible FFP & of the same ABO group as that of the recipient is preferred
- Infuse using a standard blood administration set as soon as possible after thawing
- use within 6 hours of thawing as labile coagulation factors degrade rapidly

9.39. Cryoprecipitate

Description

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- Cryo is Cryoprecipitated protein prepared from fresh frozen plasma by collecting the precipitate formed during controlled slow thawing at +4⁰ C & resuspending it in 10-20ml plasma.
- Contains about half of the factor VIII & fibrinogen in the donated whole blood : example factor VIII : 80-100iu/pack : fibrinogen: 150-300mg/pack.

Unit of issue

- Usually supplied as a single donor pack or a pack of 6 or more single donor units that have been pooled.
- It is concentrated source of von Willebrand factor, fibrinogen factor VIII, factor XIII & fibronectin.

Storage

- At -25⁰ C or colder up to 1 year. Cryoprecipitate is stable for 1 year from the date of collection whole blood(not from the date of preparation)

Indications

- As an alternative to factor VIII concentrate in the treatment of inherited deficiencies of
 - Von willebrand factor (von Willebrand disease)
 - Factor VIII (Hemophilia A, when factor VIII concentrates are not available)
 - Factor XIII

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- As a source of fibrinogen in acquired factor VIII e.g. disseminated intravascular coagulation (DIC), massive transfusion

Dosage & Administration

- If possible, use ABO compatible products
- Rh type need not be considered
- No compatibility testing required
- After thawing, infuse as soon as possible through a standard blood administration set.
- Must be infused within 6 hours of thawing.
- Each unit of factor VIII/Kg raises plasma factor VIII by 2% therefore to achieve plasma factor VIII rise of 20%, 10 units/kg has to be infused.
- The half life of factor VIII is 8 – 12 hours, so transfusion of factor VIII is to be repeated at 8 – 12 hours interval.

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9.40. BLOOD STORAGE & MANAGEMENT

Scope & Application

Blood components prepared are stored in conditions designed to optimal viability & function during the storage period

Responsibility

It is the responsibility of the technical staff from the component laboratory to keep the units in the quarantine storage. The technologist who labels the units after the testing is responsible to transfer the labeled units in their respective storage areas.

Procedure

- All untested units should be kept in the quarantine area. Separate areas should be reserved for storing untested, tested and quarantined products.
- After testing is over, transfer those deemed suitable for clinical use from quarantine area to the blood bank refrigerator meant for screened units.
- The units that are unsuitable for use are disposed off as per bio-medical waste management.
- Store whole blood and red cell concentrates (packed cells) on metal rack stand in the Blood storage cabinet (2°C-6°C). These stands have shelves. Each shelf is reserved for a particular group having its label stuck on the outer side.
- Arrange the blood bags in chronological order, group wise and according to the expiry dates in trays and then stack the trays on the shelves. This makes it very easy for the technologists on duty to remove the bags for issuing whenever required.
- Store blood collected in CPD-A1 and the red cells separated in a closed system up to 35 days. The red cells suspended in additive solutions up to 42 days. Use red cells prepared in open system like saline washed red cells within 24 hours of preparation.

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- Keep fresh frozen plasma, cryoprecipitate and FVIII deficient plasma bags in over wrap bags and then arrange in plastic trays in the deep freezer (-40° C) immediately after separation. The shelf life of all these Plasma components is one year. FFP once thawed and then refrozen is used only as F VIII deficient Plasma.
- Place platelet rich plasma and platelet concentrate in the incubator at 20° C-24° C on an agitator which has shelves to store them. Store the Platelet rich Concentrate up to 5 days.

The anticoagulant/preservative solutions are not the sole variable in maintaining the viability and stability of the blood and its products. Physical storage conditions best suited for products for maximum survival are also important. All storage equipments, like refrigerator, freezer and the platelets environmental chamber should have the following facilities.

- Refrigerator for storing blood/red cells should have a fan for circulating air to ensure proper temperature of 2-4°C in all compartments.
- All the blood bank equipments should have a system to monitor and record the temperature continuously(continuous graphic recorder). Temperature recording chart should be changed regularly every week & file them. They should also have alarm system with audible signals. It also should have battery backup. Check the alarm system every month.
- Take due care to maintain sterility of all components by keeping all storage areas clean.

PRODUCT	DESCRIPTION	STORAGE	EXPIRATION
Whole blood	All components of blood + anticoagulant-CPDA-1	2°-6°C	35days
Packed red blood cells	With anticoagulant and plasma removed- final volume 300ml with	2°-6°C	35days

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	HCT 55-65%		
Red cell-leucocyte reduced	With anticoagulant and plasma removed- final volume 300ml with HCT 55-65% and >70% leucocyte reduced retaining >70% red cells	2°-6°C	35days
Red cell-washed	Washed with normal saline	2°-6°C	Open system 24hrs
Fresh frozen plasma	200-250ml plasma + anticoagulant	Frozen -80°C Frozen -18°C After thawing at 30-37°C	5yr 1yr 4hrs
Platelets	>5.5x10 ¹⁰ in 40-70ml plasma	20-24°C with agitation	5days
Cryoprecipitate AHF	80-120U factorVIII 40-70% von willbrand factor with 30-50ml plasma	Frozen < -18°C After thawing at 30-37°C	1yr 4hrs

DOCUMENTATION

Record all blood /components released for use as well as the unsuitable units to be discarded & entered in the discarding register.

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9.41. TRANSFUSION TRANSMITTING DISEASE TESTING

Scope & Application

These samples from donors are tested for Transfusion Transmitted Diseases. These tests are mandatory.

Responsibility

It is the responsibility of technician on sample receiving desk to ensure correct samples received from patients. The responsibility of carrying out the test is of the technician in the TTI Testing Laboratory.

The most common type of testing method is the Enzyme Linked Immunosorbent Assay (ELISA). Sandwich ELISA method is highly specific ELISA in which viral antibody in test sample is bound to immobilized antigen and then detected by free enzyme-labeled viral antigen.

ELISA TEST FOR HIV (4th generation kit), HBsAg, AND HCV TESTS:

1. Carry out the test as per manufacturer's instructions given in the package insert.
2. Remove reagents from the fridge 30 min. prior to testing. Mix the reagents gently by inverting the vials without foaming.
3. Bring reagents and samples to room temperature before testing.
4. Prepare a protocol of the concern test.
5. Arrange all donor unit test tube samples, serially in ascending order in a test tube rack. Add required number of internal kit controls and external lab controls.

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6. Discard all disposable tips into hypochlorite solution.
7. Place the tray in front of the test tube rack.
8. Read the kit insert and make sure about the test procedure.
9. Prepare wash buffer.
 1. Depending upon the kit procedure dispense test sample using an auto pipette and fresh disposable tip for every sample.
 2. Add kit internal positive/negative controls
 3. Add lab external control/s
 4. Agitate using micro shaker (if required)
 5. Incubate according to the procedure.
 6. Prepare conjugate.
 7. Wash and soak each well five times (as many times required) with buffer.
 8. Add conjugate each well.
 9. Incubate according to the procedure.
 10. Prepare substrate. Avoid direct light.
 11. Wash and soak each well five times (as many times required) with buffer.
 12. Add substrate. Incubate at room temperature.
 13. Stop reaction by adding 1mol/l sulphuric acid or stopping solution to each well.
 14. Ensure thorough mixing. Avoid spilling.
 15. Read the plate within 15 minutes.
 16. Blank the reader or air and read the absorbance in each well at required filter
 17. Take out print out and calculate.

Validation

If the results fail to meet the criteria as per package insert consider the test is invalid and repeat the whole test again. Examine absorbance values of the controls before the sample results can be interpreted. Check the validity of the blank (if used) negative and positive controls absorbance value as per package insert of the kit. Cut off OD is automatically calculated or manually calculated.

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Interpretation:

Check the print out carefully for absorbance value:

- i) The samples below the cut off are considered non-reactive.
- ii) Equal to cut off are considered initially reactive.
- iii) Above cut off are considered initially reactive.
- iv) Samples close to cut off value 10% below cut off (grey zone)

Samples with grey zone results are repeated in one well.

DOCUMENTATION

File /paste the print out in the HIV file/register and also record the following details:

- The date on which the test is run.
- The name of the kit used.
- Lot no. and expiry date of the kit.
- Initials of the technologist who performed the test.
- Initials of the Supervisor and Blood Bank Officer who verifies the result.
- Reactive units are marked in red.
- Transfer the results to donor grouping register.

Reactive results are written as **“POSITIVE”** and non- reactive written as

“NEGATIVE.”

- File package inserts of each different kits for further references

Test for HIV I & II

Microwell strips are coated with monoclonal p24antibodies along with recombinant antigens, gp41 and gp36 representing both HIV I & HIV II. The presence of bound antigens /antibody is detected by adding biotinylated anti-p24 antibodies followed by antigen-HPR conjugate.

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Method

Sample, precautions and procedure are to be followed as per kit instructions.

Interpretation

- Samples with absorbance values less than the cut off value are considered non-reactive and are considered negative for HIV I&II.
- Samples with absorbance value equal to or greater than cutoff value are considered reactive. The sample should be retested in duplicate with fresh sample, reactive samples that react are considered repeatedly reactive.

All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting

Enter all results in the screening register with signature, date and time.

Test for HBsAg

Microwell strips are coated with monoclonal anti-HbsAg antibody. A polyclonal antibody to HbsAg is conjugated to horseradish peroxidase (HRPO)

Method

Sample, precautions and procedure are to be followed as per kit instructions.

Interpretation

- Samples with absorbance value less than the cutoff value are considered non-reactive and are considered negative for HbsAg.
- Samples with absorbance value equal to or greater than cutoff value are considered reactive. The sample should be retested in duplicate with fresh

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All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting

Enter all results in the screening register with signature, date and time.

Test for HCV

Microwell strips are coated with synthetic peptides representing core NS3, NS4 and NS5 antigens.

Method

Sample, precautions and procedure are to be followed as per kit instructions.

Interpretation

- Samples with absorbance value less than the cutoff value are considered non-reactive and are considered negative for HCV antibody.
- Samples with absorbance value equal to or greater than cutoff value are considered reactive. The sample should be retested in duplicate with fresh sample, reactive samples that react in both are considered repeatedly reactive.

All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting

Enter all results in the screening register with signature, date and time.

Test for Malarial Parasite & SYPHILIS

Malarial Parasite

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Blood infected with malarial parasite can also transmit the infection. Transfusion-transmitted malaria may become evident a week to several months following the transfusion of infected blood.

Test cassette contain a membrane strip, which is pre-coated with monoclonal antibody and one polyclonal antibody as two separate lines across a test strip. One monoclonal antibody are specific to the HRP-II of *p.falciparum* and the other polyclonal antibodies are pan specific to the lactate dehydrogenase of *plasmodium* species.

Method

Sample, precautions and procedure are to be followed as per kit instructions.

- Allow all the kit components and specimen to room temperature prior to testing.
- Remove the test device from foil pouch; place it on flat, dry surface.
- Clean the fingertip and prick with lancet.
- With a 5µl disposable specimen loop provided, dip the circular end of the loop into the blood specimen and carefully place the circular end of the loop into the round sample well (S).
- Add 4 drops of assay diluent into the square assay diluent well.
- Interpret test results within 20-30 minutes.

Interpretation

Negative results: The presence of one color band (“C” control line) within the result window indicates a negative result.

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Positive result: The presence of two or three color bands indicates a positive result.

If the control band (C) fails to appear within the result window, the result is considered invalid. It is recommended that the specimen be re-tested.

All samples detected reactive must be confirmed once again by Rapid before reporting

Enter all results in the screening register with signature, date and time.

Test for Syphilis

Rapid Plasma Reagin (RPR) test

Scope & Application

Investigations of Transfusion transmitted diseases for Syphilis is a mandatory test for blood unit screening before it is transfused. This is carried out on all donor units samples. It is an invitro qualitative test to diagnose syphilis using human serum/plasma. It's a simple, rapid & economical slide agglutination test.

Responsibility

It is the responsibility of technician from TTD testing laboratory to carry out the test and report as required.

Principle

The RPR reagent containing modified VDRL antigen and micro particulate carbon particles flocculate when mixed with sample containing "regain". A reactive specimen is indicated by macroscopically visible black clumps against white background, in contrast non reactive specimen appear to have smooth uniform

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light gray colour. RPR is a screening test and if positive, further testing with specific confirmatory tests is required.

Reagent storage & stability

All the reagents should be stored at 2-8° C. Do not freeze. After opening the kit, it is recommended to store the test cards at room temperature. Protect the kit from direct sunlight and elevated temperature.

Quality Control

It is vital to deliver analytical services in useful, convenient and meaningful manner as it is first and foremost step on the way to correct treatment. To ensure the reliability of the final reports, it is recommended:

- 1.To follow kit's instructions meticulously.
- 2.To run kit controls periodically to check test validity
- 3.To run third party controls as a part of internal and external quality

Procedure

Qualitative test

1. Using disposable serum dropper, place one free falling drop of serum/plasma or control on the card and spread it to fill the entire circle with the help of disposable applicator stick.

Note: Unevenly spread serum in the circle results into improper mixing of the antigen and antibody.

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2. Gently shake the RPR antigen bottle to resuspend the particles. From the dropper dispense few drops of the reagent back into the reagent bottle itself to remove air trapped in to the dropper.

3. Add one free falling drop of RPR antigen using antigen delivery dropper. Keep the delivery dropper vertical, exactly at 90° C while adding antigen suspension. Do not mix.

4. Place the card on the mechanical rotator under humidifying cover and rotate the card for 8 minutes at 100+2 rpm.

5. After 8 minutes, immediately remove the card from the rotator, rotate and tilt the card gently by hand.

6. Observe the results under a high intensity lamp or strong day light.

Interpretation

Qualitative Method

1.Large and medium black flocculesagainst white background: Reactive

2.Small black floccules against white background : Weakly Reactive

3.No floccules even grey background : Non Reactive

Qualitative Test

1. Place one free falling drop of serum/plasma or control on the card and spread it to fill the entire circle with the help of disposable applicator stick.



2.Gently shake the RPR antigen bottle to resuspend the particles.



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3. Add one free falling drop of RPR antigen using antigen delivery dropper. Keep the delivery dropper vertical, exactly at 90° while adding antigen suspension. Do not mix.



4. Place the card on the mechanical rotator under humidifying cover and rotate the card for 8 minutes at 100±2 rpm.



5. After 8 minutes, immediately remove the card from the rotator, rotate and tilt the card gently by hand.



6. Observe the results under a high intensity lamp or strong day light.

Documentation

Register and record the following details

- Sample number and result
- The date on which the test is run.
- The name of the kit used
- Lot number and expiry date of the kit
- Initials of the technologist who performs the test and Supervisor and Blood Bank Officer who verifies the results.
- Transfer the records to master Register & screening Register.

Card Method for Syphilis

Etiological agent for syphilis is *Treponema pallidum*. Blood and its components may transmit syphilis.

The cassette contains a membrane strip, which is pre-coated with recombinant *Treponema pallidum* antigens on test band region.

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Method

Sample, precautions and procedure are to be followed as per kit instructions.

Procedure

- Remove the test device from the foil pouch, and place it on a flat, dry surface.
- Transfer the specimen by a pipette or a dropper.
- Add 10µl of serum or plasma to the sample well (S) of the test device.
- Add 3- 4 drops of assay diluent and start the timer
- As the test begins to work, you will see purple color move across the result window in the centre of the test device.
- Interpret test results at 5-20 minutes.
- The result should not be interpreted after 20 minutes.

The above interpreting time is based on reading the test results at room temperature.

Interpretation

- A color band will appear in the left section of the result window “C” to show that the test is working properly. This band is the Control band.
- Negative Result: The presence of only one purple color band within the result window indicates a negative result.
- Positive Result: The presence of two color band “C” and “T” within the result window indicates positive result for syphilis antibody.
- Invalid Result: If the purple color band is not visible within the result window after performing the test, the result is considered invalid.

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9.42. LABELLING AND ISSUE OF SAFE BLOOD

Scope & Application

The blood after it is collected remains in quarantine & is released for transfusion only after all tests (grouping & for TTI) are completed. Before these blood bags are taken on inventory for use they are labeled depending on their blood groups. The label is required for identification & retrieval of blood units for use, disposal & follow up in case of adverse reactions

Responsibility

It is the responsibility of the technician from the Red Cell Serology Laboratory to label the blood & blood components units.

Procedure

After collection & processing whole blood & component units remain in quarantine storage areas. Once all the reports of blood grouping & TTI are ready & cross matching are ready, place the bags according to group wise in the blood bank refrigerator meant for screened units. The blood and blood components are used as per the need of the patient. These are issued against the prescription of a medical officer after ensuring the mandatory test results and proper labeling. Blood should be issued along with the cross matching request form. The portion of the integral tube with at least one numbered segment should remain attached with blood bag being issued.

- Blood sample for cross matching should be accompanied by request form which is duly filled and signed by the doctor.
- Enter the details regarding the Blood Requirement given in the Blood request Form in the Cross matching Register.
- Check the cross matching results in the cross matching register.
- Ensure that the compatible units are tested for TTD and found suitable for use.

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- The cross matching report should have patients Name, age, Sex, Identification number, ABO & Rh (D) type.
- The form should have donor unit, Identification number, ABO & Rh (D) type & expiry date of blood.
- Interpretation of cross matching & name of the person performing the test & issuing the blood should be recorded.
- In order to avoid outdating, implement First In and First Out policy (FIFO)
- After cross matching remove the correct unit identified by unique blood bag no from the storage area.
- Preprinted adhesive labels for all components printed as per statutory requirements.
- The labels are printed and color coded for all components as per blood groups.
 - * Group A has Yellow label
 - * Group B pink label
 - * Group O blue label
 - * Group AB has white label.
- Select the label depending on the blood /blood component used and the group.
- Write legibly the unit No, date of collection and date of expiry on each label as per the main blood bag.
- Date of collection and date of expiry is important as in case of components where it varies for each component.
- Legibly enter the patient name, age/sex and IP/OP no with the blood group in the column provided.
- The tube segment with its number must be preserved in the container labeled with the specific day of the week (Sunday to Monday) which should be preserved for 1 week from the date of Issue of Blood/Blood Components.
- At the time of issue of blood observe the following
 - Recheck the identification of the patient and donor blood.

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- Check the blood bag expiry to avoid issuing out dated blood.
- Inspect the unit to make certain that it does not have abnormal color or appearance.
- Look for the Swirling movement at the time of issue of platelet concentrates
- Ask a second technician to double check the number and the group on the bags tallying them with the records.
- Then the blood units are transported as per SOP on transportation of Blood/Blood components. Instruct the attenders to carry the blood unit straight to the ward or OT for transfusion.

Documentation

Enter the details of issue in Issue register as follows:

- Name of the patient
- Hospital registration number
- Blood Group
- Date and time of issue
- Unit No. Issued
- Blood group of unit
- Component of blood
- Signature of technician who issues
- Signature of the receiver

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9.43. INSPECTION OF BLOOD PRIOR TO ISSUE OF BLOOD UNITS

Blood must be inspected prior to issuing for patients use. Discoloration/signs of leakage may be the only warning that the blood has been contaminated and could cause a severe or fatal reaction when transfused.

1. Check for possible bacterial contamination which results in abnormal color in red cells or plasma. Red cells, often look darker/purple/black.
2. Any sign of haemolysis in the plasma indicating that the blood has been contaminated, allowed to freeze or become too warm.
3. Units are inspected for haemolysis on the line between the red cells and plasma.
4. Look for visible clots in the plasma, which may mean that blood was not mixed properly with the anticoagulant when it was collected or might also indicate bacterial contamination due to utilization of citrate by perforating bacteria.
5. Prior to issue plasma in both main bag and segments should be visually inspected for haemolysis or discolouration.
6. Look for any signs of leak in the pack or that it has already been opened.
7. In cases of haemolysed blood, the color of blood both in bag and tubing is changed to purple.

Abnormal units should not be issued and the cause be investigated.

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9.44. VERIFICATION BY THE TECHNICIAN AT THE TIME OF ISSUE OF BLOOD

- First check the allotted unit number on the blood request form and remove the correct unit from the blood bank refrigerator.
- Check the date of expiry donor unit number blood group and Rh and results of compatibility test in the cross matching register.
- Ensure that the compatible units are tested for TTD by checking in the screening register.
- Enter all the above donor's details and patients name IP Number ABO and Rh (D) groups on the color coded sticker and affix it on the blood bag on the side opposite to the sticker already pasted on it by the manufacturer of blood bag.
- Check the donors identification number, donors ABO and Rh D group collection and expiry date of blood products, Patients name ID number, Patients ABO and Rh D group interpretation of Cross matching test date and time of issue in the cross matching report from.
- At the time of issue
 - 1: Recheck the ID of the patient and donor blood units number.
 - 2: Check the blood expiry date to avoid issuing out dated blood.
 - 3: Blood units must be grossly checked for any signs of deterioration/Haemolysis and also look for leakage/breakage.
Any change in colour of plasma.
Any change in colour of red cells.
Any visible clots.

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9.45. EMERGENCY SERVICES

For emergency cases, such as Disseminated Intravascular, Coagulation, Caesarian section, Placenta Previa, Post-Partum Hemorrhage, ectopic, Intestinal obstruction, road traffic accident, burns, snake bite, dengue fever etc. Whole blood/ required components are issued immediately doing cross match by immediate spin technique. Blood/Blood Components should be issued before completion of routine cross match tests in cases where delay in providing blood may be jeopardise the patients life.

- List of group wise voluntary blood donor register is maintained.
- In very urgent cases uncrossed matched red cells of the same group as that of the patient after doing ABO and Rh typing of the patient are supplied with concurrence with the clinician. Subsequently the cross match is done.
- In extreme urgent case, it may be necessary to supply uncross matched O red cells (O negative if available otherwise O Rh (D) positive) if the group of the patient is not known or there is no time to do grouping of the recipient.
- O negative cells preferred for pre-menopausal females (where ABO and Rh group is not known).
- O positive cells can be given to O negative males and post-menopausal females(during non-availability of Rh negative blood)

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9.46. INVENTORY OF BLOOD BAGS & BLOOD COMPONENTS

Scope & Application

In order to avoid outdating & make optimum use of available blood, we follow First come first out [FIFO] policy. It is important to maintain a day to day inventory of tested blood which helps selection of blood to be cross matched for patients requiring transfusion.

Responsibility

The technician from the red cell laboratory checks the records & transfers all the units which are serologically negative & labeled to inventory.

Procedure

- Inventory is maintained on a day to day basis. After labeling the units, enter the numbers of whole blood or packed cells numbers group wise on the right hand of the inventory register kept in the main red cell laboratory. In case of packed cells units, write the alphabet "PRBC" above the unit number. PRBC denotes packed red blood cells without additive solution. The inventory bears columns for A group, B group, AB group, O group as well as negative groups of these four groups.
- Enter the unit group wise & according to the date of collection in the inventory register (daily stock). The technologist on night duty is responsible for physical checking of the printed number on the label & enters in the inventory.
- After labeling the FFP, enter the donor units numbers group wise in the stock register of FFP similar to blood units.
- Enter the labeled cryoprecipitate unit numbers in the register.
- Clearly mark the inventory of bags that have less volume of blood collected or are reserved for specific patients with specific instructions.

All unit numbers are entered group wise & expiry date wise in the inventory register.

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9.47. CRITERIA FOR ACCEPTING RETURNED BLOOD.

1. SCOPE & APPLICATION

The blood and blood units are used as per the requirement of the patients these units are issued against the issue notes by a medical officer after ensuring the compatibility and screening test results.

2. RESPONSIBILITY

It is the responsibility of the technician on duty in red cell serology laboratory to issue the blood units for which issue notes is received.

3. PROCEDURE

- FIFO policy (first in and first out policy) is implemented to avoid outdating of blood units.
- Ensure that the blood units are cross matched and units are tested TTD.
- The correct unit is removed from the blood bank refrigerator and after labeling keep it in the thermal box for transport.
- After the second technician does the double check of the entire process only then the unit is released for transport.
- Instruct the individual to carry the blood units straight to the ward or OT for transfusion.
- Then the details of issue is entered in the issue register and master register.

3.1 PROCEDURE for accepting returned blood

- Blood and blood components once released from the blood bank to OT / ward of the hospital / outside will not be taken back.

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- Exceptional cases where blood is released from the blood bank to OT/ wards within our hospital, where it may not be required by the patient due to some reason and it is returned back to the blood bank.
- If this blood unit reaches our blood bank within half an hour and cold chain is not broken, it could be taken back into the inventory and may be reissued to the same patient when requested or reused for another patient.
- Precautions should be taken to check the temperature and blood bag should be kept erect to check for haemolysis.
- If there is no haemolysis seen after spinning or standing, the blood unit may be issued safely to another patient.
- When thawed FFP is returned back due to some reason, store it at 2-8°C and issue as and when requested for either the same patient or for another patient within 24 hours of thawing.
- In case of cryoprecipitate that has been thawed should be reused within 4 hours of thawing and stored at room temperature at 22°C.
- In case of platelets concentrate that has been returned back are accepted after checking for the swirling movement and then kept in the platelet incubator and agitator.

4. DOCUMENTATION

The units that are returned back should be accompanied with the doctor's letter stating the reason for returning the units so that documentation is maintained and the details of the unit returned are entered into the particular register meant for returned units.

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9.48. QUALITY ASSURANCE

9.49. OPTIMUM STORAGE OF CONSUMABLES, REAGENTS & KITS

Scope & Application

The quality assurance system requires that all the reagents used for various test procedures are stored according to the manufacturer's instructions. Any lacunae in the storage conditions, reduces the effectivity of the reagents

Responsibility

It is the responsibility of the technician/supervisor in the red cell serology laboratory to ensure that quality controlled reagents & proper cell concentrations are used for testing for which daily quality control checks & test controls are used with proper documentation. The reagents should be stored & used as per manufacturer's instruction.

MATERIALS REQUIRED

- Domestic refrigerator
- Blood Bank refrigerator
- A.C Store room
- Stock register

PROCEDURE

a) Donor Room:

i) Store disinfectants for preparation of phlebotomy sites at room temperature (22°C-25°C) in the donor room.

ii) Store blood collection bags in air conditioned room (22°C-25°C)

b) Red Cell Serology Laboratory (RCS):

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i)Store ABO reagents Anti A, Anti-B, Anti AB, Anti D, bovine albumin, antihuman globulin, pooled A,B, and O red blood cells in the cold room maintained at 4^o-6^oC or as per manufacturer's instructions.

c)Transfusion Transmissible Infections Testing (TTI):

Store Kits for HBsAg, HIV, HCV and VDRL at 4^oC-6^oC in the domestic refrigerator meant for reagents as per manufacturer's instructions.

d)Store

i) Store chemicals like copper sulphate , Sodium Hypochlorite solution,0.9% normal saline, and distilled water at room temperature (22^o-25^oC) in the store.

DOCUMENTATION

- Daily stock of all reagents is maintained in a file.
- On receipt, make entries of number of vials/kits received, name of manufacturer, batch number and expiry date in the stock register.
- Issue the reagents for use, only after a QC check is performed.
- Record of issue entries are maintained in the file.
- Order all reagents/kits, no sooner the critical level is reached.

N.B: Critical level for all reagents/kits is normally adjusted as per the requirement of reagents, as well as the time taken by the procurement procedure to ensure the reagents are received before the stock in use is exhausted. The new batch received should be tested against the batch in use.

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9.49. EQUIPMENT MAINTENANCE - CALIBRATION

SCOPE & APPLICATION

This procedure covers those measures taken to ensure the integrity, accuracy and reliability of measurement data for equipment and instruments used in the collection, testing and storage of blood products. The procedure is applicable to all equipment used to control or evaluate suitability of starting materials, in process products and finished products.

RESPONSIBILITY

It is the responsibility of the supervisor of the section to which the equipment belongs to: i) Plan, schedule, organize and maintain records of the calibration programmes for various equipment under their control.

- ii) Ensure that equipment and instruments are continuously calibrated or are removed from use.
- iii) The Supervisor should train staff for performing calibration/performance checks.

3. PROCEDURE

Calibration schedule:

- Equipments or instruments are purchased as per specifications.
- As & when new equipments are purchased the entries are made in the equipment register regarding serial/model number, receiving date.
- Installation Report & Certificate of calibration provided by the supplier is maintained .
- Date of Calibration & Calibration Schedule (Due date) is documented .

The schedules of calibration or performance checks should be based on:

- Manufactures recommendations.

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- The history of the item as per reliability.
- Reference standards.
- Recalibrate the measuring devices based on time intervals.

Labeling:

Label all calibrated equipment with a label that has the following information:

- Date of last calibration.
- Signature of person who performed the calibration.
- Calibration Due date.

Label the equipment that has passed its calibration due date until it is re- calibrated.

DOCUMENTATION

Maintain complete records for the calibration and performance checks of all equipment and instruments.

Calibration and performance check test records should include (where appropriate):

- Asset Register Number.
- Instrument Serial Number.
- Limits for calibration
- Date of calibration/ performance check.
- Due date for next calibration.
- Any details of adjustment* or repair.
- Results of the calibration*/performance check.
- Statement of compliance, or details of non-compliance and action taken.
- Signature/ initials of the person performing the calibration/performance
- Checked by medical officer.

It is important that the results of calibration before and after any adjustment are recorded.

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Records of calibration & maintenance are documented for five years.

CORRECTIVE ACTION

If any equipment is out of calibration & needs adjustment corrective action should be taken. If adjusted back into calibration then, the equipment may be used .If adjustment cannot be made then until the situation is corrected a label should be placed on the equipment stating that the equipment is under repair and not to be used. If the parts to be replaced is not available in the market the instrument needs to be condemned & replaced by procuring new one.

RELOCATION OF INSTRUMENTS

Recalibrate the equipment (especially non-portable) when relocated. The manufacturers recommendations on the need for re-calibration shall be sought when relocating non-portable instruments.

EXTERNAL CALIBRATION CONTRACTORS

Make an agreement with the contractors to supply written reports of calibrations which should include:

- Use of standards and references traceable to national standards.
- Certification/ licensing by the equipment manufacturer, if available
- Check all certificates or reports supplied by approved external laboratories on receipt.

Following equipments are under Annual maintenance contract(AMC)

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9.50. THERMOGRAPH

SCOPE AND APPLICATION

To record the temperature of the equipments in the Blood Bank.

RESPOSIBILITY

It is the responsibility of the Technician to change the temperature graph of the equipments every week.

MATERIAL REQUIRED

- Graph sheets (Temperature recording sheets) for each equipment provided by the respective / particular company
- Graph needle.

METHOD

1. Manual monitoring of the temperature of the equipment daily at 3 hourly interval by the technician
2. At the end of 1 week, the temperature graph sheets are changed by the Technician
3. At the back of the graph sheet, the date of inserting or removal, the name of the Instrument and the name and signature of the technician is written.
4. It is countersigned by Blood Bank Incharge / Medical Officer.
5. The graph sheets are filed.

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9.51. EQUIPMENT MAINTENANCE-PREVENTIVE MAINTENANCE

1. SCOPE AND APPLICATION

This procedure applies to all the instruments and equipments used within the blood bank centre.. Equipment used in the collection, processing, testing storage and distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance. The equipment shall be observed, standardized, and calibrated on a regularly scheduled basis.

2. RESPONSIBILITY

It is the responsibility of the supervisor of each laboratory to:

- Prepare specifications and validation reports for new and modified equipments.
- The requirement may be defined in the service contract.
- Prepare the maintenance schedules for all equipment items. The schedule is to include:
 - a) Preventive
 - b) Routine
 - c) Extra maintenance.
 - d) Cleaning and sanitation

PROCEDURE:

Maintenance overview :

1. Identify each item of equipment in the unit that requires maintenance.
2. Ensure all items have an Asset Number.
3. Include clear outline of the relevant procedures, routine maintenance and preventive maintenance and cleaning of equipment. Write operator instructions for each item of equipment. Also include those responsible and names of service personnel, maintain a documented log of servicing for all items. Identify the relevant procedures for equipment maintenance determines the frequency of calibration and cleaning.

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4. Prepare a complete equipment and instrumentation list consisting of the following headings.

- Equipment name / description.
- Asset number.
- Serial number.
- Model number.
- Operation:
- Operating range.
- Calibration:
 - Frequency.
 - Referenced documents.
 - Performed by
- Performance Check:
 - Frequency
 - Referred documents

Preventive maintenance:

- Frequency
- Referenced documents.
- Performed by

Routine maintenance:

- Frequency
- Referenced documents.

Cleaning:

- Frequency.
- Referenced documents.

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5. Maintain a list of all equipment and instruments used in all sections /departments of blood bank to ensure all equipment within the department are documented.

Maintenance Schedules:

Draw up suitable schedules by maintenance type and frequency or by equipment type. Define forward dates for the completion of maintenance and record the date of actual performance in the schedule.

Service contracts:

1. Contracts need to be in place for all equipment items maintained by an external agent.
2. Each service contract shall define exactly what is carried out/the frequency and by whom it is completed.
3. At the completion of the service, a maintenance report is to be supplied, signed by the contractor and the officer in charge. The report shall detail the work carried out by the contractor.

Repair and breakdown:

1. Operating instructions for each item of equipment shall identify the steps required to be taken in the event of a fault or breakdown, and shall identify who is responsible for organizing service or replacement.
2. A register is maintained for errors and corrective actions for all equipment items. In the event of equipment breakdown, it is essential that it be clearly labeled and identified as being "OUT OF SERVICE".

Blood Bank Refrigerator

- It is provided with temperature recorder (Both digital display and graphical recording)
- The temperature recording chart should be checked frequently 4 times a day.
- The correct temperature range is 2° to 6° C.
- Temperature chart to be changed weekly.

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- The refrigerator is fitted with an audio visual alarm system.
- Periodically ,temperature inside the cabinet is counter checked with the help of thermometer.
- Calibration frequency is once in six months.

Refrigerated Centrifuge

- Checked by the service engineer every three months.
- Accuracy of speed & time should be checked with the tachometer & stop watch.
- It should be balanced properly on even surface.
- It should have continuous power supply.
- The buckets weight should be uniform.
- Calibration frequency is once in six months.

Bench Centrifuge

- This should be checked every three months for accuracy of the speed & timer & should be checked with tachometer & stop watch.
- It should be cleaned regularly.

Water bath & incubator

- Temperature should be checked daily.
- They should be kept clean.
- Accuracy of the thermometer should also be checked periodically.
- Water should be changed frequently.

Blood Collection monitors

- It should be checked daily for its performance.

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- Check its weighing system with a known weight in grams.
- Calibration done once in six months.

Deep freezers

- It is provided with temperature recorder (Both digital display and graphical recording)
- It should have inbuilt temperature monitoring sensor.
- Check the Temperature chart & the digital temperature display frequently atleast 4 times a day.
- Periodically check the temperature of digital system by thermometer kept inside the cabinet.
- Check alarm system once in a week.
- Defrosting done whenever needed.
- Calibration done once in six months.

Platelet Incubator & Agitator

- It should be balanced properly on even surface.
- It is provided with temperature recorder (Both digital display and graphical recording)
- It should have inbuilt temperature monitoring sensor.
- Temperature chart changed weekly.
- Check the Temperature chart & the digital temperature display frequently atleast 4 times a day
- Agitator speed should be 70 strokes per minute.

Microscope

- Keep microscope in dust free atmosphere & covered when not used.
- Keep the coarse & fine adjustments well lubricated.

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- Keep the stage, lenses, condenser, objective clean.

Autoclave

- Temperature, Pressure & time should be set for sterilization.
- Temperature should be 120° C/250° F.
- Pressure should be 1° atmospheric pressure (151 lbs/sq inch).
- Time should be in minutes.

DOCUMENTATION:

- File for service reports of all equipments are maintained.
- Enter the details of all routine service & repair & breakdown service by the service engineer in the equipment repair & breakdown register.
- A file is maintained for manufacturer's instructions of all equipments and where required is displayed close to the equipment.
- Record the name, address and telephone number of the service engineer to be contacted in case of need & also displayed close to the equipments

Quality control of Blood bank equipments		
Name of the equipment	Quality control	Frequency of control
Blood bank refrigerator	Temperature chart, Digital temperature	

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Sl.No	Equipments	Performance	Frequency	Frequency of Calibration
1.	Temperature recorder of blood storage cabinets freezer -40 & -80 c	Compare against thermometer	Daily	As often as necessary
2.	Refrigerated centrifuge	Observes speed & temperature	Each day of use	As often as necessary
3.	General lab centrifuge	Observes speed & time	Each day of use	Check speed tachometer every 6 months
4.	Blood collection monitor	Observes weight of the first container of blood filled for correct results	Each day of use	Standardized container of known mass/volume before initial use and after repairs
5.	Blood bag weighing scale (Electronic)	Standardized against contain of known weight	Each day of use	As often as necessary
6.	Water Bath	Observe temperature	Each day of use	As often as

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				necessary
7.	Autoclave	Observe temperature	Each day of use	As often as necessary
8.	Lab Thermometer		Each day of use	Before initial use
9.	Urinometer,	Standardized against distilled water	Each day of use	
10.	Platelet incubator & agitator	Number of stokes 70 +10/min & temperature to be compared against thermometer	Each day of use	As often as necessary
11.	Serologic rotater	Observe controls for correct results	Each day of use	Speed as often as necessary
13.	ELISA Reader	Check for proper utilization & OD values,Cord,fuse,power voltage,plate movement	Each Day of use	As often as necessary
14.	ELISA Washer	Check for accuracy of the dispensing volume,rinsing to be done after completion of work ,Check for the proper functioning	Each day of use	As often as necessary

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		of the sensor of the wash bottle		

9.52. QUALITY CONTROL OF ANTISERAS & REAGENTS

SCOPE AND APPLICATION

The anti-seras which are used in the serology laboratory should meet the criteria.

RESPONSIBILITY

It is the responsibility of the technician in the serology lab to do the titration of the supplied antisera. The quality control test is done at least once in a month and also when received a new lot.

MATERIALS REQUIRED

- Glass micro tubes or khan tubes
- Red Cell Suspension of AI, A2, B, AIB, A2B, O groups
- Anti-seras

PROCEDURE

Quality control of antiseras

The quality control of all the anti-sera should be carried out by

1. Avidity
2. Titration
3. Specificity

1. Avidity Test (for anti A, B, D (Rh))

- a) Take 3 micro slides and label as A, B and D (Rh)

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b) Put one drop of 50% thick red cell suspension to each slide and put one drop of anti-sera to respective slides, separately.

c) Mix the red cells and anti-sera. At the time of mixing start the stop watch to note the time of agglutination. Once the agglutinations is seen, stop the stop watch and note down the time.

Normal Values

- i) Anti 'A' - A1 Cells - 10-15 seconds
- A2 Cells - 15-20 seconds
- A1B Cells - 10-15 seconds
- A2B Cells - 15-20 seconds
- ii) Anti 'B' - 10-15 seconds
- iii) Anti 'D' (Rh) - 15-20 seconds

2. Titration (for anti A, B & D (Rh))

a) Antisera 'A'

- i) Take 10 micro tubes and label as undiluted, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256 and 1:512 and make the dilution of the antisera accordingly.
- ii) Prepare 5% red cells suspension of A1 cells, A2 cells, A1B cells A2B cells with normal saline.
- iii) Take 10 x 4 Rows of micro tubes and label first row as 'A1' second row as 'A2', third row as 'A1B' and fourth row as 'A2B'. And label each row of the 10 tubes as undiluted 1: 2, 1: 4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256, and 1:512.
- iv) Take one volume of 5% red cell suspension of all A1, A2, A1B and A2B into respective tubes and mix all the tubes with one volume of diluted anti-sera respectively and centrifuge all the tubes at 1000 rpm for 2 minutes and note the agglutination pattern by gently shaking.

Normal Range

- 1) 'A1' Cells - 1 : 128 dilution

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2) 'A2' Cells - 1 : 64 dilution

3) 'A1B' Cells - 1 : 128 dilution

4) 'A2B' Cells - 1 : 64 dilution

b) Anti-sera 'B'

i) Take 10 X 2 rows of micro tubes label first as anti-'B', second row as anti 'D' (Rh) and label each row of 10 tubes as undiluted, 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256, 1:512 and make the dilution of both anti-seras accordingly.

ii) Prepare 5% red cell suspension of known 'B' and known 'Rh' positive cells.

iii) Take 10 X 2 rows of micro tubes and label first row as 'B' and second row as 'D' (Rh) and label each row of the ten tubes as undiluted 1:2, 1:4, 1:8, 1:16, 1:32, 1:64, 1:128, 1:256, 1:512.

iv) Take one volume of 5% red cell suspension of both known 'B' cells and known Rh positive cells into all respective tubes and mix with one volume of diluted anti 'B' and anti 'D' (Rh) respectively and centrifuge the tubes at 1000 rpm for 2 minutes. Note the agglutination pattern by gently shaking.

Normal range

1) Anti 'B' - 1:256 dilution

2) Anti 'D' (Rh) - 1:256 dilution

NOTE: With all the above said each test we have to fulfill the following details:-

- Appearance
- Monoclonal or Polyclonal
- Name of the Manufacturer
- Batch number/ lot number
- Manufacturing date.
- Expiry date

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Acceptable titer and Avidity of ABO reagent

3. Specificity for anti A, B, D (Rh)

a) Anti-sera 'A'

- i) Take 8 number of each known 'A' group cells, 'B' group cells and 'O' group cells, 'AB' group cells in a different test tubes and wash the all group cells 3 times with normal saline and make 5% red cell suspension of each group cells.
- ii) Take 8x4 micro tubes in a rack and label first row as 'A' cells, second row as 'B' cells third row as 'O' cells and forth row as 'AB' cells.
- iii) Add one drop of each 5% red cells into each tubes respectively and add one drop of anti-sera 'A' into all tubes (8x4 tubes) mix the tubes and centrifuge at 1000 RPM for 2 minutes.
- iv) After completion of 2 minutes centrifugation take the tubes from centrifuge and shake gently each tube for agglutination.

INTERPRETATION:

In this test known group of 'A' cells must show the agglutinations and other group cells like 'B' cells, 'O' cells, 'AB' cells must show no agglutinations. If any one of 'B' cells, 'O' cells, 'AB' cells shows the agglutinations that indicates the anti-sera is not good.

NOTE: With the above said test we have to fulfill the following details:

1. Appearance
2. Monoclonal or Polyclonal
3. Name of the Manufacturer
4. Batch No./ Lot No.
5. Manufacturing Date.
6. Expiry Date.

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Antisera	Type of reagent	Type of red cell	Titer	Avidity	Specificity/Intensity
Anti-A	Monoclonal	A1	1:256	3-4 sec	+++
Anti-B	Monoclonal	B	1:256	3-4 sec	+++
Anti-D(IgM)	Monoclonal	Rh cell	1:64	6-10 sec	+++

The same procedure will follow for anti sera 'B' and anti sera 'D' (Rh) specificity test

DOCUMENTATION

A register is maintained separately for different anti-seras and the

Following are entered:

- 1 Name of the Manufacturer
2. Batch No./ Lot No.
3. Manufacturing Date.
4. Expiry Date.
5. Interpretation of Avidity, Titration, Specificity
6. Test done by

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Quality Control of reagents

Quality Control of reagent Red Blood Cell		
Parameter	Quality requirement	Frequency of control
Appearance	No hemolysis or turbidity in supernatant by visual inspection	Each day
Reactivity and Specificity	Clear cut reaction with known sera against red blood cell antigen	Each day

Quality Control of reagent ABD		
Parameter	Quality requirement	Frequency of control
Appearance	No turbidity, precipitates, particles or gel formation by visual inspection.	Each day
Specificity	Clear cut reaction with red cell having corresponding antigen and no reaction with negative control.	Daily and each new lot
Avidity	Macroscopic agglutination with 50% red cell suspension using slide test	Daily and each new lot

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Reactivity	No immune hemolysis, rouleaux formation or prozone.	Each new lot
Potency	Undiluted sera should give ++++ reaction in tube testing using a 5% red cell suspension at room temperature. Titer should be atleast 128 for Anti-A & Anti-B. A titer of 32-64 for Anti-D	Each new lot

Anti-human globulin reagent

- One vial from every new batch should be checked for its specificity & reactivity using (incomplete anti – Rh) IgG coated cells.
- Each test should include positive & negative controls.
- Non-sensitized A, B & O cells should be checked to rule out non-specific reactions.
- All negative AHG tests should be confirmed by addition of IgG coated cells in the test. IgG coated cells should give positive agglutination.

Bovine serum albumin

- The reagent should be free of the non-specific agglutinins & should not react with saline suspension of A, B & O cells.
- Reagents should give positive reaction with Rh (D) positive cells coated with incomplete anti Rh(D).

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Quality Control of Saline

- 0.9% saline is used widely in the immune-haematology laboratory for washing of red cells, to prepare red cell suspension & as diluents for various sera & serological reagents. The standard saline solution of 0.9% is prepared by dissolving 9 grams of good quality of sodium chloride in 1 liter of distilled water. The pH of saline used for red cell serology should be between 6.5-7.5 as this is the optimum pH for most antigen antibody reactions. These solutions should be checked daily for pH (6.5-7.5). Absence of haemolysis with random A, B & O cells provide a useful indication for its suitability.

DOCUMENTATION

The results are recorded & signed by the technician in the daily quality control form & filed.

9.53. QUALITY CONTROL OF BLOOD & COMPONENTS

SCOPE & APPLICATION

Quality control of blood component involves quality measures taken at donor selection, type of bag used and anticoagulant preservation solution used for blood collection, volume of blood collection, storage, transport condition, the procedure involved in preparation of components. The quality monitoring should be acceptable only after the process has been fully validated and introduced into routine use.

RESPONSIBILITY

The technician involved in preparation of blood component is responsible for assessment of quality control of the various components prepared. Since it is not possible to test each individual component, so randomly selected sample of the unit must be evaluated. (1% of total prepared component is tested at the end of the storage period). Smaller centers can collaborate with hematology laboratories for checking the quality parameters of various blood components.

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MATERIALS REQUIRED

- Prepared components
- Glass bottles/vials or sample container

PROCEDURE

- 1% of total prepared components are tested for the following parameters at the end of the storage period and sterility to be checked.
- 75% units tested for quality control must meet the quality requirement. When test results are unacceptable corrective action to be under taken and recorded.
- Take a sample of the component approximately 3 to 5 ml and send to the respective laboratory to do the following parameters.

DOCUMETATION

A register to be maintained and the results are recorded. The reports are filed separately.

Quality Control of Whole Blood		
Parameter	Quality requirement	Frequency of control
Volume	350/450 ml +/- 10%	1% of all units
PCV (HCT)	30-40 %	4 units per month
Sterility	By culture	1% of all units
HBsAg	Negative by ELISA	All units
Anti-HCV	Negative by ELISA	All units
Anti-HIV I&II	Negative by ELISA	All units
Syphilis	Negative by screening test and	All units

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	rapid	
Malarial parasite	Negative by screening test and rapid	All units

Quality control of red cell concentrate (prepared from 450ml of blood)		
Parameter	Quality requirement	Frequency of Control
Volume	280 +/- 40ml	1% of all units
PCV (HCT)	70 % +/- 5%	1% of all units
Hemoglobin	>45 gms/unit	1% of all unit
Quality control of platelet concentrate prepared from 450ml of whole blood		
Parameter	Quality requirement	Frequency of control
Volume	50-70ml	All units
Platelet count	$\geq 5.5 \times 10^{10}$	4 units per month
pH	>6.0	4 units per month
RBC contamination	0.5ml	4 units per month
WBC contamination	5.5×10^7 to 5.0×10^8	4 units per month
Appearance	Colourless & transparent	4 units per month

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- pH of the platelet concentrate is checked by the technician using ABG machine which is available in the ICU of the Hospital Campus.
- Swirling movement of platelet concentrate to be checked.
- The test for functional viability of the platelets to be checked near expiry date by swirling movement .
- A, B, O, AB grouping is done if the platelet concentrate is contaminated with RBC's

Quality control of Fresh Frozen Plasma		
Parameter	Quality control	Frequency of control
Volume	200-220ml plasma	4 units per month
Stable coagulation factor	200units of each factor	4 units per month
Factor VIII	0.7 IU/ml	4 units per month
Fibrinogen	200-400mg	4 units per month

QUALITY CONTROL

The HIV Tri-dot test is a visual, rapid, sensitive and accurate immunoassay for the differential detection of HIV-I & II antibodies (IgG) in human serum or plasma using HIV I & II antigens immobilized on an immunofiltration membrane. The test is a screening test for HIV I & II.

PRINCIPLE: HIV antigens are immobilized on a porous membrane. Sample and reagents pass through the membrane and are absorbed into the underlying absorbent. As the patient's sample passes through the membrane, HIV antibodies, if present, bind to the immobilized antigens.

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Conjugate binds to the Fc portion of the HIV antibodies to give distinct pinkish purple DOT against a white background.

PRECAUTIONS: Take care of the following points before starting the test.

- Bring all the reagents and specimens to room temperature (25 - 30°C) before beginning the test. The immunological sequence of reaction which take place during different procedural steps shows best performance at room temperature. DO NOT HEAT OR REPEATEDLY FREEZE/THAW SPECIMEN.
- Place the required number of HIV TRI-DOT test devices at the working area.
- Tear off the pouch and take out the device for performing the test. Write the sample no. to be tested on the device.
- While adding sample/reagents to the device, be sure to ALLOW EACH SOLUTION TO SOAK IN BEFORE ADDING THE NEXT SOLUTION.
- However drops of each solution should be added in continuous stream to wet the entire area of membrane.
- If the solution does not soak-in within 40-60seconds; observe the sample for any suspended particulate matter. If it is present, centrifuge the sample at 10,000rpm for 15min, and use a fresh device to re-run the test
- All solutions and sample should be added to the CENTRE OF MEMBRANE.
- For consistent result ensure FREE FALLING OF DROPS on the membrane.
- Do not use kit components beyond the expiration date.
- The liquid conjugate should not be subjected to frequent temperature fluctuations.
- The procedural sequence of reagent addition should be strictly adhered to avoid any discrepant result.

TTD – HIV Tridot

PROCEDURE:

- Add 3 drops of Buffer solution to the centre of the device.

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- Hold the dropper vertically and add 1 drop of patient's sample (serum/plasma) using the sample dropper provided (use a separate sample dropper for each specimen to be tested).
- Add 5 drops of Buffer solution.
- Add 2 drops of Liquid Conjugate directly from the conjugate vial.
- Add 5 drops of Buffer solution and read results.
- Read results immediately and discard the device as potentially infectious.

INTERPRETATION OF RESULTS:

Non – Reactive:

- If only one DOT (only the control dot) appears, the specimen is non reactive for antibodies either to HIV I or II. Interpret sample as non-reactive.

Reactive:

- If two dots, one for the control and other for HIV-II appear, the specimen is reactive for antibodies to HIV-II.
- If all three dots, one each for control, HIV I & II appear, the specimen is reactive for antibodies to HIV I & II.

Invalid:

- If no DOT appears after the test is complete, either with clear background or with complete pinkish/purple background the test indicates ERROR. This may indicate a procedural error or deterioration of specimen/reagent or particular matter in the specimen. The specimen should be tested on a new device.

All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting

Enter all results in the screening register with signature, date and time.

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HEPACARD is a visual, rapid, sensitive and accurate one step immunoassay for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in Human Serum/Plasma. The assay is intended to be used as an aid in the recognition and diagnosis of acute infection and chronic infectious carriers of the Hepatitis B Virus (HBV).

PRINCIPLE: HEPACARD is a one step immunoassay based on the antigen capture, or “sandwich” principle. The method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The test sample is introduced to and flows laterally through as absorbent pad where it mixes with the signal reagent. If the sample contains HBsAg, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. The complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody “T” (test line), the complex is trapped forming an antibody-antigen-antibody colloidal gold complex. This forms a pink band indicating the sample is reactive for HBsAg. To serve as a procedural control, an additional line of anti-mouse antibody “C” (control) has been immobilized at a distance from the test line on the strip. If the test is performed correctly, this will result in the formation of a pink band upon contact with the conjugate.

PRECAUTIONS:

- Consider all specimens as hazardous
- Do not open the foil pouch to remove the product until it attains room temperature and you are ready to perform the test.
- Interpret the result at the end of 20 minutes only.
- Take out the cards from the pouch just before performing the test to avoid denaturation of antisera to atmospheric exposure.
- **Optimal test performance requires strict adherence to the test procedure described in the insert.**

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PROCEDURE:

- Bring the required no. of HEPACARD foil pouches and specimen to room temperature prior to testing.
- Take out HEPACARD device from the foil pouch.
- Label the test card with patient's name or identification number.
- Add 2 drops (70µl) of human serum/plasma specimen into the sample well using the dropper provided (use separate dropper/microtip for each specimen)
- Allow reaction to occur during the next 20minutes.
- Read results at 20 minutes.

Discard the HEPACARD immediately after reading at 20 minutes, considering it to hazardous.

INTERPRETATION OF RESULT:

Reactive:

- Appearance of pink colored line, one each in test region "T" and control region "C" indicates that the sample is REACTIVE for HBsAg.
- A difference of intensity in color may occur between the test line & control line depending on the concentration of the HBsAg in the serum but this does not affect interpretation of the result.

Non-Reactive:

- Appearance of one distinct pink line in the control region "C" only indicates that the sample is "NON REACTIVE" for HBsAg.

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Invalid:

- When neither control line nor test line appears on the membrane, the test should be treated as invalid.
- The test should be repeated using a new HEPACARD and test sample.

All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting

Enter all results in the screening register with signature, date and time.

The 4th generation HCV Tri-dot is rapid, visual, sensitive and qualitative test for the detection of antibodies to Hepatitis C Virus in human serum/plasma & has been developed and designed with increased sensitivity for core and NS3 antibodies using a unique combination of modified HCV antigens. They are for the putative core (structural), protease/helicase NS3 (non-structural), NS4 (non structural) and replicase NS5 (non structural) regions of the virus in the form of two test dots “T1” & “T2” to provide a highly sensitive and specific diagnostic test.

PRINCIPLE:

- HCV antigens are immobilized on a porous immunofiltration membrane. Sample and the reagents pass through the membrane and are absorbed into the underlying absorbent pad.
- As the patient's sample passes through the membrane, HCV antibodies if present in serum/plasma, bind to the immobilized antigens. In the subsequent washing step, unbound serum/plasma proteins are removed.
- In the next step, the protein-A conjugate is added which binds to the Fc portion of the HCV antibodies to give distinct pinkish purple dot against a white background at the test region (“T1 or T2”). At the control region “C” a built- in quality control dot has been devised to confirm the proper functioning of the device, reagent and correct procedural application.

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PRECAUTIONS: Take care of the following points before starting the test.

- Bring all the reagents and specimens to room temperature (25 - 30°C) before beginning the test. The immunological sequence of reaction which take place during different procedural steps shows best performance at room temperature. DO NOT HEAT OR REPEATEDLY FREEZE/THAW SPECIMEN.
- Place the required number of HIV TRI-DOT test devices at the working area.
- Tear off the pouch and take out the device for performing the test. Write the sample no. to be tested on the device.

While adding sample/reagents to the device, be sure to ALLOW EACH SOLUTION TO SOAK IN BEFORE ADDING THE NEXT SOLUTION

- However drops of each solution should be added in continuous stream to wet the entire area of membrane.
- If the solution does not soak-in within 40-60seconds; observe the sample for any suspended particulate matter. If it is present, centrifuge the sample at 10,000rpm for 15min, and use a fresh device to re-run the test.
- All solutions and sample should be added to the CENTRE OF MEMBRANE.
- For consistent result ensure FREE FALLING OF DROPS on the membrane.
- Do not use kit components beyond the expiration date.
- The liquid conjugate should not be subjected to frequent temperature fluctuations.
- The procedural sequence of reagent addition should be strictly adhered to avoid any discrepant result.

PROCEDURE:

- Add 3 drops of Buffer solution to the centre of the device.
- Hold the dropper vertically downwards and add 1 drop of patient's sample (50µl serum/plasma) using the sample dropper provided. (Use a separate sample dropper for each specimen to be tested).

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- Add 5 drops of buffer solution.
- Add 2 drops of Protein-A conjugate.
- Add 5 drops of Buffer solution.

Read results immediately and discard the device immediately considering it to be potentially infectious

INTERPRETATION OF RESULTS:

Non-Reactive:

- Appearance of only one dot at the control region “C” indicates that the sample is NON REACTIVE for antibodies to HCV.

Reactive:

- Appearance of two dots, one at the control region “C” & other at the test region “T1” indicates that the sample is REACTIVE for antibodies to HCV.
- Appearance of two dots, one at the control region “C” & other at the test region “T2” indicates that the sample is REACTIVE for antibodies to HCV.
- Appearance of all the three dots, one each at “C” “T1” & “T2” region indicates that the specimen is REACTIVE for antibodies to HCV.

Invalid:

- If no dot appears after the completion of test, either with clear background or with complete pinkish/purplish background the test indicates ERROR.
- This may indicate a procedural error or deterioration of specimen/reagents or particulate matter in the specimen.
- The specimen should be retested on a fresh device.

All samples detected reactive must be confirmed once again by Rapid/ELISA before reporting.

Enter all results in the screening register with signature, date and time.

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External Quality Assessment Scheme (EQAS)

We participate in the EQAS program – Transfusion Module, conducted by Christian Medical College(CMC) Vellore. We receive samples once in four months(3 surveys in a calendar year).

9.54. EQUIPMENT PERFORMANCE MONITORING

Scope & Application

This procedure covers those measures taken to ensure the integrity, accuracy & reliability of measurement data for equipment & instruments used in the collection, testing & storage of blood products. The procedure is applicable to all equipment used to control or evaluate suitability of starting materials, in process products & finished products.

Responsibility

It is the responsibility of the supervisor of the section to which the equipment belongs to:

- Plan, Schedule, organize & maintain records of the calibration programmes for various equipment under their control.
- Ensure that equipment & instruments are continuously calibrated or are removed from use.
- The supervisor should train staff for performing calibration/performance checks.

PROCEDURE

- All equipments used in collection, processing, testing, storage and distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate regular cleaning and maintenance.

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- All the equipments must be checked on routine basis. Each and every Laboratory staffs should be responsible for the equipment he / she uses.

- All equipments need preventive maintenance including cleaning, regular calibration

And periodic verification of performance accuracy which is either carried out by the concerned superior under maintenance service contact. This should be planned properly in order to minimize disruption of service.

9.55. STERILITY TEST

SCOPE AND APPLICATION

Randomly selected whole blood as well as all types of components prepared in the blood bank should be tested for sterility.

Purpose :

- To determine the methodology for processing blood culture samples and blood bags sterility received by the Microbiology laboratory.
- See also Section on Anaerobes, Brucella, etc. All media should have reached RT, before inoculating the blood.

Note : The blood bags received from the blood bank are processed as for blood cultures.

Responsibility

It is the responsibility of the technician to send randomly selected blood bags for blood culture per month.

Each unit should be sent for bacterial and anaerobic and fungal culture test.

MEDIA AND BLOOD TO BE INOCULATED :

A. Aerobic bacteria

1. For Brain Heart Infusion Broth (BHI) of 50 ml, 5 ml of blood to be inoculated.

B. Brucella

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1. BHI [50 ml] 5ml
2. Casaneda's Bi-Phasic medium [50 ml] 5m

C. Anaerobic Bacteria

1. Thioglycollate broth (TB)[3 ml] 1.5 ml
(Freshly hated and cooled tube)
- Robertson's medium (tube) [3ml] 1.5ml

D. Fungi

1. Biphasic Sabouraud's media 2 bottles [50ml] -5 ml each.

E. Leptospira

1. Three tubes of EMJH medium 1-2 drops each.

Procedures in the Laboratory :

Inoculated media are received in the laboratory and incubated. After overnight incubation:

3. First day of receipt :

Examine the BHI broth for turbidity and if turbid proceed for identification.

If no growth, further incubate .

1. Processing when BHI broth is turbid :

- a. Do a smear and 1st subculture on the second day of receipt with a syringe and needle .
- b. If negative , do a second subculture on the 7th day and final open subculture on the 14th day on ¼ plate .For suspected fungal blood stream infections an additional two weeks of incubation done with weekly subcultures.
- c. Discard BHI bottles on the 16th day for routine aerobic cultures and on 30th day for fungal cultures.

3.1If GNB , inoculate on to MacConkey's agar , inoculate the biochemicals and perform direct antibiotic susceptibility on Mueller Hinton agar and report .

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3.2 GPC in clusters – do slide Coagulase , inoculate on blood agar / chocolate agar and perform direct antibiotic sensitivity on Mueller Hinton agar and report.

3.3 GPC in pairs in BHI – do Latex Agglutination (see at the end of this section) on broth supernatants subculture on blood agar / chocolate agar and perform direct sensitivity on blood or chocolate agar and report.

3.4 Whenever cultures are grossly contaminated , another specimen should be requested immediately since the growth of the contaminant inhibits the growth of a pathogen .

3.5 Whenever gram positive non-spore forming organisms are found , tests for differentiation between diphtheroids , which might be skin contaminants and the morphologically similar , but pathogenic *Listeria monocytogenes* should be carried out .

Note : Preliminary report is to be given as soon as growth suggestive of a recognized or a potential pathogen occurs to the clinician and immediately do the sensitivity for the isolate .

4. Further follow up of cultures :

Any time growth is detected by turbidity in the broth, make smears, subculture on appropriate media and follow up for identification and report.

Procedure for processing blood bags for sterility :

- Sterile precautions to be taken while doing this procedure in microbiology department.
- Selected random blood bags and Brain heart infusion broth bottles to be kept vertically in the laminar flow under UV light for 20 minutes.
- Label the Brain heart infusion broth bottles according to the blood bags.
- Under aseptic precautions wipe out the pricking area of the bag with 70% alcohol. Allow it to dry.
- Draw 5 ml of blood from the bag with the help of sterile syringe & needle.

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- Carefully dispense into the 50 ml of Brain heart infusion broth bottle. Mix gently.
- Similarly do it with other blood components.
- Incubate at 37° C for 48 hours for a maximum of 30 days in case there is no growth.
- Supplementary reports will be sent only if there is growth with identification details of the isolate grown .
- **A final report will be dispatched irrespective of the growth after 4 weeks of incubation to the blood bank .**

SPECIAL NOTE:

1. First Report : Even if no growth is detected by the second subculture , send the first report as “No growth so far” with a note that a supplementary report will follow if growth occurs after further incubation .
2. When Coagulase negative staphylococci or gram negative bacilli which are probably contaminants are found , a special note may be added to report that repeated isolation of the same organism may be significant in the diagnosis of infective endocarditis or septicaemia and suggest that a repeat specimen should be sent to confirm the significance of the isolate .
3. Supplementary Report must be made when the identification is completed , sensitivity report is ready or when pathogens are isolated after subsequent after subsequent follow up of the originally inoculated bottles.
4. When BHI shows Gram positive cocci morphologically suggestive of pneumococci, carry out the pneumococcal Latex test on the BHI broth
5. Refer appropriate sections when Anaerobic bacteria, Brucella or fungi are suspected.

*** Preliminary Report is to be given as soon as growth suggestive of a recognized or potential pathogen occurs—Do a sensitivity test immediately.**

Documentation:

A register to be maintained with the following details:

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- Date, unit number, name of the sample, name of the company, batch/lot number of the bag, date of manufacture, date of expiry, and sent by Columns to be entered .
- The culture report of 24 hrs, 1 week, 2nd week, 3rd week & 4th week to be entered at respective unit number.
- The reports to be filed separately.

9.56.PROCURING BLOOD FROM OUTSIDE DURING NON-AVAILABILITY

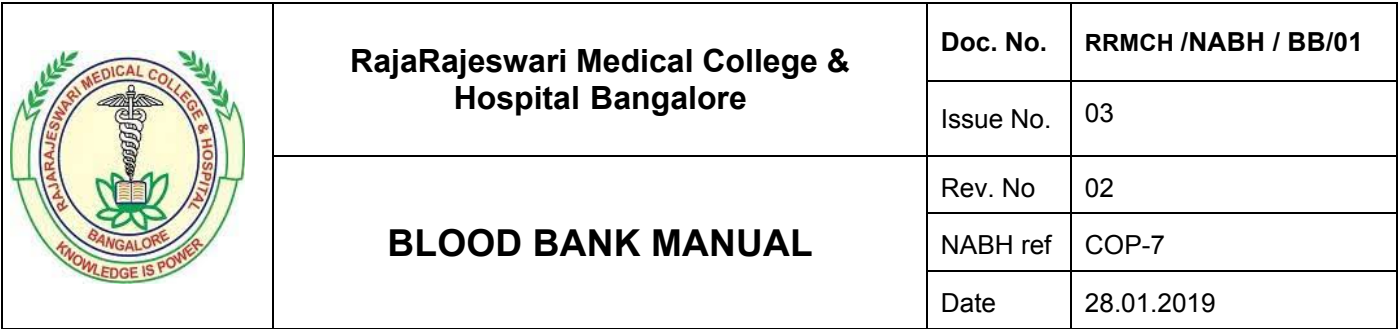
Scope: - When there is a shortage of common group blood and requirement for rare blood group blood Bags, the patient attender's are sent to other reputed blood banks for blood.

Responsibility

Technicians

Procedure:

- The patient relatives/friends approach for blood/blood components to the blood bank.
- Technician on duty checks for the stock position of the required blood/blood component.
- We have MOU with Blood Banks such as Lions Blood Bank.
- If the particular blood/blood component is not available in the stock the patient relatives/friends are sent to the below mentioned reputed/licenced blood bank.
 - Manipal Blood Bank
 - TTK blood Bank
 - BGS Blood Bank
- The patient relatives/friends are sent to the above mentioned blood bank after confirmation of availability of stock.



- The patient relatives/friends are instructed to carry a request form and 2 samples (EDTA & Clotted) before going to collect the blood.
- The patient relative/friends obtain the blood bag to our blood bank and hands over to technician on duty.
- The technician checks for the following details before receiving the blood bag.

➤ Name of the patient, Age/Sex	Blood Bag No.
➤ IP No of the patient	Blood Group
➤ Compatibility/Screening report	Collection/Exp Date

- All the details are entered in the register meant for blood units brought from outside blood bank maintained in blood bank.
- The patient relatives are instructed to get the patient sample for re-cross matching and grouping.
- The request for issue of the cross-matched blood will be sent in writing in the prescription form with the details of the patient (Name, IPNo. Ward) with the name and signature of the doctor.
- Before releasing of the unit the blood bag is re-crossmatched and grouped.
- After checking the details in the file the technician on duty releases the blood bag with the receiver's signature in the register.

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9.57. TRANSPORTATION OF BLOOD

Scope & Application

To transport blood & blood products in a safe, secure under acceptable cold chain temperature.

Responsibility

Technicians on duty

Blood units may have to be transported either within the hospital complex or to other hospitals

TRANSPORTATION TO HOSPITALS OTHER THAN RRMCH

- It is important that the blood must be kept within the temperature range of 2-8⁰ C during transportation. This is achieved by using sturdy well insulated carriers/insulated cold boxes.
- The blood should be packed in to the cold boxes surrounded by the ice packs making sure that the blood should never touch ice pack directly. Ice should be placed at the top inside the container so that the cool moves down through the box.
- In climates that are extremely warm and transportation involving long journey ice may also be packed at the bottom of the container.

Note:- Ice should not come in direct contact with blood at any time as it can cause haemolysis of the red cells or blood.

- It is important to measure the temperature of the container /blood at the time of arrival and also check the blood for any evidence of haemolysis.

Transportation of frozen components

- FFP and cryoprecipitate must be transported maintaining temperature of -30⁰C or below.
- Dry ice is used to maintain the frozen state. Place the dry ice at the top inside well insulated container. As this frozen components are fragile, insulate the products by dry packing material/plastic air bubbles to check breakage during transportation.

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Transportation of Platelets

- For transportation of platelets well insulated container with **no ice** is used to maintain temperature between 20-24⁰ C.

TRANSPORTATION OF BLOOD/BLOOD COMPONENTS WITHIN THE HOSPITAL

- The blood and red cells should be transported with in the hospital in insulated carrier/in insulated cold box if the ambient temperature is greater then 25⁰ C.
- Always record the time of issue once blood is issued from the blood bank.
- For transportation of platelets well insulated container with no ice is use to maintain temperature between 20-24⁰ C.

Transportation of FFP and Cryoprecipitate

- For transportation of thawed FFP and Cryoprecipitate well insulated container is used.
After transportation, on receiving end the blood units must be grossly checked as per SOP on verification of blood and blood products.

After transportation, on receiving end the blood units must be grossly checked for any sign of deterioration or haemolysis & also looks for any

- ✓ Leakage or breakage
- ✓ Any change in colour of plasma
- ✓ Any change in the colour of the red cells
- ✓ Any clots or abnormal mass formation

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9.58. MANAGEMENT OF BLOOD SPILLS IN BLOOD BANK

1. Prior to beginning the clean – up of spillage of blood, wear gloves.
2. Cover the spill area with 1% sodium hypochlorite solution.
3. Place absorbent paper (tissue paper) over the spill .Allow a contact time of 15-20 minutes.
4. Wipe up the blood spills with an absorbent towel and dispose the blood spills with absorbent towel in the Yellow bag.
5. Any glass, needles or other sharp objects that may puncture skin will be picked up by brush, dust pan, tongs or forceps and discarded in puncture resistant containers containing 1% sodium hypochlorite solution.
6. After the contaminated area has been cleaned, apply a disinfectant to the blood spills area.
7. Wash hands with gloves on.
8. Remove gloves & thoroughly wash hands with soap and water or alcohol based hand rub.
 - Discard all disposable articles contaminated with blood in plastic bags or in containers with sodium hypochlorite solution.
 - Disinfect all non-disposable and reusable items like dust pan, forceps, buckets etc. before sterilization.

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Bio – hazard Exposure :

If suspected of any exposure to (skin puncture or splash to eyes or mucous membrane) bio hazard material that had not been de-contaminated with bleach solution follow the recommended step

- **Skin exposure** – vigorously wash affected skin with plenty of soap and water.
- **Eye exposure** – Wash eyes for atleast 10 minutes with copious amount of water lifting upper and lower lid occasionally.
- Report the incident to HICC Co-ordinator for further follow up and management.

9.59. PROCEDURE FOR DISPOSAL OF BIO – HAZARD WASTE

SCOPE AND APPLICATION

All blood and biomedical waste generated in the blood bank should be discarded after proper disinfection so that all personnel in blood bank inturn do not infect themselves.

RESPONSIBILITY

It is the responsibility of all personnel in blood bank to keep their areas of work clean and tidy and follow universal precautions of safety.

PROCEDURE

a) Before carrying out any standard procedures all blood bank personnel should wear person protective equipment like eye protection, face mask, apron and gloves

b) **Blood spills** : Any spillage of blood and blood products on floor or table tops should be covered with absorbent towel/blotting paper/tissue paper.

- Put 1% hypo chloride solution on the absorbent towel/blotting paper/tissue paper for 20 minutes.

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- Remove the absorbent towel/paper & dispose it in yellow colour code, infective disposal bin.
- Wipe it clean
- Dispose off the person protective equipment in yellow colour code infectious bin.
- Wash hands with soap & water & an alcohol based disinfectant.

c) All reusable glassware after use should be soaked in 1% hypochlorite bleach solution kept in wide mouth plastic container and then cleaned and dried before reuse.

d) All other medical waste like plastic, paper, cotton swabs, testing cards, etc which are not reused should be put in respective color coded bags labeled "Biohazard", when $\frac{3}{4}$ full it is sealed and sent for disposal.

e) Blood bags which are tested positive for HIV, HCV, HBsAg, VDRL, MP are discarded after autoclaving at 121°C for 60 minutes.

- The Blood bags are disposed in yellow bin & is taken by the out sourced Bio – Medical waste agency.
- The pilot samples with blood are also soaked in bleach and later emptied in the sink.
- The bags and pilot tubes are put separate in disposal bag labeled "biohazard" and sent for disposal.
- Outdated bags, leaking bags are also autoclaved and sent for disposal as per Bio – Medical waste management.

f) Needles /tips and any other sharp items are dropped into a sharp disposal containers when $\frac{3}{4}$ full it is sealed and sent for disposal.

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PROTECTION OF BLOOD BANK PERSONNEL.

1. Universal precautions must be practiced with all samples at all times that is all samples must be treated as if they are infectious.
2. Always wear disposal gloves while handling Blood/Blood components.
3. Always wear laboratory coats to ensure that their clothes are kept free from infectious agents & remove the coat before leaving the laboratory.
4. Wash hands before leaving the blood bank.
5. Wash hands, if accidentally hands come in contact with blood, when gloves not worn.
6. If apron gets soiled with blood serum change to clean one. The soiled one should be autoclaved before laundered
7. Any cuts or scratches, wound and skin abrasion on hands must be kept covered & protected with adhesive/band aids & gloves worn on this.
8. Do not pipette any fluid by mouth
9. No eating, drinking, smoking or application of cosmetics in the laboratory.
10. Do not store any food items in refrigerators meant for reagents.
11. The working table, equipments etc must be cleaned with disinfectant before & after each working day.
12. Pre employment check for HbsAg and chest X ray is a mandatory safeguard.
13. All staff to be immunized against HEPATITIS B and records to be maintained
14. All needle injuries to be reported to Blood bank officer .

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PROTOCOL TO BE FOLLOWED WITH NEEDLE STICK INJURY

1. Squeeze and let the blood come out as much as possible.
2. Wash thoroughly with soap, water and then with savlon.
3. Test your blood sample for HBsAg,HIV,HCV & VDRL tests immediately and once again after 3 months.
4. If the test is positive for HIV start ART immediately.
5. If the test is positive for HBsAg,HCV or VDRL consult a physician for further management.

DOCUMENTATION

Needle stick injury, and status of immunisation records are maintained.

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9.60. DECONTAMINATION OF EXPIRED BLOOD BAGS

1.Purpose

- A protocol has been formulated to describe the procedure for decontaminating/sterilizing blood/blood products.
- Expired and infected blood bags pose a threat of biohazard and acts as potentially source of infections if not handled appropriately and decontaminated before final disposal.

2.Scope

Saturated steam under pressure is more efficient way of sterilization as compared to dry heat because as it provides greater lethal action. It is quicker in heating up the exposed articles and it penetrates the porous material such as cotton wool, stoppers, paper, cloth wrapper etc.

3.Responsibility

Technician posted in blood bank section under the supervision of blood bank officer.

4.Procedure

- All the expired and infected blood bags will be decontaminated immediately using the decontamination autoclave on the day of expiry/day of screening test for TTD.
- Personnel responsible for decontamination will wear heavy duty rubber gloves, mask and a plastic disposal apron while loading and unloading the decontamination autoclave.
- Following decontamination the blood bags are cut open, the contents put in yellow biohazard cover tied labeled and disposed to the biomedical waste agency.
- The emptied plastic bags are then discarded into the blue biohazard cover tied and labeled before disposal.

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SOP for maintenance of the decontamination autoclave

- Autoclave will be calibrated after installation & there after once in every 6 months.
- Autoclave will be validated after full installation & once in a year thereafter
- Leak test will be performed everyday.
- Monthly biological indicator will be tested.
- Chemical indicators that is batch monitoring strip will be used with each load.
- In case of failure of chemical indicator, the load will be re-sterilized using an indicator strip from a new lot along with a biological indicator. If the biological indicator fails then the load will not be released for disposal, as it indicates failure of sterilization. The manufacturer or the AMC person will be contacted for further management in the earliest. If the instrument cannot be rectified then it will be replaced with a new one on an emergency basis.
- If the Biological indicator passes and the chemical indicator fails then the problem will be with the chemical indicator itself and will be tested with one from a new lot number. Still there is failure, the the company persons or the AMC people will be notified for further action.

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9.61. OPERATING & MAINTENANCE INSTRUCTIONS FOR AUTOCLAVE

1. **Principle:** Autoclave uses steam under pressure as the sterilizing agent. Steam under pressure is able to penetrate objects which have cooler surfaces as it is immediately condensed to water, producing a concomitant 1,870 fold decrease in steam volume. This creates a negative pressure at the point of condensation and draws more steam to the area. Condensation continues so long as the temperature equilibrates, a saturated steam environment is found. Moist heat kills the microorganism by causing coagulation of essential proteins.
2. **Procedure to operate the instrument:**
 - a. Check the functioning of safety valves thoroughly when the autoclave is used for the first time. Ensure that none of the parts are broken or damaged in transit.
 - b. Unscrew locking nuts and lift the lid.
 - c. Fill water upto the water level mark.
 - d. Stick chemical indicator tape to the loads to be decontaminated.
 - e. Load the bag bags to be decontaminated or sterilized.
 - f. Place the lid on the container and tighten the lid by opposite locking nuts.
 - g. Now close the Air Exhaust Valve and vacuum release knob. Switch on the autoclave.
 - h. As soon as the gauge shown 2lbs pressure, allow the enclosed air to escape by opening the Air Exhaust valve
 - i. Close the Air Exhaust valve as soon as the pressure gauge shows Zero pressure continue heating till pressure gauge reaches 15 lbs, pressure (1.05 kgf persq.cm).
 - j. The main safety valves will now automatically come into operation and keep on blowing excess steam maintaining pressure of 15 lbs.
 - k. Duration of time for decontamination of expired and infected blood bag is set to 30 minutes at 121⁰ C,15psi
 - l. Close the steam release valve after the steam has ceased to come out freely and lift the autoclave, with all closed valves, allow it to cool down for 5 to 10 minutes, thus creating a vacuum

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inside which will extract residual steam in the contents. After the autoclave is cool enough, open the Air Exhaust Valve to destroy vacuum.

m.Unlock the locking nuts and open the lid. Remove sterilized contents. Change water once a day.

n. Check the autoclave tape for colour change.Stick the tape in the register.

o.Validation with use of biological indicator(*Bacillus sterothermophilus*) is done once a month.

Cautions:

- Exhaust to be switched on whenever autoclaving is done.
- Mask & gloves to be worn while operating autoclave.
- Alkaline solution should not be used in this apparatus.
- Make sure that the release of steam is completed and then open.
- Donot open the lid till the pressure falls to zero.
- Do not switch on the autoclave without checking the water level.
- Clean inside of autoclave with cloth or wash with water after each day work

9.62. REVIEW OF RECORDS & RECORD MAINTENANCE

1.Scope & Application

Each blood bank should develop a practical record keeping system, which serves its needs.Review of records is very essential part of blood banking as documentation of every procedure is important.

2.Responsibility

It is the duty of all blood bank technicians to update all records everyday countersigned by Blood Bank Officer.

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3.Importance of Records

- The record system should make it possible to trace a unit of blood/blood component from source to final destinations.
- The system should ensure confidentiality of donor and patient records.
- Records should be legible and corrections should be initialed.
- Record the date of performance of procedures, tests and interpretation.

4.Records Maintained

The records that are maintained in our blood bank are:-

1.Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical officer In-charge.

2.Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml.ABO/Rh group, testing of HIV I and HIV II antibodies, Malaria, VDRL, Hepatitis B surface antigen and Hepatitis C virus antibody and irregular antibodies(if any), name and address of the donor with particulars, utilization issue number, components prepared or discarded and signature of the Medical Officer Incharge.

3. Issue Register : It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, unit/institution, details of cross matching report, indication of transfusion.

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4. **Records of components supplied:** quantity supplied, compatibility report, details of recipient and signature of issuing person.

5. Records of A.C.D/C.P.D/CPD-A/SAGM bags giving details of manufacturer , batch number, date of supply, and results of testing.

6. Register for anti-seras, diagnostic kits and reagents used : name of the kits/reagents, details of batch number, date of expiry and date of use.

7. Records of purchase, use and stock in hand of disposal needles, syringes, blood bags, shall be maintained.

8. Transfusion adverse reaction records.

Other records which blood bank should maintain are as follows:

1. **Donor adverse reaction register** :-This should have donor details, bag number, nature of adverse reaction, measures taken by the medical officer.
2. **Register of blood/blood components brought from other hospitals**
3. Discarding register
4. Grouping register(both donor & patient)
5. Donor Questionnaire form/consent form.
6. Blood request form.
7. Daily Blood stock register
8. Records of Blood Bag procured
9. Cross Matching register
10. Screening register

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11. Voluntary blood donor register
12. Emergency drug register
13. Proficiency record of blood bank staff

Note :- The above said records are maintained in blood bank for 5 years. Review of records is done once a year. The records are sent to MRD section of our hospital where the records are disposed off by shredding after the retention period.

9.63. BLOOD REQUISITION

- Blood request form accompanied by patient's pre transfusion samples (clotted/EDTA blood) should be sent to the blood bank.
- The Blood request form should be filled completely & legibly as it is one of the requirements for Pre – Transfusion compatibility testing which helps the Blood Bank in the right choice of Blood group & Blood Components.
- All the request form for Cross matching must be written & signed by the treating doctor / his representative (PG's / Intern's)
- **The request form should contain the following information**
 - a) Patient's full name, IP No. & Ward.
 - b) Patient's age & gender.
 - c) Details of request eg. Type of product & number of units.
 - d) Clinical Diagnosis.
 - e) Date & time of requirement of Blood / Blood products.
 - f) Mention the threshold levels indicating the need for transfusion like Hb% (for RBC transfusion), Platelet count (for Platelet transfusion) or prothrombin time for FFP transfusion
 - g) Details of previous transfusion, transfusion reaction & pregnancy.

Quantity & type of Blood sample

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Every Blood requests must be accompanied by a sample of 3-5cc of clotted Blood & 2cc of EDTA Blood.

NOTE: The cross matched blood/ blood components will be reserved for particular patients for 48 hours only. Afterwards no claim can be made if the blood bank staff is not informed early. After 48 hours of reservation cancellation is done and taken for blood inventory for the usage of other patients.

9.64.Patient Identification & Collection of Blood sample

1. The correct patient's Blood sample should be taken in a clean & appropriate test tube & the blood sample must be correctly labelled at the bedside of the patient after drawing the sample.
2. If the patient is conscious at the time of collection of the sample, ask him/her to identify themselves by the given name or any other appropriate information.
3. If the patient is unconscious, ask a relative or a second member to verify the patient's identity.
4. Label the sample tube clearly & accurately with the following information at the time of collecting the Blood sample:-
 - Patient's Name, Age & Gender.
 - Patient's IP No. & Ward
 - Date & Time of collection of sample
 - Name & signature of the person collecting the Blood sample
 - **Do not label the sample tube before collecting the sample because of the risk of putting the patient's Blood sample into the wrong tube.**
5. Check if the **details on the Blood sample tube match those on the Blood request form / patient's file** & are uniquely identifiable with the patient.

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- When the details of the patient on the sample container & the Blood request form or the patient's file **do not match** or if there is any **discrepancy** which raise doubts about patient's identity, the sample will be discarded & not returned to the ward. A new sample & a fresh request form should be sent for cross matching.
6. In case of a need for further Blood transfusion , fresh Blood sample with the request form to be sent if the earlier transfusion was given more than 48 hours earlier. The previous record of ABO & Rh type of patient shall not be used for cross matching. A new cross matching report will be generated with the signature of the technician & will be entered in the cross matching register.

9.65. SURGERIES

- For elective surgery requisition along with the sample to be sent the previous day, before 12 noon so that cross match procedure is done before surgery & the Blood/Blood Components is made available at the time of requirement.
- Cross matched Blood is reserved for 48 hours only unless informed early.
- Request for Blood for elective procedures / surgeries must be sent at least 48 hours in advance so that Cross matching procedure is done before surgery so that blood is made available as and when required.
- Duly filled blood request form along with a pre – transfusion sample of clotted & EDTA Blood as described under (Patients identification & collection of Blood sample) should be sent.
- For elective surgeries autologous Blood may be recommended if the patient meets the criteria.

9.66. Discrepancy

One technician performs the red cell testing & the other serum testing. The results are checked by technical supervisor. Problems arise when there is a

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discrepancy between the results of forward & reverse grouping. The concerned people & the treating doctor should be informed.

- On detecting a discrepancy in ABO cells & serum grouping repeat the test using the **fresh sample** to rule out discrepancy due to contamination or unidentified samples. If discrepancy persists the sample should be handed over to the advanced red cell serology lab for further workup.
- Perform DCT
- Re – test cells with freshly opened Anti – A, Anti – B, Anti – AB, Anti – A1 & Anti – H antisera.
- Test the serum against A, A2, B & O Cells. Autologous cells should be used as controls for detection of auto agglutination.
- Test at room temperature , 4⁰ C, for 35 – 40 minutes & interpret the result. Weak & negative results to be examined microscopically.

9.67. License

The license for operating Blood Bank is granted by the state license & Central license approving authorities. The license will be valid for a period of 5 years from the date of inspection.. The copy of license is made available in the Blood Bank & is renewed periodically.

9.68. Ordering of Blood

1. Confirm the availability of the blood and components (of that particular group) in the Blood bank.
2. Blood sample of the patient is to be sent for blood grouping to the Blood Bank.
3. Ordering the blood/components as required by the patient, through a completely filled Blood – Requisition form.

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4. The Blood Requisition Form preferably filled by the treating Doctor/Intern/requesting PG should provide the following information.

- Name, age and sex of the patient
- I.P. number (is a must)
- Clinical diagnosis
- Indication for blood transfusion
- The type and number of blood components required.
- Name and signature of the requesting Doctor/Intern is a must.

5. The duly filled Blood Requisition form and the blood sample of the patient collected by the staff nurse should be sent to the Blood Bank by the ward attender.

6. The patient's sample is received by the Blood Bank staff & the time, date and signature of the receiver is filled in the Requisition form.

7. The sample is subjected to a 2nd counter check by the technician who proceeds with the sample.

8. Grouping and cross matching is done by spin saline method. The results are confirmed both by macroscopy and microscopy.

9. Once the blood is compatible, it is informed to the concerned ward to collect the blood.

10. The time frame for providing blood to the patient in emergency is 15 Minutes.

9.69. OBTAINING INFORMED CONSENT FORM FOR DONATION & TRANSFUSION

- All donors will receive Pre donation counseling & will be asked to fill up Blood donor questionnaire & informed consent is taken for donating Blood voluntarily & for testing Hepatitis B, Hepatitis C, Malarial Parsite, HIV & other venereal disease which is required to ensure Blood safety. Thus, the

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consent of the donor is taken along with donors signature or thumb impression.

- Informed consent of patient in writing along with donor's signature or thumb impression for **transfusion** needs to be taken by the treating consultant.
- The clinician treating the patient has the responsibility to explain the benefits & risk of transfusion to the patients & relatives & record in the patients file.
- In case the patient is unable to give consent, a responsible family member must be asked to do so.

9.70. ADMINISTRATION OF BLOOD

1. Complete venipuncture before obtaining blood from the blood bank and have an IV line in place.
2. Once the unit is issued, will not be taken back by the blood bank staff.
3. Blood should not be stored in the unmonitored refrigerators available in the ward.
4. Blood should be taken only just before transfusion.
5. For issue of Fresh Frozen Plasma, the time of transfusion must be confirmed & blood bank must be informed 30-45 minutes earlier. Fresh Frozen Plasma is thawed at 37°C for 30 minutes and then issued for transfusion of Fresh Frozen Plasma.
6. The final identity check at the patient's bed side is the last opportunity to detect any identification error. Check the patient's name, ID Number, blood group, blood unit number, date of collection, date of expiry to prevent a potentially incompatible transfusion which may be fatal.

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7. Discoloration or signs of any leakage may be the only warning that the blood has been contaminated by bacteria (change of color in the red cells like purple /blue) and also look for hemolysis and for any clot. If the pack appears abnormal in any way, unit must not be transfused and the blood bank must be informed immediately.
8. Anti-cubital veins are the preferred veins for transfusion.
9. Use 18-19 gauge needle for PRBC transfusion and smaller needles 22-23 gauge maybe used for transfusion FFP, platelets and cryoprecipitate.
10. **Do not warm blood but transfuse blood at the same temperature at which they are issued from the blood bank.**
11. Whole blood / RBCs should be infused within 30 minutes of removal from refrigerator.

Time limits for Infusion

There is a risk of a bacterial proliferation or loss of function in blood products once they have been removed from the correct storage conditions.

- Transfuse slowly at the rate of 1-2ml for first 10-15mins, so as to detect major incompatibilities if any.
- Increase the rate after 15mins so as to complete transfusion of the unit within 2 ½ - 3 hours
- Maximum permissible time is 4 hours or less when the ambient temperature is high.

NOTE:- If a unit is not completed within 4 hours, discontinue its use and dispose the remainder through clinical waste system

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TIME LIMITS FOR TRANSFUSION GUIDELINES.

COMPONENTS TRANSFUSION	INFUSION	COMPLETE
Packed Red Blood Cells/ Whole Blood – PRBC/WB	Start infusion Immediately	within 2 ½ - 3hours (maximum 4 hours or even less in high ambient temperature)
Fresh Frozen Plasma – FFP	Immediately	30-60minutes
Random Donor Platelets - RDP (Do not put in Refrigerator)	Immediately	15-30 minutes
Cryoprecipitate	Immediately	5 – 10 minutes

- If the patient appears to be experiencing an adverse reaction,
- STOP TRANSFUSION
- INFORM the treating doctor
- INFORM Blood Bank
- Do not discard the blood pack and infusion set but return to the blood bank immediately.
- Fill the transfusion reaction form with details and send it to the blood bank.
- After the patient is stabilized send post transfusion blood sample collected from the opposite arm, post transfusion sample of urine and duly filled transfusion reaction form for further investigations and complete work up.

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10. TRANSFUSION REACTION

Scope & Application

This Standard Operating Procedure (SOP) provides the protocol to be followed to identify the cause of an adverse transfusion reaction & prevent its re occurrence.

Responsibility

It is the responsibility of the technician in the Red Cell Serology Laboratory to accept the blood/component in case of transfusion reaction which is returned from the ward/OT. It is the duty of the same technician to ensure that there is documented evidence of the nature of reaction either on the transfusion request form or on a separate letter addressed to blood bank, along with the post-transfusion blood sample (both EDTA & clotted) & urine specimen, if necessary. The direct anti globulin test (DAT) should be performed on the post-transfusion EDTA sample immediately. The unit & samples should be preserved properly & handed over to the advanced red cell serology technician who is responsible for detail investigation.

Principle:

Red cell Serological tests are based on the principle of agglutination and help to identify haemolytic transfusion reactions caused either by ABO incompatible transfusion or irregular red cell antibodies in patient's blood. Serum bilirubin total and indirect are raised in case of haemolysis.

The sulfosalicylic acid test helps to differentiate between haemoglobin and non-protein pigment, probably porphyrin in the urine. The ammonium sulphate precipitation test is based on the fact that haemoglobin and myoglobin are precipitated in urine at different degrees of ammonium sulphate saturation.

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11. Investigation & analysis of transfusion reaction

- The time between the suspicion of a transfusion reaction and the investigation and the initiation of appropriate treatment should be as short as possible.
- It is the responsibility of the technician in the Red Cell Serology Laboratory to accept the blood/component incase of transfusion reaction which is returned from the ward/OT.
- It is the duty of the same technician to ensure that there is documented evidence of the nature of reaction either on the transfusion request form or on a separate letter addressed to blood bank, along with the post-transfusion blood sample (both EDTA & clotted) & urine specimen, if necessary.
- The unit & samples should be preserved properly & handed over to the advanced red cell serology technician who is responsible for detail investigation.
- Stop the procedure in case any reaction occurs to the patient at the time of transfusion.
- Send the Bag to the Blood bank for further investigation with a new blood sample and a urine sample of the patient.
- Occurrence of the transfusion reaction for bags will be checked for contamination
- The direct antiglobulin test (DAT) should be performed on the post-transfusion EDTA sample before refrigeration immediately on receipt .If test is positive perform DAT on the pre – transfusion sample to verify whether sensitization is due to transfusion or it pre – existed.

11.1 Investigation for transfusion reaction

- Obtain the patient's post transfusion sample, blood unit and attached transfusion set.
- Label the donor and patient's pre transfusion pilot samples as A.
- Label the patient's post transfusion sample as B.
- Collect the blood sample from the blood bag and label it as C.

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11.2. Test on post transfusion urine sample

Red colour indicates haematuria or haemoglobinuria.

Examine the post transfusion urine sample & Blood Sample.

- Centrifuge the post transfusion blood specimen and inspect the serum or plasma for evidence of hemolysis comparing it with normal sample. Plasma is pink if haemoglobin is present, & icteric if bilirubin is present.
- Examine the post transfusion urine sample of the patient for evidence of RBC's and urine Hb, if urine is pink or red.

11.3. Check the label - Check if there has been any error in identifying the patient or the blood unit by counter checking the label on the blood container and all records.

11.4. Repeat Blood Grouping - Do the blood grouping for all A,B and C tubes by tube method. In case of packed cell unit do only cell grouping. In case of FFP, do only serum grouping.

11.5. Repeat Cross matching - Re-crossmatch the pre and post transfusion sample of the patient by saline, albumin and coombs and record the result.

11.6. DCT & ICT - Perform DCT and ICT of the pre and post transfusion sample of the patient.

11.7. Microbiology –

1. Send the donor unit for smear & culture (at 37°C, room temperature & 4°C to microbiology department).
2. Make proper entries in the microbiology dispatch book & request form & send along with the unit
3. Grams stain of the content of the blood bag to be done, to detect whether the reaction may be due to bacterial contamination.

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4. Collect the report from the microbiology department.

5. If donor unit reveals bacteremia, then request the attending doctor to get the patient's blood culture done & report the findings to the blood bank officer.

11.8. Bio-chemical tests:

- Note colour of plasma. Plasma is pink, if haemoglobin is present and icteric if bilirubin is present.
- Separate the patient's pre and post transfusion serum and to biochemistry department in a container/bottle bearing the date, patient and test identification for estimation of serum bilirubin total, direct and indirect and estimation of plasma haemoglobin.
- Send the biochemistry request form with proper entries along with the sample.

Collect the report from biochemistry lab.

- Enter all the test report in the Transfusion reaction report form.
- Inform the concerned doctor in case of any abnormality.

Interpretation

1. Any red cell incompatibility found during the investigation explains a haemolytic transfusion reaction.

2. The DAT will be positive & a mixed field reaction will be seen if in vivo sensitization of transfused red cells has occurred.

3. DAT may be negative even in cases of haemolytic transfusion reaction if the red cell destruction is severe.

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4. If any antibody is detected in patient's serum, the donor cells should be positive for the corresponding antigen.

5. Serum bilirubin total & indirect is raised in case of hemolysis.

Haemoglobinemia & haemoglobinuria are highly suggestive of red cell destruction but are not necessarily caused by antigen antibody reaction unless confirmed.

Limitations

The non serological possibilities of haemoglobinemia and haemoglobinuria are -

1. Hemolysis of blood before transfusion.
2. Poor technique of collecting post transfusion sample.
3. Myoglobinuria following major surgery.
4. Infusion of distilled water during prostatectomy.
5. Hemolysis due to artificial valve.
6. Patient's clinical condition; autoimmune haemolytic anemia or paroxysmal nocturnal hemoglobinuria.
7. Use of glucose or dextrose through the same line before starting blood.
8. Addition of certain drugs to blood such as ethacrynic acid, hydrocortisone or diphenyl hydantion.

11.9. Analysis of transfusion reaction

- File all the transfusion reaction form after the investigation is over.
- Analyze the reason for the reaction.
- Identify corrective and preventive actions based on the root cause analysis.
- Implement the same and document it and file the same

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DOCUMENTATION

The details of the patient and post transfusion investigations done should be entered in the separate register and reports should be filed.

12. Guidelines for the recognition & management of acute transfusion reactions

Category 1 : Mild Reactions

Signs	Symptoms	Possible cause
- Localised Cutaneous reactions -urticaria -Rash	Pruritus	Hypersensitivity (mild)

Category 2: Moderate Severe Reactions

Signs	Symptoms	Possible cause
Flushing	Anxiety	Hypersensitivity (moderate-severe)
Urticaria	Pruritus	
Rigors	Palpatations	Febrile non Haemolytic transfusion reactions
Fever	Mild dyspnea	-Antibodies to

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White blood cells,
Platelets
-Antibodies to
proteins,including IgA

- Restlessness Headache

- Tachycardia Possible
Contamination with
pyrogens &/or
bacteria

Category 1 : Mild reactions

Immediate management

- Slow the transfusion
- Administer antihistamine IM (e.g Chlorpheniramine 0.1mg/kg or equivalent).
- If no clinical improvement within 30 minutes or if signs & symptoms worsen **treat as category 2.**

Category 2 : Moderately Severe reactions

Immediate management

- Stop the transfusion. Replace the infusion set & keep line open with normal saline.
- Notify the doctor responsible for the patient & the blood bank immediately.
- Send Blood unit with infusion set, freshly collected urine & new blood samples (1 clotted & 1 anticoagulated) from vein opposition infusion
- Site with appropriate request form to blood bank for laboratory investigations.

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- Administer antihistamine IM (e.g. Chlorpheniramine 0.1mg/kg or equivalent) & oral or rectal antipyretic (e.g paracetamol 10mg/kg : 500mg -1g in adults). Avoid aspirin in thrombocytopenic patients.
- Give IV corticosteroids & bronchodilators if there are anaphylactoid features (e.g bronocospasm, stridor).
- Collect urine for next 24 hours for evidence of haemolysis & send to laboratory.
- If clinical improvement, restart transfusion slowly with new blood unit & observe carefully.
- If no clinical improvement within 15 minutes or if signs & symptoms worsen, **treat as category 3.**

Category 3 : Life Threatening reactions.

Signs	Syptoms	Possible cause
▪ Rigors	Anxiety	Acute intravascular Haemolysis
▪ Fever	Chest pain	
▪ Restlessness	Pain near infusion site	
▪ Hypotension (fall Of 20% in systolic BP)	Respiratory distress/ Shortness of breath	Fluid overload
▪ Tachycardia (rise Of 20% in systolic BP)	Loin/back pain	Anapylaxis
▪ Haemoglobinuria (red Urine)	Headache	Transfusion associated acute Lung injury (TRALI)
▪ Unexpalined Bleeding (DIC)		

Note

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1. If an acute transfusion reactions occur, first check the blood pack labels & the patient's identity. If there is any discrepancy, stop the transfusion immediately & consult the blood bank.
2. In an unconscious or anesthetized patient, hypotension & uncontrolled bleeding may be the only signs of an incompatible transfusion.
3. In a conscious patient undergoing a severe haemolytic transfusion reaction, signs & symptoms may appear very quickly-within minutes of infusing only 5-10ml of blood. Close observation at the start of the infusion of each unit is essential.

Category 3 : Life threatening reactions

Immediate management

1. Stop the transfusion. Replace the infusion set & keep IV line open with normal saline.
2. Infusion normal saline (initially 20-30ml/kg) to maintain systolic BP. If Hypotensive, give over 5 minutes & elevate patient's legs.
3. Maintain airway & give high flow oxygen by mask.
4. Give adrenaline (as 1:1000 solution) 0.01-mg/kg body weight by slow intramuscular injection.
5. Give IV corticosteroids & bronchodilators if there are anaphylactoid features (e.g broncospasm, stridor)
6. Give diuretic : e.g frusemide 1mg/kg IV or equivalent.
7. Notify the doctor responsible for patient & blood bank immediately.
8. Send blood unit with infusion set, fresh urine sample & new blood samples (1 clotted & 1 anticoagulated) from vein opposite infusion site with appropriate request form to blood bank for investigations.
9. Check a fresh urine specimen visually for signs of haemoglobinuria.
10. Start a 24 hours urine collection & fluid balance chart & record all intake & output. Maintain fluid balance.

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11. Assess for bleeding from puncture sites or wounds. If there is clinical or laboratory evidence of DIC , gives platelets (adult 5-6 units) & either cryoprecipitate (adult 12 units) or fresh frozen plasma (adult 3 units).

12. Reassess. If hypotensive :

- Give further saline 20-30ml/kg over 5 minutes
- Give inotrope, if available.

13. If urine output falling or laboratory evidence of acute renal failure (rising K⁺, urea, creatinine):

- Maintain fluid balance accurately
- Give further frusemide
- Consider dopamine infusion, if available.
- Seek expert help : the patient may need renal dialysis.

14. If bacteraemia is suspected (rigors, fever, collapse, no evidence of the Haemolytic reaction), start broad-spectrum antibiotics IV.

Type of drug	Effects	Example		Notes
Intravenous Replacement fluid	Expands blood volume	Normal saline	If patient hypotensive 20-30ml/kg over 5 minutes	Avoid colloid solutions
Antipyretic	Reduces fever & inflammatory response	Paracetamol	Oral or rectal 10mg/kg	Avoid aspirin-containing products if low platelet count
Antihistamine	Inhibits histamine mediated	Chlorphen-amine	IM or IV 0.1 mg/kg	

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	response			
Bronchodilator	Inhibits immune adrenaline mediated bronchospasm	Adrebackube Consider salbutamol Aminophylline	0.01mg/kg (as 1:1000 solution slow IM injection By nebulizer 5mg/kg	Dose may be repeated every 10 minutes according to BP & pulse until improvement.
Intrope	Increase myocardial contractility	Dobutamine	IV infusion 1µg/kg /minute IV infusion 1- 10µg/kg/minute	Low dose induce vaso-dilation & improve renal perfusion Dose above 5µg/kg/minute cause vaso- constriction & worsen heart failure
Diuretic	Inhibits fluid reabsorption from ascending loop of Henle	Furosemide	Slow IV injection 1mg/kg	

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13.0. Purchase of reagents & consumables

- **Reagents such as Antisera**

Anti – A, Anti – B, Anti – D, Anti – H (Lectins), Anti A1 (Lectins), Anti human globulins (AHG)

- HIV, HBsAg, HCV - **ELISA kits**
- Glasswares, Gloves, Pipettes, Blood bags & other consumables

The above reagents, kits & consumables are purchased by the purchase department & the stock is maintained in the stores.

An indent is placed & the reagents, kits & consumables are procured from the hospital stores & adequate stock is maintained in the Blood bank stores for the smooth functioning of the blood bank.

14.1. Universal Precautions

- Any wound and skin abrasion on hands should be dressed with adhesives /band aids and gloves worn on this.
- Wash hands before eating , drinking .
- Wash hands before leaving from blood bank , after using toilets .
- Wash hands if accidentally hands come in contact with blood when gloves not worn.
- If apron gets soiled with blood serum change to clean one .The soiled one should be autoclaved before laundered.
- Do not pipette any fluid by mouth.
- All needle injuries to be reported to Blood bank officer .
- Do not store any food items in refrigerators meant for reagents.
- Pre employment check for HbsAg and chest X ray is a mandatory safeguard.
- All staff to be immunized against HEPATITIS B and records to be maintained

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15.0. DATA INFORMATION

15.1 All the quality indicators are mentioned at appropriate interval as defined in the policy.

15.2 The report shall be submitted to the quality department or NABH co – ordinator.

15.3 Improvements on the quality care indicator shall be discussed in the quality assurance Committee.

15.4 Appropriate corrective & preventive actions shall be taken & the documentation done of the same

16.0. TRAINING OF STAFF:

- Hospital Pharmacy and Therapeutic Committee in coordination with HR department is responsible for training the staff on the policies of blood transfusion.
- All staff in blood bank shall be trained in Blood transfusion medicine periodically.

Mode Of Training:

This policy document is available with Blood Bank, all the nursing stations, critical care units, operation theaters, nursing superintendent for the staff to be aware of. Additionally, the Blood Bank staff - Blood Bank Technical Supervisor & Technicians, Nursing staff & Blood Bank officer are trained through sessions periodically by attending following Programs –

- **CMEs & seminars conducted by ISBTI, ISTM & in house staff.**
- **EQUAS training program**
- **Workshops & training program conducted by KSAPS, NACO.**

17.0. INDUCTION TRAINING

The newly recruited technician first reports to the Medical Superintendent & then he/she is asked to the Blood Bank Officer. They are given orientation regarding the different sections of the blood bank & the working pattern of the blood bank for the first week. For the first three months the technician is posted for general shift 9AM-4PM. After reviewing his/her performance, he/she is

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posted for second shift (2PM – 8PM) & night shift (8PM – 9AM). All new employees will compulsorily require to undergo induction training. Communication of the hospital's mission/values shall be carried out to all employees during their induction period.

PROBATION

All employees are appointed on a probation of 6-12 months, during which period their performance will be reviewed. In case the employees performance does not meet the desirable level, his/her probation may be extended for a period of 6months/12months.

REFERENCES

1. AABB – 15th EDITION
2. COMPENDIUM OF TRANSFUSION MEDICINE –DR.R.N.MAKROO
3. MODERN BLOOD BANKING & TRANSFUSION PRACTICES –
DENISE.M.HARMENING
4. THE GAZETTE OF INDIA
5. BLOOD TRANSFUSION TECHNIQUES & PROCEDURES – MANIPAL ACADEMY
OF HIGHER EDUCATION
6. TEXT BOOK OF MEDICAL LABORATORY TECHNOLOGY – RAMNIK SOOD
7. DAILEYS NOTES ON BLOOD – JOHN.F.DAILEY
8. ESSENTIALS OF BLOOD BANKING – S.R.MEHDI

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10. NACO GUIDELINES

11. CLINICAL DIAGNOSIS & MANAGEMENT BY LABORATORY METHODS – JOHN BERNARD HENRY

MILESTONES

Sl.No	Achieved	Year
1.	Establishment of Central Research Lab	2012-2013.
2.	High end equipments like IHC/ISH slide staining instrument, Cobas e 411 (Roche-Hitachi;USA) Autoanalyzer, and HPLC were installed	2013
3.	Helena Electrophoresis Unit with power pack for Hemoglobin electrophoresis was installed in the year	2013
4.	Genomics division was established with PCR, RT PCR, Gel Doc and Nanodrop Spectrophotometer equipments	2013-2014
5.	Two Scientific Papers were Published in 2013 first time from Central Research Lab	2013
6.	Recognition of Scientific and Industrial Research Organisations (SIROs) was obtained from DSIR, Govt. of India	2014
7.	First Extramural Project was awarded by VGST Karnataka Govt. to Dr. S Prabhakara	2014
8.	Dr. S. Prabhakara may be the first person to do PRRT2gene sequencing in Indian Lab (Ann Indian Acad of Neurol).	2014
9.	Animal Cell culture lab was established with Trinocular Inverted Tissue culture Microscope with camera, CO ₂ Incubator and Laminar Air Flow	2014-2015
10.	Dr. S. Prabhakara Senior Research Scientist from Central Research Lab received ‘‘Young Scientist’’ award from VGST, Karnataka Govt. in the year	2014-2015
11.	Seven Extramural Projects were awarded by Rajiv Gandhi University of Health Sciences in Bangalore	2016-2017
12.	Dr. Anbazhagan Kolandaswamy of Central Research Lab in collaboration with Department of OBG, Orthopedics and Biochemistry has got external funding of 57.87 lakhs from ICMR Govt. India	2018
13.	Lifetime achievement award to Dr. Sahajanand for his services, teaching and research by ISA. (Indian Society of Anesthesiologist, Bangalore)	2017

ACHIEVEMENTS AND AWARDS

- Dr. H. Sahajanand received Lifetime achievement award for his services, teaching and research by ISA. (Indian Society of Anesthesiologist, Bangalore)
- Dr. H. Sahajanand received Vijay rattan gold medal award and certificate of excellence for outstanding achievements and remarkable role in the field of Medicine.
- Dr. H. Sahajanand received Award for medical Excellence by ISC council New Delhi in Aug 2017
- Dr. H. Sahajanand received Teacher day award July 2017 for EXEMPLARY services from RajaRajeswari Medical College & Hospital.
- Dr. S. Prabhakara received “Young Scientist” award with seed money of 4 lakhs from VGST, Karnataka Govt. for the project entitled “Genetic investigations in patients suffering from paroxysmal dyskinesias and Benign familial infantile epilepsy” from Karnataka Govt. for the year 2014-2015.
- Dr. Basavaraj Bandare received “Credible Milestone” Certificate of Honor his distinguished services in service humanity in the field of research.

FACILITIES IN CENTRAL RESEARCH LAB (CRL)

- ❖ The CRL has dedicated and well qualified faculty, infrastructure and state of art research facilities for carrying out advanced research.
- ❖ PRRT2 gene sequencing for patients with Benign Familial Infantile Epilepsy and Paroxysmal dyskinesias (PDs).
- ❖ Reporting microRNAs expression in Post-Menopausal Osteoporosis Women.
- ❖ Screening for early prediction and diagnosis of Pre-eclampsia in Indian women by Congo red dot test.
- ❖ Conducting and reporting PFT, EEG and ENMG test for diagnostic and research purpose.
- ❖ IHC, ISH, and FITC tests and to know status of estrogen receptor (ER), progesterone receptor (PR) in Breast cancer patients.
- ❖ HPLC (High-performance liquid chromatography) and Digital microbalance for conducting drug concentration and toxicology studies
- ❖ Central research laboratory provides facilities to study Mycobacterium tuberculosis bacterium (Tuberculosis causing pathogen) and Plasmodium vivax (Malaria causing pathogen) by using fluorescent microscopy.
- ❖ Hands on Training for the Graduates, Postgraduates and Staff on advanced Instruments like PCR, RT PCR, Agarose Gel electrophoresis, High Performance Liquid Chromatography; HPLC, Nanodrop Spectrophotometer, Fluorescent Microscope, Cobase e 411 Autoanalyzer, Fully Automated IHC/ISH Slide Staining Instrument, EEG and ENMG instruments.
- ❖ To Guide and support the faculty in completing their External Funding Research Projects like ICMR Govt. of India, RGUHS and VGST Govt. of Karnataka.
- ❖ To Mentor and support the Postgraduates in completing their Research Projects and Thesis.
- ❖ To Guide and support the Undergraduates, to complete their STS ICMR Projects and Research projects.
- ❖ Supporting for completion of Collaborative Research Projects.



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This laboratory safety manual is compiled to be used as a binding document for all personnel working in laboratories to ensure safe work conduct and practices on the NCBS/inStem/CCAMP campus.

Procedures and Rules within this Manual are formulated for three reasons:

- 1.) To avoid health risks and accidents for our personnel.
- 2.) To be in a position to act appropriately in case of emergencies.
- 3.) To minimize the environmental burden and risks caused by our work.

This manual cannot cover all circumstances where safety procedures must be applied; it is intended to set up a framework of how NCBS/inStem/CCAMP personnel/students should work in scientific laboratories. The avoidance of safety risks for the personnel at the institutional level requires knowledge of possible hazards in our environment; chemicals, biological agents or radioactivity. In this regard students and personnel of NCBS/inStem/CCAMP are required to familiarize themselves with safe practices for applied laboratory operations.

This manual will be amended as various situations might arise and come to our attention.

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1.0 - GENERAL SAFETY

People who work in scientific laboratories are exposed to various hazards. Most workplaces have hazards that are well recognized (those of ordinary fire, for example) with well- defined actions to control the situation. Laboratories, however, involve a greater variety of possible hazards and some of these hazards need precautions not ordinarily encountered. An introduction to safe practices for a variety of widely used laboratory procedures is listed below.

1.1 - GENERAL SAFETY AND OPERATIONAL RULES

1. No running or jumping in a laboratory is permitted. Stored items or equipment shall not block access to the fire extinguisher(s), safety equipment, or other emergency items. Stairways, hallways, passageways/aisles and access to emergency equipment and/or exits must be kept dry and unobstructed; i.e., no storage, no equipment, phone or other wiring. No combustible material such as paper, wooden boxes, pallets, etc., shall be stored under stairwells or in hallways. Hallways shall be kept free of boxes and materials so that exits and normal paths of travel are not blocked.

2. Eating or drinking within laboratories is not permitted. In all laboratories specific office areas may be designated for food in coordination with the Safety Committee. They must be physically separated from any laboratory operations. In the specified office areas no consumables, reagents or any tools should be shared with work areas.

3. No food or beverage may be stored in the cold rooms/Laboratory refrigerators and freezers.

4. No employee shall work alone in a laboratory or chemical storage area outside the core working hours. Permission for students and staff to work outside of the core time has to be granted by the PI in charge in writing.

5. Animals, except those that are the subject of experimentation (approved by the Animal Experimentation Committee) are to be excluded from all laboratory areas.

6. Clothing worn in the laboratory should offer protection from splashes and spills, should be easily removable in case of an accident. Nonflammable, nonporous aprons offer the most satisfactory and the least expensive protection. Lab jackets or coats should have snap fasteners rather than buttons so that they can be readily removed. These coats are to be fastened closed while working and removed prior to exit from the laboratory. It is highly recommended that no

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sandals or open-toed shoes shall be worn by laboratory personnel in the laboratory. Laboratory clothing should be kept clean and replaced when necessary. In procedure performed in biosafety level 2 and chemical operations it is required that lab coats, gloves, closed shoes and safety glasses are worn.

7. Mouth pipetting is never allowed.

A. Electrical

The typical laboratory requires a large quantity of electrical power. This increases the likelihood of electrically-related problems and hazards. One must address both the electrical shock hazard to the facility occupants and the fire hazard potential. The following recommendations are basic to a sound electrical safety program in the laboratory.

1. All electrical equipment shall be properly grounded.
2. Sufficient room for work must be present in the area of breaker boxes. All the circuit breakers and the fuses shall be labeled to indicate whether they are in the "on" or "off" position, and what appliance or room area is served. Fuses must be properly rated.
3. Equipment, appliance and extension cords (junction boxes) must be in good condition and must be routinely dusted..
4. Extension cords shall not be used as a substitute for permanent wiring.
5. Electrical cords or other lines shall not be suspended unsupported across rooms or passageways. Do not route cords over metal objects such as emergency showers, overhead pipes or frames, metal racks, etc. Do not run cords through holes in walls, ceilings, doorways or windows. Do not place under carpet, rugs, or heavy objects. Do not place cords on pathways or other areas where repeated abuse can cause deterioration of insulation.
6. Multi-outlet plugs shall not be used unless they have a built-in circuit breaker. This causes overloading on electrical wiring, which will cause damage and possible overheating.

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7. Most of the portable multiple outlets are rated at 15 amps. Employees shall check when all connections are made to determine that the total input average will never exceed 15 amps. (The amperage on electrical equipment is usually stamped on the manufacturer's plate).

8. All building electrical repairs, splices, and wiring shall be performed by the

Electrical Department. B. Vacuum Operations

In an evacuated vacuum system, the higher pressure is on the outside, rather than the inside, so that a break causes an implosion rather than an explosion. The resulting hazards consist of flying glass, spattered chemicals, and possibly fire.

1. When working with a vacuum be aware of implosion hazards. Apply vacuum only to glassware specifically designed for this purpose, i.e., heavy wall filter flasks, desiccators, etc.

2. Never evacuate scratched, cracked, or etched glassware. Always check for stars or cracks before use.

3. Vacuum glassware which has been cooled to liquid nitrogen temperature or below should be annealed prior to reuse under vacuum.

4. Rotary evaporator condensers, receiving flasks, and traps should be taped or kept behind safety shields when under a vacuum.

5. When a vacuum is supplied by a compressor or vacuum pump to distill volatile solvents, a cold trap should be used to contain solvent vapors. Cold traps should be of sufficient size and low enough temperature to collect all condensable vapors present in a vacuum system. If such a trap is not used, the pump or compression exhaust must be vented to the outside using explosion proof methods.

6. After completion of an operation in which a cold trap has been used, the system should be vented. This venting is important because volatile substances that have been collected in the trap may vaporize when the coolant has evaporated and cause a pressure buildup that could blow the apparatus apart.

7. After vacuum distillations, the vessel must be cooled to room temperature before it is vented.

8. All desiccators under vacuum should be completely enclosed in a shield or wrapped with friction tape in a grid pattern that leaves the contents visible and at the same time guards against flying glass should the vessel collapse. Various plastic (e.g., polycarbonate) desiccators now on the market reduce the implosion hazard and may be preferable.

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C. Handling Glassware

1. Glass breakage is a common cause of injuries in laboratories. Only glass in good condition should be used.
2. Clean all glassware before sending for repair. Glassware that has been in contact with infectious agents shall be disinfected before disposal or repair.
3. Protect hands with leather gloves when inserting glass tubing. Hold elbows close to the body to limit movement when handling tubing.
4. Use glassware of the proper size. Allow at least 20% free space. Grasp a three-neck flask by the middle neck, not a side neck.
5. Conventional laboratory glassware must never be pressurized or used with vacuum.

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2.0 - Safe Handling of Chemicals

General Guidelines.

Working with potentially harmful chemicals is an everyday occurrence in a laboratory. Employees are requested to inform themselves about toxicological information and procedures for handling and storage of chemicals used. For most commercially available substances, detailed instructions are available in the Material Safety Data Sheet (MSDS). Facilities for collection and storage are provided within the NCBS/InStem/CCAMP campus. A hardcopy of MSDS for each lab is required.

A. Gathering General Information on Chemicals

The Material Safety Data Sheet (MSDS) describes properties, reactivities, potential chemical hazards, and safe handling procedures for commercially available chemicals you are working with. These sheets must be archived in a specified folder; all lab personnel must know where it is kept. This MSDS log must be updated at regular intervals. Information that is contained in the Material Safety Data Sheets is also required by law to be conveyed to employees on a chemical-by-chemical basis.

MSDSs are generally written for chemicals that are used in the industrial setting therefore some of the information provided on the MSDS may not be applicable to laboratory usage. The use of chemicals in a laboratory is generally in a more controlled environment than in the industrial setting and much smaller quantities of the chemical are being used at any one time. Nevertheless, a great deal of information on hazards associated with laboratory chemicals can be obtained by reading the MSDS.

Familiarize yourself with the pictograms and Hazard codes widely used to mark risks.

PICTOGRAMS AND HAZARD CODES



B Biohazard



C Corrosive



E Explosive



F Highly Flammable
F+ Extremely Flammable



Xn Harmful
Xi Irritant



N Dangerous for the environment



O Oxidizing



R Radioactive



T Toxic
T+ Very Toxic

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Figure source: <http://www.sigmaaldrich.com/sigma-aldrich/help/help-welcome/risk-and-safety-statements/risk-and-safety.html#pictograms>

Risk and Safety Phrases are widely used and should be known by any user when handling chemicals in the course of laboratory procedures. Further information upon chemical stability can be obtained from **Fluke Brand F Code**.

B. Handling and Transportation of Chemicals

Many laboratory accidents occur by carrying chemicals from one place to another or transferring them from one container to another. The chemicals used in a laboratory are often corrosive, toxic or flammable and any accident involving these has the potential for personal injury. Therefore, it is good practice to assume that **all** chemicals are potentially hazardous.

1. When large bottles of acids, solvents, or other liquids are transported within the laboratory without a cart, only one bottle should be carried at a time. The bottle should be carried with both hands, one on the neck of the bottle and the other underneath. Do not hook a finger through the glass ring on top of the bottle, allowing it to dangle while being transported. Never carry or attempt to pick up a bottle by the cap.
2. Large quantities of concentrated mineral acids, e.g., sulfuric, nitric and hydrochloric acids, shall be kept in specific storage rooms or cabinets for corrosive substances.

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C. Chemical Storage

Proper storage of chemicals is necessary to maximize employee safety with regard to chemical compatibility, spill control, fire/explosion control, to provide security, identification, and provide a "user friendly" system with respect to point-of-use.

1. All containers used for storage (even short term) shall be labeled.
2. Quantities greater than one litre of highly flammable liquids (Methanol, Chloroform) should be stored in specified metal cabinets. Quantities smaller than or equal to one litre of chemicals may be held at individual work stations but only one of the same kind. Chemicals should be stored as close as feasible to the point of use in order to maximize efficiency and minimize transport distance.
3. Out-of-date chemicals shall be disposed of on a periodic basis to reduce overall hazard potential and minimize inventory tracking and updating. Contact Laboratory Support Office.
4. Reduce large inventory of chemicals in the laboratory.
5. **Never** pipette by mouth. **Always** use a bulb to pipette.
- 6.. Chemical containers that have been emptied have to be cleaned off remaining residues by triple rinsing with water or other suitable solvent and air-dried before disposal. Contact Laboratory kitchen (labkitchen@ncbs.res.in) for disposal of empty containers.

2.1 CHEMICAL SPILLS

Any chemical is a possible threat to your personal health and your colleagues. In case of accident causing the release of hazardous chemicals a calm and determined action is required to prevent an escalation of the emergency situation.

Thus, for any individual incident, isolation of the spill and/or securing the area is best prior to or simultaneously with contacting concerned personnel. This should be done according to all available information on the chemical nature of the spill. Under all circumstances, a laboratory coat, safety glasses, and gloves should be used for self-protection.

A. Spill Kits may be obtained from Stores



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1. Always send for help first and report the necessary information.

a) Where did the incident happen?

b) how many people are injured?

c) What is the chemical?

d) Is there an intermediate risk of fire, explosion, intoxication or suffocation known?

1.If the spill presents an immediate danger, leave the spill site and warn others, control entry to the spill site, and report to reception.

2.Remove contaminated clothing. Flush skin/eyes with water at least 15 to 30 minutes; use soap for intermediate and final cleaning of skin areas.

3.Protect yourself, then remove injured person(s) to fresh air, if safe to do so.

4.Notify nearby persons and evacuate as necessary. Prevent entry, as necessary, by posting a guard in a safe area and/or shutting doors.

5.If flammable vapors are involved, do not operate electrical switches unless to turn off motorized equipment. Try to turn off or remove heat sources, where safe to do so. TURN OFF ELECTRIC AT THE MAINS, NOT AT SWITCHES INSIDE THE LABORATORY.

6.Do not touch the spill without protection, gloves etc..



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8. Where the spill does not present immediate personal danger, try to control the spread or volume of the spill. This could mean shutting a door, moving nearby equipment to prevent further contamination, repositioning an over-turned container or one that has a hole in the bottom or side, creating a dike by putting an absorbent around a spill or opening the sashes on the fume hoods to facilitate removal of vapors.

9. Never assume gases or vapors do not exist or are harmless because of lack of smell.

10. Increase ventilation by opening closed fume hood sashes to the 12 inch or full open position. Exterior doors may be opened to ventilate non-toxic vapors.

11. Use absorbents to collect substances. Reduce vapor concentrations by covering the surface of a liquid spill with absorbent. Control enlargement of the spill area by diking with absorbent.

B. Spilled Liquids

1. Confine or contain the spill to a small area. Do not let it spread.

2. For small quantities of inorganic acids or bases, use a neutralizing agent or an absorbent mixture (e.g., soda ash or diatomaceous earth). For small quantities of other materials, absorb the spill with a nonreactive material (such as vermiculite, clay, dry sand, or towels).

3. For larger amounts of inorganic acids and bases, flush with large amounts of water (provided, the water will not cause additional damage refer to MSDS for this information). Flooding is not recommended in storerooms where violent spattering may cause additional hazards or in areas where water-reactive chemicals may be present.

4. Mop up the spill, wringing out the mop in a sink or a pail equipped with rollers.

5. Carefully pick up and clean any cartons or bottles that have been splashed or immersed.

6. If needed, vacuum the area with a HEPA filtered vacuum cleaner designed and approved for the material involved.

7. If the spilled material is extremely volatile, let it evaporate and be exhausted by the laboratory hood (provided that the hood is authorized for use with the spilled Chemical).

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C. Spilled Solids

Generally, sweep spilled solids of low toxicity into a dust pan and place them into a container suitable for that chemical. Additional precautions such as the use of a vacuum cleaner equipped with a HEPA filter may be necessary when cleaning up spills of more highly toxic solids.

1. Dispose of residues according to safe disposal procedures. Remembering that personal protective equipment, brooms, dust pans, and other items may require special disposal procedures.
2. Report the chemical spill in writing as required above to laboratory support office.

2.2 Guidelines for Mercury Handling and Spill Clean Up

A. Health Effects

Mercury vapors are odorless, colorless, and tasteless. Mercury poisoning from exposure by chronic inhalation can cause emotional disturbances, unsteadiness, inflammation of the mouth and gums, general fatigue, memory loss, and headaches.

B. Storage and Handling

Because of the health effects of mercury, the extremely difficult and time-consuming procedures required to properly clean spills, every effort should be taken to prevent accidents involving mercury. Always store mercury in unbreakable containers and store in a well-ventilated area. When breakage of instruments or apparatus containing mercury is a possibility, the equipment should be placed in an enameled or plastic tray or pan that can be cleaned easily and is large enough to contain the mercury. Transfers of mercury from one container to another should be carried out in a hood, over a tray or pan to confine any spills. If at all possible, the use of mercury thermometers should be avoided. If a mercury thermometer is required, many are now available with a Teflon® coating that will prevent shattering. Always wash hands after handling mercury to prevent skin absorption or irritation.

Always wear nitrile gloves while handling mercury. If mercury has been spilled on the floor, the workers involved in cleanup and decontamination should wear plastic shoe covers. . Spill Kit for Mercury is available from the Laboratory Manager. Southern Labs has mercury spill kit located with the chemical spill kits near the fume hoods on the first floor.

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2.3 Guidelines for Ethidium Bromide (EtBr) Waste Management & Disposal

Ethidium bromide (*3,8 diamino-5-ethyl-6-phenyl phenanthridinium bromide, dromilac, CAS #1239-45-8*), is a compound used in many laboratories. Ethidium bromide is available as a dark red, crystalline, non-volatile solid and is moderately soluble in water. Since it fluoresces readily with a reddish-brown color when exposed to ultraviolet (UV) light and with increased brightness when bound to double stranded-DNA and single-stranded RNA, it is commonly used in gel electrophoresis applications for visualization of these molecules. For these applications, liquid ethidium bromide solutions are incorporated into the electrophoresis gel as a dye for the DNA, RNA, or other molecules to be visualized.

Ethidium bromide is mutagenic and moderately toxic and must be handled with care. The powder form is considered an irritant to the upper respiratory tract, eyes, and skin. Preparation of stock solutions and any operations capable of generating ethidium bromide dust or aerosols should be conducted in a fume hood to prevent inhalation. Nitrile gloves, a lab coat, and eye protection must be worn at all times.

When working with ethidium bromide, minimize the potential for spills. Where practical, purchase pre-mixed stock solutions from chemical manufacturers in lieu of preparing solutions. If solutions of ethidium bromide must be prepared, perform this process in a fume hood. Perform all processes that generate ethidium bromide dusts or mists inside the fume hood to minimize inhalation exposures. Prevent accidents by transporting small quantities of ethidium bromide in secondary containment.

***Do Not Use sodium** hypochlorite (bleach) to treat ethidium bromide. Bleach treatment can produce mutagenic products and leave behind up to 20% of the original ethidium bromide.

Ethidium Bromide Waste Disposal

Ethidium bromide waste should **NOT** be poured down the drain or thrown in the trash, unless the waste has been deactivated or filtered. The following are the recommended disposal procedures for ethidium bromide.

NOTE - Ethidium bromide DOES NOT go in red bags or red containers, should not be labeled with a biosafety symbol, and especially should not be treated in an autoclave.

A. Electrophoresis Gels, Contaminated Gloves and EtBr contaminated Solids

Handle ethidium bromide gels, contaminated gloves just as you would chemical hazardous waste. Use sealable,



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disposable plastic baggies to store ethidium bromide gel waste. Minimize free flowing liquids in these bags when they are brought for disposal.

A bin is kept for gloves and gels contaminated with EtBr

1) At the Centrifuge Room in the first floor near the Gel documentation system.

2) At the Common equipment room ground floor next to the Gel documentation system.

B. EtBr Liquid disposal Intermediate storage and collection of liquid EtBr waste is the responsibility of the individual laboratory. **A logbook must be maintained listing: concentration, volume, date and the person who generated it.** The liquid EtBr waste should be collected in an appropriately labeled 2- or 5- liter glass reagent bottle.

A Bind-ET Ethidium Bromide Removal System (Elchrom Scientific) for final disposal of liquid EtBr waste is located in the Laboratory kitchen first floor(Southern Laboratory) Disposal of the decontamination filters is done by the laboratory

Kitchen personnel. **A log-book entry has to be generated for every disposal entering LAB-number,volume, concentration and date.**

C. Sharps Contaminated with Ethidium Bromide

If contaminated blades or sharps need to be discarded they should be carefully rinsed with water into the Intermediate liquid waste container. **No disposal of sharps or blades is permitted into regular biohazard redbins or blue glass bins.** We recommend reusing the labeled blades specifically for EtBr work.

D. Ethidium Bromide Alternatives

Consider switching to less-toxic alternatives to ethidium bromide (GelRed , SYBR Safe™ DNA gel stain, Biotium) to reduce Potential hazardous exposures in the lab.



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2.4 Guidelines for Bis-Acrylamide

When handling Bis-Acrylamide formulations gloves, eye protection and Lab coat are required. Dispose remaining acrylamide in original chemical containers by polymerization. For that add 100µl TEMED and 100µl of 10% Ammonium Persulfate (APS) and shake it thoroughly and allow to react over night. Dispose the Container in the red biohazard bin.

2.5 Guidelines for Phenol/Chloroform

Handle Phenol or Phenol/Chloroform formulation only with gloves, eye protection and Lab coats. These liquids have to be disposed in dedicated organic solvent containers.

The tubes should be collected separately and allowed to dry in the chemical fume hoods in common equipment rooms in Ground and Second Floor.

2.6 COMPRESSED GAS SAFETY

A. Identification

1. The contents of any compressed gas cylinder shall be clearly identified for easy, quick, and complete determination by any laboratory worker. Such identification should be stenciled or stamped on the cylinder or a label, provided that it cannot be removed from the cylinder. If the labeling on a cylinder becomes unclear or an attached tag is defaced to the point the contents cannot be identified, the cylinder should be marked "contents unknown" and returned directly to the manufacturer. Users are requested to inform themselves through the Material safety data sheets (MSDS) about safe handling of the specific technical gas.

Examples of color code used in India for identification of gas

cylinders:	:	Peacock
1 . Argon	Blue	with black band on the shoulder of
2 . Nitrogen	: French Grey	black the
cylinder		
3 . Helium	: Light Brown	
4 . CO2	: Black with a silver band	on the shoulder of the
cylinder		
5 . Oxygen	: Black	
6 . Zero Air	: French Grey	



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(Ambient air filtered to contain less than 0.1 parts per million (PPM) of total hydrocarbons.)

7 : Signal

. Hydrogen Red

8

. D.A : Maroon

(Dissolved Acetylene)

B. Safe Use of High pressure cylinders

1. Gas cylinders shall be secured at all times to prevent tipping. Cylinders may be attached to a bench top, individually to the wall, placed in a holding cage, or have a non-tip base attached.

2. When new cylinders are received, they should be inspected; insure the proper cap is securely in place and the cylinder is not leaking. Cylinders shall have clear labels indicating the type of gas contained. If the cylinders are acceptable, they shall be stored in a proper location.

3. Standard cylinder-valve outlet connections have been devised to prevent mixing of incompatible gases. Cylinders should be placed with the valve accessible at all times. Cylinder valves should be opened slowly. Main cylinder valves should never be opened all the way. Valves should not be closed with force.

4. Regulators are gas specific and not necessarily interchangeable. Always make sure that the regulator and valve fittings are compatible. Never use oil or grease on the regulator of a cylinder valve.

5. For transportation of high pressures cylinders general precautions are required. To protect the valve during transportation, the cover cap should be screwed on hand tight and remain on until the cylinder is in place and ready for use. When moving large cylinders, they should be strapped to a properly designed wheeled cart to ensure stability. Cylinders should be moved only with dedicated trolleys. Cylinders should never be rolled or dragged.

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C. Leaking of compressed gas cylinders

If a leak is suspected, do not use a flame for detection; rather, a flammable-gas leak detector or soapy water should be used. If the leak cannot be remedied by tightening a valve gland or a packing nut, emergency action procedures should be initiated. Laboratory workers should never attempt to repair a leak at the valve threads or safety device; rather, they should consult with the supplier for instructions.

2.7 Safe handling of Cryogenic Liquids (liquid Nitrogen)

In the context of the NCBS/inStem/CCAMP campus this refers largely to liquid nitrogen. Usage of other cryogenic liquids has to be performed under supervision of trained individual and such operations should be reported to PI in charge and the Lab manager (Ranjith,).

The transfer of liquefied gases from one container to another should not be attempted for the first time without the direct supervision and instruction of someone experienced in the operation. In all procedures involving liquid nitrogen cryo-gloves and eye protection (preferably a face shield) should be worn at all times. Gloves should be chosen that are impervious to the fluid being handled and loose enough to be tossed off easily.

Fire/Explosions; Neither liquid nitrogen nor liquid air should be used to cool a flammable mixture.

Adequate ventilation must always be used to avoid suffocation or the possibilities of build up to explosive gas mixtures.

Only appropriate impact-resistant containers must be used that have been designed to withstand the extremely low temperatures for handling and storage of larger quantities of cryogenic liquids. Only dedicated Polyurethane Foam Ice Buckets are permitted for usage with liquid nitrogen. Styrofoam boxes (thermo col) are NOT allowed for handling liquid nitrogen at any time.

2.8 Safe Handling of Dry Ice

Dry ice is solidified carbon dioxide (CO₂). Dry ice sublimates (changes directly from solid to gas), releasing CO₂. Carbon dioxide vapor is substantially heavier than air. In confined, poorly ventilated spaces it can displace air, causing asphyxiation. It is even possible for CO₂ vapor to accumulate in low-lying areas, out-of-doors. Gloves and eye protection (preferably a face shield) should be worn at all times when handling dry ice.

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Dry Ice is obtained in blocks and has to be crushed for usage. Use only provided tools, during this procedure eye protection and gloves are a must.

Never store dry ice in glass or other sealed (airtight) containers or coolers. Storage in a sealed container can result in a rupture or explosion of the container from over-pressurization.

A. Disposal of Unused Dry Ice

Allow the dry ice to sublime or evaporate to the atmosphere in a well-ventilated area where no build-up of carbon dioxide vapor can occur.

Do not dispose of dry ice in sewers, sinks or toilets. The extreme cold will harm sink disposal, toilet parts and pipes. Do not dispose of dry ice in garbage receptacles or garbage chutes.

2.9 Guidelines for Imaging Stations

When an ultraviolet(UV) light source is used in work with ethidium bromide, added caution is required. As a general rule, avoid exposing unprotected skin and eyes to intense UV sources. Eye protection must be worn if a face shield is not available.

Leave the imaging station in a clean and EtBr-free state.

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3.0 BIOLOGICAL SAFETY

Four bio-safety levels are established to regulate laboratory practices, techniques and safety equipment appropriate for handling of biological agents. Biological agents in that context are:

- a) Microorganisms
- b) Arthropods
- c) Toxins of different origin and those produced using rDNA technology
- d) Viruses
- e) Allergens of different origins and those produced using rDNA technology

At NCBS, the area of biological safety is under the guidance of the BioSafety and Bioethics Committee and the Biological Safety Officer. For Biological Safety Levels I or II, researchers are bound to follow the Committee guidelines and inspections.

Bio-safety Level I:

Practices and safety facilities are appropriate for working with well-defined biological agents. These biological agents are not known to cause disease in healthy adult humans and pose only a minimal potential hazard for laboratory personnel and the environment. *Bacillus subtilis*, *Naegleria gruberi*, infectious canine hepatitis virus and non infectious *E. coli* are representative of those microorganisms meeting these criteria. Many agents not ordinarily associated with disease processes in humans are, however, opportunistic pathogens and may cause infection in the young, the aged, immunodeficient or immunosuppressed individuals.

Bio-safety Level II:

Practices and safety facilities must meet the prerequisites to deal with a broad spectrum of indigenous moderate-risk agents. These agents are known to cause diseases but immunization or antibiotic treatment is available. Examples are Hepatitis B virus, the *Salmonellae*, *Toxoplasma* spp. and infectious *E. coli* strains. Primary hazards to personnel working with these agents may include accidental autoinoculation, ingestion, and skin or mucous membrane exposure to infectious materials. Procedures with aerosol potential that may increase the risk of exposure to personnel must be conducted in primary containment equipment or devices.

Bio-safety Level II+:

The term 'Infectious Material' applies to blood, any other body fluid, and other potentially infectious material like biopsies. All body fluids shall be considered as infectious materials. Research involving Biological Safety Levels II+ shall contact the Biological Safety Committee for

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appropriate authorization, guidelines and inspections. Such work can only be performed in the Biohazard laboratory in the Ground Floor.

Bio-safety Levels III and IV are not applicable to NCBS/InStem/CCAMP.

3.1. Basic Working Principles in Bio-safety laboratories

The primary principle of biological safety is containment. This refers to a series of safety procedures which have to be conducted to reduce or eliminate human and environmental exposure to potentially harmful biological agents. While working in NCBS/inStem/CCAMP laboratories one might handle specimens, cultures and agents without full knowledge of the biohazard risk; these materials may contain infectious agents. To minimize exposure, observe universal precautions when handling any biological specimen.

While working in any of the above defined bio-safety levels it is required of any personnel at NCBS/inStem/CCAMP to follow the regulations listed below:

A. Wash your hands thoroughly:

1. Before and after working with any biohazard
2. After removing gloves, laboratory coat, and other contaminated protective clothing
3. Before eating, drinking, smoking, or applying cosmetics
4. Before leaving the laboratory area
5. Do not touch your face when handling biological material
6. Never eat, drink, smoke, or apply cosmetics in the work area



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B. Clothing Guidelines:

1. Always wear appropriate lab clothes and gloves when working with biological agents.
2. Wear gloves over gown cuffs.
3. Remove gloves by peeling them from the inside out.
4. Never wear contact lenses when dealing with infectious agents.
5. Do not wear potentially contaminated clothing outside the laboratory area.
6. Additional appropriate protective clothing should be selected and worn based upon the task and degree of exposure anticipated.

C. Handling Procedures liquid infectious materials:

1. Use mechanical pipetting device (examples; pipette aid, pipetteman or bulb).
2. Minimize aerosol generation. Decanting culture supernatants, opening of culture and streaking of plates should only be done in Safety cabinets or in a circular area around a burner of 0.5 meter radius. Decanting/Transferring of cultures in common equipment rooms outside of safety cabinets is forbidden.
3. Add disinfectant to water baths for infectious substances.
4. Use only closed tubes for centrifuging procedures. Inspect the tubes before use.
5. Use secondary leak-proof containers when transporting samples, cultures, inoculated petri dishes, and other containers of biohazardous materials within the institute.
6. Avoid using syringes and needles whenever possible. Special care has to be taken when usage of needles is not avoidable:
 - Use a needle-locking or disposable needle unit. Take care not to stick yourself with a used needle.
 - Place used syringes into a pan of disinfectant without removing the needles.
 - Do not place used syringes in pans containing pipettes or other glassware that require sorting. Do not recap used needles.
 - Dispose of needles in an approved sharps container.

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D. Work Area:

1. Keep laboratory doors shut when experiments are in progress.
2. Limit access to laboratory areas when experiments involving biohazardous agents are being performed.
3. Ensure that warning signs are posted on laboratory doors. These sign should include the universal biohazard symbol and the approve biosafety level for the laboratory.
4. Transport contaminated materials in leak-proof containers.
5. Keep miscellaneous material (i.e., books, journals, etc.) away from potentially contaminated working areas.
6. Follow a rigorous disinfection plan:
 - Completely decontaminate equipment before having maintenance or repair work done.
 - Decontaminate work surfaces daily and after each spill.
 - Decontaminate all potentially contaminated equipment.
 - Decontamination should only be performed with these disinfection solutions such as 70%Ethanol 5-10% Sodium hypochlorite (bleach) solutions - Work of Bio-safety Level II has to be performed at assigned workbenches. Ensure that warning signs are posted accordingly. All procedures generating aerosols have to be performed in safety cabinets. Minimize traffic in the area where Bio-safety Level II work is done.

E. Safety Equipment (Containment Barriers) Safety equipment includes a variety of personal protection items and laboratory devices which provide the ability to keep infectious agents in a specified contained area that is easily accessible. The biological safety cabinet is the principal device used to provide containment of infectious aerosols generated by many laboratory procedures. Open-fronted Class I and Class II biological safety cabinets are partial containment cabinets which offer significant levels of protection to laboratory personnel and the environment when used with good microbiological techniques. As part of the individual familiarization with laboratory procedures individual PIs are asked to ensure proper handling of the Safety cabinets.

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F. Disposal of liquid cultures:

1. All culture supernatants in conical plastic tube never more than 25ml can be disposed in the red biohazard bin. Tubes have to be closed but not overly tight.
2. All cultures ≥ 25 ml must be put in a glass beaker or Erlenmeyer flask and treated to become 10% with bleach in a **biosafety cabinet**. Examples; 30 ml culture/3-4 ml of straight bleach, 250 ml culture/25-30 ml straight bleach, let stand at least 30 minutes. Dispose off in sink: Turn on the water faucet, pour treated culture in, keep water running for a minute or two after you have finished pouring the culture.
3. Cultures with other hazardous chemicals and/or heavy metals must be disinfected as above and then disposed of according to the method prescribed in the MSDS.

3.2 Biohazard spills

Biological spills outside biological safety cabinets will generate aerosols that can be dispersed in the air throughout the laboratory. These spills can be very serious if they involve microorganisms that require Biosafety Level II and above containment. The Biosafety lab has its own procedures to follow.

General reaction plan for a biological spill:

1. Cordon off the area to stop anyone from spreading the contamination throughout the laboratory.
2. Cleaning procedures should be started in a timely manner by a person from the lab where the spill has occurred. Before starting to clean the spill, Personal Protection Equipment (gloves, face mask, safety goggles, long sleeve lab coat and shoe covers) must be obtained and put on.
3. Disinfect the area, all surfaces using 70% Ethanol in a spray bottle. Any material used to wipe up the spill must be placed in a biohazard bag and decontaminated using an autoclave.
Decontamination should only be performed with these disinfectants: 70%Ethanol or 10% Chlorox A. Spills on the Body
 1. Remove contaminated clothing.
 2. Apply disinfection solution. Vigorously wash exposed area with soap and water for one minute.
 3. Obtain medical attention.
 4. Report the incident to the Laboratory Manager (Ranjith)

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B. Bio-safety Level I Organism Spill decontamination procedure

1. Wear disposable gloves.
2. Soak paper towels in disinfectant (70% ethanol or 10% chlorox) and place over spill. Allow a 30-minute contact period on the spill.
3. Place towels in a biohazard bag and decontaminate using an autoclave before disposal.
4. Clean up spill area with fresh towels soaked in disinfectant.

C. Biosafety Level 2 Organism Spill

1. Shut down the air conditioning units for your laboratory or section of the building. (call Sub Station 6425/26)
2. Alert people in immediate area of spill.
3. Put on protective equipment, a laboratory coat with long sleeves, back-fastening gown or jumpsuit, disposable gloves, disposable shoe covers, safety goggles, mask or full-face shield.
4. Cover spill with paper towels or other absorbent materials.
5. Carefully pour a freshly prepared disinfectant around the edges of the spill and then into the spill. Avoid splashing. Allow a 30-minute contact period. We recommend using a spray bottle.
6. After the spill has been absorbed, clean up the spill area with fresh towels soaked in disinfectant.
7. Place towels in a biohazard bag and decontaminate in an autoclave. Please inform the laboratory kitchen to autoclave infected material before being sent for final disposal.

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4.0 Specialty Laboratories

4.1 Working with Radioactive Materials

The Radioactive Laboratory (Rad Lab) facility at NCBS has been classified as a Type I radioactive laboratory. The radioactive nuclei that the Radioactive Laboratory is equipped to handle are H-3, S35, P-32, C-14, Fe-55 and Ca-45.

The process to become a Radioactive Laboratory user is to fill out an application form available with Laboratory manager (Ranjith), pass written test conducted by NCBS Radiological Safety Officer (Dr. Shivaprasad) and go through a rigorous orientation programme under the supervision of the Radioactive Laboratory student representative. One of the most important aspects of the orientation program and tests is that the candidates must be aware of the specific protocols for disposal of waste materials generated during experiments performed in the Rad Lab. Once cleared by the test and passed through the orientation, the user must obtain badges before starting to use the Radioactive Laboratory. This process may take 1 to 2 months. Initially you will be under the supervision of a senior Rad Lab user before you become an independent user.

Forms may be obtained at this site:

http://int_ranet.ncbs.res.in/nod e/ 139

4.2 Laser Laboratory

A special training process must be undertaken to use lasers in the laboratory. Please contact your PI for appropriate instruction. Safety glasses have to be worn at all times within Laser Laboratories.



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Laboratory Waste Management

SL No.	BIN Type	Waste Type
1.	RED Bin Biohazard – Laboratory waste	Tips, tubes, Gloves, SDS PAGE gel, serological pipette, TC Flask, Plastic petridish , tubes 15ml and 50ml etc..
2.	BLUE BIN Broken Glass ware	Disinfected/Treated broken Glass wares, Any glass equipment containers, pipettes
3.	Halogenated Solvent Waste White Canister, 5 Ltrs	Chloroform, Dichloromethane, Carbon tetrachloride, Tetrachloroethylene ...
4.	Non-Halogenated Solvent waste White Canister, 5 Ltrs	Acetone, Acetonitrile, Diethylether, Ethanol, Hexane, THF, Methanol, Toluene, Methyl tert-butyl ether (MTBE), Dimethyl sulfoxide (DM/SO), Dimethyl formamide(DMF) ...
5.	White round Container	Syringes and needles
6.	White square Container	Sharps, slides, coverslips, blades etc...
7.	LARGE GREY BIN Ethidium Bromide (Imaging Stations)	Ethidium Bromide Gel, gloves, tubes and tips which contaminated with EtBr
8.	Liquid Ethidium Bromide Waste (Ground Floor Kitchen)	Buffers containing Ethidium Bromide
9.	Paper Recycle	Waste papers
10.	GREEN BIN (Near Lab 7 and Lab 1)	Books, papers, catalogues...
11.	CYAN BIN E-waste (Ground Floor Kitchen)	Battery, CDs, pendrive, cartridge, floppy etc..
12.	SMALL GREY BIN Phenol/Chloroform Solid Waste (Ground / Second Floor Fume Hoods)	Eppendorf tubes, falcon tubes, tips contaminated with phenol
13.	New Bins For Fly Labs For Broken Bottles and Vials With Media	Broken fly vials with media in them

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5.0 Waste Disposal System at KARNATAKA POLLUTION CONTROL BOARD

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6.0 EMERGENCY RESPONSE

6.1 FIRES

Fires are a common emergency in a laboratory.

ACTION TO BE TAKEN IN CASE OF FIRE

- ❑ ON SEEING FIRE, DO ALERT OTHERS BY SHOUTING “**FIRE, FIRE, FIRE**” REPEATEDLY. BREAK GLASS OF MANUAL CALL POINT (MCP) AND ACTUATE ALARM.
- ❑ INFORM RECEPTION (**Tel 2020**), SECURITY OFFICER (**Tel 2111**). ALERT OCCUPANTS USING PUBLIC ADDRESS SYSTEM.
- ❑ STAY CALM –DO NOT GIVE RISE TO PANIC.
- ❑ JUDGE THE TYPE OF FIRE – USE RIGHT TYPE OF FIRE EXTINGUISHERS.
- ❑ TYPE OF FIRE FOR WHICH EXTINGUISHER TO BE USED IS MARKED ON THE EXTINGUISHER ITSELF, VIZ

A-SOLID FIRE

C-ELECTRIC FIRE

K- KITCHEN FIRE

B-LIQUID/GASEOUS FIRE

D-METAL FIRE

Participate and learn about these fire extinguishers by our security team’s periodic demonstrations
For small fires/fires to a body, use the fire blanket.

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ACTION TO BE TAKEN IN CASE OF FIRE

- ❑ IN CASE OF ELECTRIC FIRE, **SWITCH OFF** POWER SUPPLY AND AC UNITS. INFORM SUBSTATION (**TEL 2020**).
- ❑ DO NOT FIGHT FIRE IF IT IS TOO LARGE TO CONTROL AND ATMOSPHERE IS TOXIC. CALL FOR THE HELP. COVER FACE/NOSE WITH WET CLOTH TO AVOID INHALING OF TOXIC GAS.
- ❑ EVACUATE THE PREMISES ENSURING ALL DOORS AND WINDOWS ARE **CLOSED**.
- ❑ DO **NOT** USE ELEVATORS FOR EVACUATION. USE ONLY BUILDING STAIR CASE. WALK BRISKLY DO NOT RUN TO AVOID STAMPEDE AND DO NOT STOP TO PICK UP BELONGINGS, GIVE WAY TO STAFF ATTENDING FIRE.
- ❑ DOUSE THE FIRE AT THE BOTTOM AND THEN MIDDLE LEVELS; DO **NOT** USE WATER ON ELECTRIC FIRE.
- ❑ IN CASE OF MAJOR FIRE, ON HEARING THE FIRE ALARM ALL THE PERSONNEL IN THE AFFECTED AREA SHOULD EVACUATE THE BUILDING IMMEDIATELY. NCBS NORTHERN LAB WILL ASSEMBLE AT GROUND FLOOR. PAVE WAY FOR EASY APPROACH TO INCIDENT SPOT BY FIRE FIGHTING PERSONNEL. SOUTHERN LAB PERSONNEL WILL MEET AT THE CRICKET NET ON THE LAWN
- ❑ Contact our emergency extension 2020/ RECEPTION/SECURITY will CALL FOR AMBULANCE ALONG WITH MEDICAL ATTENDENT FOR FIRST AID AND EVACUATION OF INJURED TO HOSPITAL.
- ❑ IN CASE OF THICK SMOKE FILLED ROOM, DO NOT WALK; INSTEAD CRAWL WITH WET CLOTH COVERING NOSE AND MOUTH.

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6.2 ACCIDENT REPORTING

All injuries shall be reported to Laboratory safety .Minor injuries many times are not reported because they are perceived to be embarrassing or that "careless actions" lead to the accident. However, minor injuries can sometimes lead to more serious complications that only become evident at a later time. In addition, all minor accidents should be investigated by safety and management personnel. Taking corrective action as a result of a minor accident may keep a major incident from happening. Without knowledge of all minor accidents, the desirable investigation is circumvented.

Employees should understand that the purpose of reporting and documenting accidents is not to affix blame, but instead to determine the cause of the accident so that similar incidents may be prevented in the future.

6.3 Emergency Contact Information

In case of medical, fire and major non-containable accidents it is required that you first inform the TEL 2020 The reception acts as an information hub to contact all concerned personnel.



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AMENDMENT SHEET

S.no	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority	Date of amendment
1	6.3 Page 14	Change in Competency matrix (faculties)	Faculty Resignation and new recruitment			27/12/2018
2	6.4 Page 15	Change in competency matrix (Technical staff)	Technical staff Resignation and new recruitment			27/12/2018
3	26 page 49	Annexure 4	Fresher's induction programme			27/12/2018
4	26 page 50	Annexure 5	Purchase policy			27/12/2018
5	26 page 50	Annexure 6	Calibration of instruments			27/12/2018
6	15.1 page 31	Change in EQAS center	As per new update			27/12/2018
7	15.2 page 32	Change in Inter-lab QC center	As per new update			27/12/2018

Approved By : Prof. Dr.Sangeetha.S	Doc. No.	RRMC-MICRO-QM- 01
	Issue No.	02
Issued By : Prof. Dr.Govindaraju	Rev. No	00
	Date	24.01.2019
Prepared By : Dr.Sunilkumar D Chavan, Dr. Vishwajith	Page	Page 1 of 53

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Service Name :	QUALITY MANUAL MICROBIOLOGY LABORATORY SERVICES
Date Created :	24.01.2019
Approved By :	Medical Superintendent Name : Prof. Dr.Govindaraju Signature :
Issued By :	Head of the Department Name : Prof. Dr.Sangeetha.S Signature :
Responsibility of Updating :	Quality Manager Name : Dr. Vishwajith Signature :
	Technical Manager Name : Mr. Pradeep and Miss. Bhavya Signature :

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QUALITY MANUAL

1.0 INTRODUCTION:

The department of Microbiology, Rajarajeswari Medical College has prepared a quality manual that describes and outlines all of the quality processes and procedures designed to meet our quality standards. The quality system ensures that this laboratory has processes that are efficient, effective and meet regulatory requirements.

The Microbiology laboratory is committed for generating quality reports with no compromise in the adherence of standard techniques for collection, processing of clinical specimens and timely reporting of the results.

2.0 DESCRIPTION AND TYPE OF LABORATORY :

The department of Microbiology caters to the diagnostic needs of RajaRajeswari Medical College and Hospital since the time of its inception in 2007 .The Microbiology laboratory is located on the first floor of Radiology Block of the Hospital. RajaRajeswari Medical College and Hospital is located in Kambipura, Mysore road, Bangalore 560074.

It comes under the category of large laboratory catering above 750 patients per day.

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3.0 OBJECTIVE:

The objective of this document is to define the services that will be provided by Department of Microbiology Laboratory services, RajaRajeswari Medical College and Hospital, Bangalore.

- 3.1 To ensure timely communication and documentation of the critical test values.
- 3.2 To ensure minimum reporting errors.
- 3.3 To ensure minimum re-dos of tests.
- 3.4 To ensure compliance of test results with the patient diagnosis.
- 3.5 To ensure compliance with the quality assurance programme.
- 3.6 To ensure compliance with safety programme.
- 3.7 To ensure compliance with the biomedical waste management techniques.

4.0 SCOPE:

The scope of this document is restricted to the services provided by Department of Microbiology Laboratory Services, RajaRajeswari Medical College and Hospital, Bangalore.

Clinical microbiology is a multidisciplinary unit comprising of Immunology, Parasitology, Bacteriology, Virology, Mycology Mycobacteriology and Medical Entomology. The department of Microbiology caters to the diagnostic needs of

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RajaRajeswari Super Specialty Hospital in addition to carrying out teaching programmes and research activities. Over 1, 50,000 microbiological investigations are carried out annually in different sections of the department namely Bacteriology, Serology, Immunology, Parasitology, and Mycology & Virology. On an average about 950-1000 samples are received and reported per day.

The overall scope and use of the manual is as follows:

- a. The policies set out in this manual are mandatory for all staff members.
- b. This manual has been prepared with input from all staff.
- c. The Quality Manager under the guidance of HOD- Dept. of Microbiology and Laboratory Manager will be responsible for all updates and its contents.
- d. In order to reflect the current best practices and continuous improvement, changes or additions to the manual are documented in the amendment sheet.
- e. The document will be reviewed within one year from date of issue.
- f. The retention period for the document will be 1 year from the date of issue.
- g. Obsolete documents will be disposed and only those in current use will be made available for reference.
- h. This manual is a controlled document and unauthorized alterations and copies must not be made.

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5.0 QUALITY POLICY :

All faculty of department of Microbiology are committed to continuous improvement in order to provide our technicians with knowledge, tools , resources and training necessary to deliver quality microbiological services that meet the expectations of our patients and clients as per the ISO 15189:2015 and NABL norms.

5.1 Laboratory policy

- 5.1.1** The department of Microbiology caters to the diagnostic needs of RajaRajeswari Medical College and Hospital.
- 5.1.2** All the tests are done as per the protocol of standard test procedures which are available.
- 5.1.3** The individual samples are processed as per standardized test procedures by manual, semi-automated and automated techniques.
- 5.1.4** All the results of the laboratory investigations are available for the physicians or patients as per the time frame according to the laboratory test schedule.
- 5.1.5** All the critical results and the results of Emergency Departments like ITU, ICU and Casualty are intimated immediately to the concerned physician, ward Medical officers or the ward in-charge.
- 5.1.6** The investigations which are not available in the department and those that require expert opinion are sent to the NABL Accredited Laboratories like –

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Department of Microbiology, CMC Vellore, PGI Chandigarh, JIPMER & Thyrocare laboratory which are maintaining Quality Assurance Procedures.

- 5.1.7** Samples are sent in a safe and secure manner as per QA protocol.
- 5.1.8** All personnel concerned with examination activities have necessary qualification and are competent. They shall be familiar with the quality documentation and implementation of policies and procedures at all time.

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6.0 QUALITY INDICATORS:

S. No	Performance indicator	Numerator	Denominator	Standardization factor
1	Number reporting errors per 1000 investigations	Number of reporting errors picked up before dispatching of report	1000 investigations	1000
2	Percentage of Re-dos – laboratory	Number of Re-dos in Microbiology	Total number of investigations	100
3	Percentage of laboratory reports correlating with clinical diagnosis of malaria	Number of patients with positive test for malaria	Number of patients where clinical diagnosis of malaria has been made	100
4	Percentage of adherence to safety precautions by employees	Number of employees adhering to safety precautions	Number of employees	100

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6.1 RESPONSIBILITIES:

6.1.1 Head of the Department of Microbiology:

HOD, Department of Microbiology will be responsible for supervising overall functioning of the laboratory activities. Issues related to discipline, man power, section postings, inclusion of newer test kits or change of test methodology, indenting new instruments, laboratory safety etc., will be supervised by the HOD.

6.1.2 Laboratory Manager :

Laboratory Manager will be directly responsible for the smooth functioning of the laboratory activities. Issues related to technician postings, allotment of holiday duties, issuing materials for testing, materials indent, laboratory safety, etc., will all be directly dealt by the Lab Manager. The Laboratory Manager will be reporting to the Department HOD.

6.1.3 Quality Manager :

The quality manager will be incharge of the overall quality aspects of the laboratory ensuring quality reporting by the laboratory. Ensures that appropriate quality control are being adhered to by all the section heads. Responsible for updating and amending the quality manual periodically under the supervision of department HOD. Ensure training of the technicians as per the laboratory policy.

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6.1.4 Section heads:

Faculty posted in various sections of Microbiology laboratory as section heads will be directly responsible for smooth functioning of their respective sections. It is the primary responsibility of the section heads to see to it that minimum stocks are maintained and supervise timely quality controls are being carried out in order to ensure quality reports.

Section heads report to the Laboratory Manager

6.1.5 Technical Manager :

Technical Manager will be responsible for the technical aspects of the laboratory services. He will be responsible for adherence to the standard operative procedures for processing clinical samples. He has to ensure that all the samples received by the laboratory are all processed appropriately and all the reports are being appropriately dispatched. He will supervise that minimum stock is being maintained as per laboratory protocol.

6.1.6 Technicians :

Technicians will be responsible for processing all the samples received in the laboratory appropriately and on time. They will be directly reporting to their respective section heads and also the Technical manager. They shall maintain the minimum stock of consumables in their respective sections and indent the same when necessary.

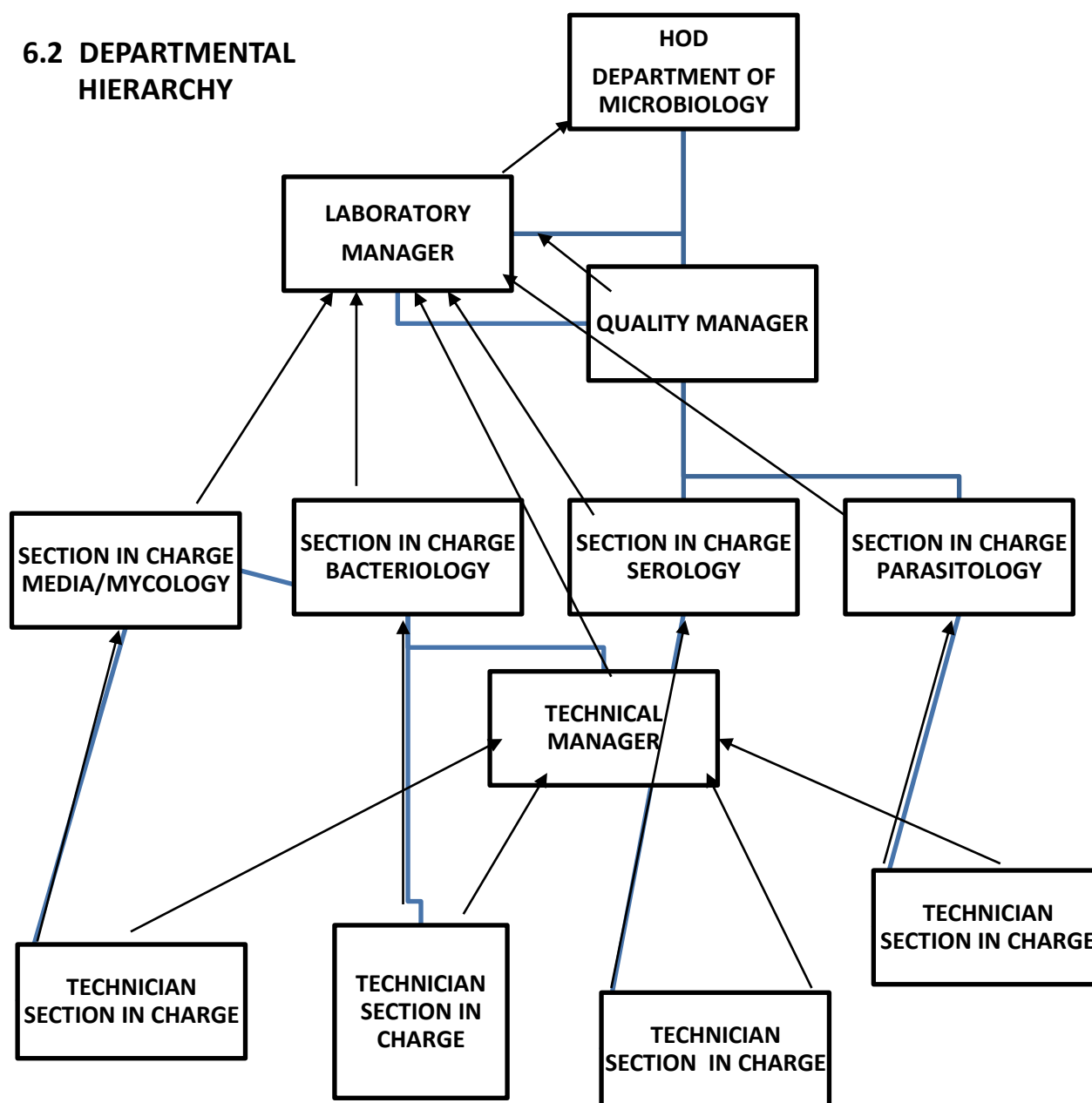
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**6.2 DEPARTMENTAL
HIERARCHY**



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6.3 COMPETENCY MATRIX [Faculty]:

DEPARTMENT OF MICROBIOLOGY LABORATORY SERVICES

RajaRajeswari Medical College and Hospital

Sr. No.	Name of the staff	Designation	Educational qualification	Experience		
				Present	Previous	Total
1.	Dr.Sangeetha.S	Professor and HOD ,	MD in Microbiology	10 yrs 1 month	8 yrs	18 yrs 1month
2.	Dr. Prakash R	Associate Professor and lab Manager	MD in Microbiology	2 years 2months	7 years 9 months	9 years 11 months
3.	Dr. Lakshminarayana S A	Assistant Professor and Section incharge, Bacteriology	MD in Microbiology	4 years	6 years 4 months	10 years 4 month
4.	Dr.Vishwajith (Quality manager)	Asst.Professor , Section incharge, Parasitology	MD in Microbiology	3 year 3 months	3 years	6 years 3 months
5.	Dr.Yashashwini MK	Asst.Professor and Section incharge, Mycology and Media	MD in Microbiology	2 years 9 months	3 years	5 years 9 months
6.	Dr. Santhoshini Vaijinath	Asst.Professor	MD in Microbiology	2 years 6 months	3 years	5 years 6 months
7.	Dr. Archana Rao K	Asst.Professor	MD in Microbiology	2years 6 months	3 years	5 years 6 months
8.	Dr. Kanthishree	Asst.Professor	MD in Microbiology	2 year	3 years	5years
9.	Dr. Kirtilaxmi KB	Asst.Professor	MD in Microbiology	1 year	6years	7years
10.	Dr. Nandini L	Asst.Professor	MD in Microbiology	1 year 5months	4years	5years 5 months
11.	Dr. Archana BR	Asst.Professor	MD in Microbiology	2 year 2 months	4 years	6years 2 months

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6.4 COMPETENCY MATRIX [Technical staff]:

Sl. No.	Name of the Technical Staff	Designation	Educational qualification	Experience		
				Present	Previous	Total
1.	Mrs. Latha	Technician	DMLT	9 years	4 years	13 years
2.	Mr. Pradeep (Technical manager)	Technician	BSc, MLT	9 years	-	9 years
3.	Miss. Bhavya	Technician	DMLT	5 Years 3 months	1 Year 9 Months	7 years
4.	Mr. Imran	Technician	DMLT	5 years	-	5 years
5.	Mr. Vasanthkumar	Technician	DMLT,Bsc	5 years	-	5 years
6.	Mrs. Bhavani	Technician	BSc, MLT	4 years	-	4 years
7.	Mrs. Rajalakshmi	Technician	DMLT	4 years	-	4 years
8.	Miss. Abhilasha	Technician	DMLT	3 years	-	3 years
9.	Mrs. Anitha	Technician	DMLT	3 years	-	3 years
10.	Miss. Selvi	Technician	DMLT	2 years, 6 months	-	2 years 6 months
11.	Miss. Sunitha	Technician	DMLT	1 year 5months	1 year	2 years 5months
12.	Miss. Fiza naz mehdi.R	Technician	DMLT	12 months	-	12 months
13.	Mr. Rajashekar S	Technician	DMLT	8 months	-	8 months
14.	Mr. Purushottam	Technician	DMLT	6 months	-	6 months
15.	Mrs. Nisha	Technician	DMLT	6 months	8 years	8 years 6 months

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16.	Miss. Savithri	Technician	DMLT	4 months	-	4 months
17.	Miss. Priyanka	Technician	MSc	3 months	-	3 months
18.	Miss. Jyothi	Technician	DMLT	3 months		3 months
19.	Miss. Chitradevi	Technician	DMLT	2 months	-	2 months
20.	Miss. Vijaya	Technician	DMLT	1 month		1 month

7.0 DEPARTMENT WORKING HOURS:

All faculty, Laboratory Manager, Quality Manager and Technical manager will be on general shift from 9AM to 4 PM.

Technical staffs are posted on shift basis, 9 AM to 4PM, 2 PM- 8 PM and 4 PM TO 9 AM.

Sl. No	Designation	Working hours
1.	HOD , Microbiology	9 AM to 4 PM
2.	Laboratory Manager	9 AM to 4 PM
3.	Quality Manager	9 AM to 4 PM
4.	Section Heads	9 AM to 4 PM
5.	Technical Manager	9 AM to 4 PM
6.	Technical Staff	As per the duty roster on shift basis, from 9 am-4 pm, 2 pm-8pm, 4pm-9 am

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8.0 REFERENCE TO NABH STANDARDS:

S.No	Chapter	Relevant NABH Standard / Objective Element
1.	Access to assessment and continuity of care	The organization has a well-defined registration and admission process AAC.2. A – E.
2.	Access to assessment and continuity of care	Laboratory services are provided as per the scope of services of the organization AAC 6. A – H.
3.	Access to assessment and continuity of care	There is an established laboratory quality assurance programme. AAC 7. A – E.
4.	Access to assessment and continuity of care	There is an established laboratory safety programme. AAC .8. A – E.
5.	Access to assessment and continuity of care	Patient care is continuous and multidisciplinary in nature AAC.13. A – E.
6.	Patient rights and responsibility	A documented procedure for obtaining patient and / or family's consent exists for informed decision making about their care. PRE .4 A – H.
7.	Hospital infection control	Proper facilities and adequate resources are provided to support the infection control programme HIC.5. A – D.
8.	Hospital infection control	Statutory provisions with regard to Bio medical waste(BMW) management are complied with HIC.8.A – F.
9.	Continuous Quality Improvement	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tool for continual Improvement. CQI.3.
10.	Continuous Quality Improvement	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tool for continual improvement CQI.4.
11.	Responsibility of Management	The service provided by each department are documented ROM.3.

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9.0 Turn Around Time:

For the time of reporting, Please refer the table of TAT for the laboratory test reporting. It is the time from sample collection to report ready for dispatching.

For details refer Annexure – 02.

10.0 REJECTION CRITERIA FOR UNACCEPTABLE SAMPLES:

The samples must be rejected for the following reasons:

- 10.1. Clinical sample containers without barcode or label or those not correlating with the details mentioned on requisition form.
- 10.2 Clinical sample containers without requisition form.
- 10.3 Clinical sample containers without date and time of sample collection.
- 10.4 Samples collected in inappropriate containers.
- 10.5 Inadequate samples.
- 10.6 Samples collected in unsterile containers.
- 10.7 Leaky containers.
- 10.8 Swabs for AFB smear and culture.
- 10.9 Stool/urine sample filled to the brim.
- 10.10 Sputum sample containers with saliva.
- 10.11 Broken sample containers or containers with cracks.
- 10.12 Formed stools or semi-formed stools for hanging drop.
- 10.13 HIV serology samples without consent forms.

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10.14 Samples transported to laboratory without maintaining cold chain.

10.15 Hemolysed samples for serology.

10.16 Refrigerated, inoculated blood culture bottles, stool samples, anaerobic culture samples, CSF samples.

10.17 Sample for anaerobic sent in open container/swabs

10.18 Dry swabs for culture.

10.19 Culture samples sent in formalin.

10.20 Swabs from the or pharynx representing sputum.

11.0 CRITICAL TESTS:

11.1 Purpose:

To ensure immediate reporting of critical values / results to appropriate care providers to enable provision of timely, appropriate treatment to the patient.

11.2 Scope:

All critical cases. The following are the critical alerts in Microbiology.

11.2.1 Methicillin resistant Staphylococcus aureus (MRSA)

11.2.2 Positive blood culture

11.2.3 Vancomycin Resistant Enterococci (VRE)

11.2.4 Carbapenamase resistant GNB

11.2.5 Candida (fungal culture)

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- 11.2.6 Endotracheal aspirate culture
- 11.2.7 Catheter blood stream infection (CRBSI)
- 11.2.8 VRSA (Vancomycin resistant Staphylococcus aureus)
- 11.2.9 VISA (Vancomycin intermediate Staphylococcus aureus)
- 11.2.10 Serology positive blood (HIV, HCV, HBsAg, dengue, Leptospira IgM)
- 11.2.11 Fluorescent immune assay tests – PCT, D-dimer, NT Pro BNP, Troponin I.

11.3 Responsibility:

All Faculty & laboratory Technicians.

11.4 Definition:

A critical test is defined as a STAT test with critical values/ results or other results that are determined by the laboratory to be critical to the patient's subsequent treatment decisions.

11.5 Procedure:

All critical results and critical values must be called immediately to the Consultant or attending physician (Medical officer) or ward in-charge. Documentation of the call including time and date and who received the critical value/result must be made as a permanent practice. All shall be recorded in critical report intimation register properly.

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12.0 Outsourcing Tests:[4.5 ISO 15189:2015]

12.1 Purpose: To establish Standard Operating Procedures for Outsourced Laboratory Tests.

12.2 Scope:

12.2.1 Some of the tests that cannot be performed by the laboratory or those that require expert opinion are outsourced to outside Laboratories and diagnostic centers.

12.2.2 The hospital has recognized the Laboratories and diagnostic centers as per their quality assurance program such as NABL accreditation for Laboratories.

12.2.3 A memorandum of understanding has been made with the outsourcing laboratories as part of documentation.

12.2.4 The laboratory shall have an effective documented procedure for evaluating and selecting referral laboratories as well as consultants who are to provide second opinion.

12.3 Responsibility:

Primary Responsibility: Laboratory manager

Secondary Responsibility: Quality Manager

12.4 Procedure:

12.4.1 Samples to be sent to outsourced laboratories are registered in the same way as other tests performed in-house and the bill shall be generated.

12.4.2 Laboratory samples are either collected by the outsourced Laboratory or sent to them.

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12.4.3 Specimens are appropriately labeled and the requisition form filled with all the details mentioned.

12.4.5 Specimens are transported in special leak proof boxes with biohazard label ideal for transportation.

12.6 List of outsourced tests to Thyrocare Laboratories:

Sl. No	Test Code	Test Description	Units	Method	Frequency	Cost [Rs]
1.	AHCV	ANTI HEPATITIS C VIRUS-TOTAL (AHCV)	S/ CO	C.L.I.A	DAILY	550
2.	ASO	ANTI STREPTOLYSIN-“O”(ASO)	IU/mL	NEPHELOMETRY	DAILY	250
3.	C3	COMPLEMENT 3 (C3)	g/L	NEPHELOMETRY	DAILY	300
4.	C4	COMPLEMENT 4 (C4)	g/L	NEPHELOMETRY	DAILY	300
5.	CD4	CD4+T HELPER CELLS PERCENTAGES OF CD3	%	FLOWCYTOMETRY	DAILY	750
6.	CM_AV	CYTOMEGALOVIRUS AVIDITY	%	E.L.I.S.A	DAILY	150
7.	CM_G	CYTOMEGALO VIRUS(CMV)-IgG	OD RATIO	E.L.I.S.A	DAILY	150
8.	CM_M	CYTOMEGALO VIRUS(CMV)-IgM	OD RATIO	E.L.I.S.A	DAILY	150
9.	CRP	C-REACTIVE PROTEIN (hsCRP)	mg/dL	NEPHELOMETRY	DAILY	250
10.	EAG	HEPATITIS B ENVELOPE ANTIGEN (HBeAg)	RATIO	C.L.I.A	DAILY	350
11.	AHAVIG M	ANTI HEPATITIS A VIRUS(HAV)-IgM	RATIO	C.L.I.A	DAILY	350

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12.	AHAVT	ANTI HEPATITIS A VIRUS-TOTAL ((HAVT)	OD RATIO	E.L.I.S.A	DAILY	350
13.	HC_G	HERPES SIMPEX VIRUS (HSV)-IgG	OD RATIO	E.L.I.S.A	DAILY	150
14.	HC_M	HERPES SIMPLEX VIRUS (HSV)-IgM	OD RATIO	E.L.I.S.A	DAILY	150
15.	HEVM	ANTI HEPATITIS E VIRUS (HEV)-IgM	OD RATIO	E.L.I.S.A	DAILY	500
16.	HIVE	HIV (AG/AB)COMBO ASSAY	S/CO	C.L.I.A	DAILY	350
17.	HS1G	HERPES SIMPLEX VIRUS I (HSV)-IgG	OD RATIO	E.L.I.S.A	DAILY	150
18.	HS1M	HERPES SIMPLEX VIRUS I (HSV)-IgM	OD RATIO	E.L.I.S.A	DAILY	150
19.	HS2G	HERPES SIMPLEX VIRUS II (HSV)-IgG	OD RATIO	E.L.I.S.A	DAILY	150
20.	HS2M	HERPES SIMPLEX VIRUS II (HSV)-IgM	OD RATIO	E.L.I.S.A	DAILY	150
21.	IGA	IMMUNOGLOBULIN A (IgA)	g/L	NEPHELOMETRY	WED/SUNDAY	350
22.	IGG	IMMUNOGLOBULIN G (IgG)	g/L	NEPHELOMETRY	WED/SUNDAY	350
23.	IGM	IMMUNOGLOBULIN M (IgM)	g/L	NEPHELOMETRY	WED/SUNDAY	350
24.	LP_M	LEPTOSPIRA-IG M	OD RATIO	E.L.I.S.A	DAILY	400
25.	RB_AV	RUBELLA AVIDITY	%	E.L.I.S.A	DAILY	150
26.	RB_G	RUBELLA (RUB)-IgG	OD	E.L.I.S.A	DAILY	150

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			RATIO			
27.	RB_M	RUBELLA (RUB)-IgM	OD RATIO	E.L.I.S.A	DAILY	150
28.	RFAC	RHEUMATOID FACTOR (RF)	IU/mL	NEPHELOMETRY	DAILY	300
29.	SAG	HEPATITIS B SURFACE ANTIGEN (HBSAG)	IU/mL	C.L.I.A	DAILY	350
30.	TIGE	TOTAL IgE(TIGE)	IU/mL	C.L.I.A	DAILY	200
31.	TX_AV	TOXOPLASMA AVIDITY	%	E.L.I.S.A	DAILY	150
32.	TX_IGG	TOXOPLASMA GONDII(TOXO)- IgG	OD RATIO	E.L.I.S.A	DAILY	150
33.	TX_IGM	TOXOPLASMA GONDII(TOXO)- IgM	OD RATIO	E.L.I.S.A	DAILY	150
34.	WEST	WESTERN BLOT		P.C	DAILY	1200
35.		TORCH ALL TEN				1400
36.		TORCH ALL EIGHT				1200

12.7 List of out sourced tests to CMC, Vellore & PGI, Chandigarh:

Sl. No	Test Description	Units	Method	Frequency	Cost[Rs]
1.	Identification and sensitivity of bacterial isolate [Rare isolates and for second opinion]	NA	Standard techniques as per the sample to be processed.	As and when required.	As requested by the institute.
2.	Identification and sensitivity of Fungal isolate [Rare isolates and for second opinion]	NA	Standard techniques as per the sample to be processed.	As and when required.	As requested by the institute.

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12.8 List of out sourced tests to JIPMER , Pondicherry :

Sl. No	Test Description	Units	Method	Frequency	Cost[Rs]
1.	Identification of parasite /larva /cyst.	NA	Standard techniques as per the sample to be processed.	As and when required.	As requested by the institute.

12.9 MONITORING REFERRAL LABORATORIES :

12.9.1 Laboratory management with the advice of the users of laboratory services where appropriate shall be responsible for selecting and monitoring the quality of the referral laboratories and consultants and shall ensure that the referral laboratory or referral consultant is competent to perform the requested examinations.

12.9.2 Arrangements with referral laboratories shall be reviewed periodically to ensure that requirements, including the pre-examination and post examination procedures are adequately defined, documented and understood.

12.9.3 The referral laboratory is able to meet the requirements and that there are no conflicts of interests.

12.9.4 Selection of examination procedures is appropriate for intended use.

12.9.5 Respective responsibilities for the interpretation of examination results are clearly defined.

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12.9.6 Records of such reviews shall be maintained in accordance with national, regional or local requirements.

12.9.7 The laboratory shall maintain a register of all referral laboratories.

12.9.8 A register shall be kept for all samples that have been referred to another laboratory.

12.9.9 The name and address of the laboratory responsible for the examination result shall be provide to the use of laboratory services.

12.9.10 A duplicate of the laboratory report shall be retained in both the patient record and in the permanent file of the laboratory.

13.0 Laboratory safety program:

The Laboratory ensures that the appropriate safety techniques are adopted and known to the staff. Laboratory safety manual are available at the work area, and regular staff training is conducted. Computer security and backups for data and case documentation records has been provided.

For details refer to the Laboratory safety manual.

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14.0 Maintenance of Equipments:

14.1 Purpose:

The laboratory uses equipment suitable for the methods employed and has documented protocol for maintenance of Equipments.

14.2 Responsibility:

Primary Responsibility: Technical Manager

Secondary Responsibility: Quality Manager

14.3 Labelling:

All the instruments in the laboratory have been identified with a unique identification number which will be displayed on the instrument along with details of installment date, due date for the next AMC , due date for calibration and contact number of company personnel for contacting during machine break down or for AMC.

14.4 Placement:

Equipments have to be placed in appropriate places as recommended by the manufacturer, with sufficient space away from the wall .Exposure to direct sunlight is avoided and will be placed in places where there is no disturbances due to frequent movement of lab personnel.

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14.5 Temperature and Humidity:

The laboratory temperature shall be appropriately maintained with air conditioning as per manufacturer's recommendations.

14.6 Calibration

14.6.1 The laboratory shall have a documented program for calibration and annual maintenance of all the equipment's used in the laboratory.

14.6.2 The frequency of the calibration is determined by the company personnel as per requirement.

14.6.3 Documentation of the same will be maintained by the technical manager.

14.6.4 Calibration and validation for all instruments shall be done at the time of installation, following rectification of the instrument breakdown and as per the manufacturer's instructions and shall be documented.

14.6.5 For those requiring in- house calibration, it will be done as advised by the company personnel by the technical manager under the supervision of the Quality Manager.

14.6.6 Training regarding the operation of the instrument will be provided both at the time of induction as well as a part of routine training program of the Laboratory technical staff.

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15.0 Verification and validation of performance specifications:

The laboratory compares patient test results for consistency with patient age, sex, diagnosis or pertinent clinical data, and relationship with other test parameters. For each test system, the clinical laboratory has established a control procedure to monitor the accuracy and precision of the complete analytic process. At a minimum, the quality control process will detect: Immediate errors and errors occurring over time. Errors occurring due to test system failure. Environmental condition changes. Operator performance.

15.1 External Quality Assurance Programme:

15.1.1 Responsibility:

Primary Responsibility: Quality Manager

Secondary Responsibility: Technical Manager

The Microbiology laboratory at RRMCH&H has a documented external quality control programme. The laboratory is enrolled with CMC, Vellore, for external quality assessment scheme for viral serology, routine serology, culture and direct smears.

EQAS samples are received every fourth month, processed and reported. Marks will be allotted for the performance and identification, corrective actions will be documented in

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case of mistakes in identification or performance of the test and the hard copies of the same are filed for future reference.

15.2 Inter laboratory Quality Control Programme :

15.2.1 Responsibility:

Primary Responsibility: Quality Manager

Secondary Responsibility: Technical Manager

The Microbiology laboratory at RRMCH has a documented interlaboratory quality control program with Thyrocare, Hebbal, and Bangalore for ELISA and serology.

The ELISA samples will be received once in every three months and will be processed and reported which in turn will be accessed and communicated to us. Corrective actions will be taken in case of mistakes in performance of the tests and will be documented.

15.3 Internal Quality Assurance Program:

15.3.1 Responsibility:

Primary Responsibility: Quality Manager

Secondary Responsibility: Technical Manager

The Microbiology laboratory at RRMCH has a documented internal quality control protocol. For details refer to quality control in Microbiology document.

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16.0 Post – analytic system:

16.1 Test reporting:

The laboratory maintains written procedures for generating and maintaining documentation for tested samples. The laboratory maintains written procedures for the release of tested sample information. The laboratory maintains the following examination documentation:

16.1.1 Technician: generated notes, to include identity of person generating notes.

Date and time of analysis completed.

16.1.2 Review of reports: The laboratory follows written procedures for technically reviewing all tested samples information and results. The technical review is conducted by a technically qualified individual other than the preparer of the report, notes, data and other documents under review.

16.1.3 Authorized personnel will sign the reports. All the laboratory reports are verified and signed by qualified Microbiologist.

16.1.4 Normal ranges where appropriate are provided. Errors in patient's reports will be corrected in timely fashion and will be documented in the error report file. Corrective action will be initiated by the laboratory Manager and will be documented. Incident report shall be raised for errors of serious nature.

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16.1.5 Complaints about lab investigations: The laboratory has a system in place to ensure that it documents all the complaints and problems reported to the laboratory. Patient feedback forms are made available in the collection centre and the patients are requested to fill the feedback forms after giving the sample. The feedback forms will be analyzed by the Quality Manager on a day to day basis and will be intimated to the Laboratory Manager regarding the same to initiate necessary action and will be documented.

16.1.6 Corrective and Preventive actions: The laboratory follows procedure for corrective action whenever analytical errors and / or proficiency testing discrepancies are detected. The laboratory Quality Manager maintains documentation for the Corrective & Preventive actions.

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17.0 Retention period for Specimen, Registers, Reports:

Sl. No	Specimen	Duration
1.	Serology	5 days
2.	Urine culture samples	Till the sample is processed
3.	Stool	Till the sample is processed
4.	Pus , swabs	24 hours
5.	Sterile body fluids [CSF , synovial , peritoneal , pericardial , pleural etc.,]	48 hours
6.	CAPD fluid [after centrifuge]	48 hours
7.	Registers (logs) containing daily readings , results	1 year
8.	Uncollected reports	2 months
9.	Copies of reports of outsourced tests	1 Year

18.0 House Keeping and Miscellaneous Safe Practices:

The House keeping staff will be provided with all the necessary PPEs for carrying out cleaning activities inside the laboratory.

Dry mopping with microfiber brooms is done followed by wet mopping using two bucket system containing 1% Bleach as the disinfectant .Cleaning activities are carried for three times a day where in all horizontal surfaces are cleaned with 1% bleach at the beginning of the day and at the end of the day. Afternoons only floor mopping with 1% bleach is practiced.

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19.0 Disposal of Waste

Proper waste disposal and management of biohazardous wastes is essential to limit the risk of infections to the health care workers which is followed as per the hospital policy in accordance with the local biomedical waste management agency.

19.1 Segregation: Segregation of wastes generated in the laboratory is the responsibility of every laboratory worker. The house keeping staff are responsible for ensuring that every section of the laboratory has disposal containers with all the bags as mentioned below. The colour code provided by Maridi, a local biomedical disposal agency shall be strictly followed and the poster depicting the same is made available at all areas where the color-coded bins are placed.

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20.0 Laboratory Areas:

The laboratory shall have designated areas for laboratory work and access to such areas shall be limited to the laboratory employees.

20.1 Visitors in laboratory areas: Children under 12 years of age shall not be permitted into laboratory except for tests. Each laboratory supervisor is responsible for the safety of adult visitors to the laboratory.

20.2 Hazard warning signs and labels: The following four symbols may be used by the laboratory to communicate the extent of risk in the laboratory.

20.2.1 NOTICE - states a policy related to safety of personnel or property but not a physical hazard.

20.2.2 CAUTION - indicates a potentially hazardous situation, which may result in minor or moderate injury.

20.2.3 WARNING - indicates a potentially hazardous situation, which may result in death or serious injury.

20.2.4 DANGER - indicates an imminently hazardous situation that if not avoided, will result in death or serious injury.

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21.0 Laboratory Accidents:

Though the laboratory provides all facilities to avoid accidents, it is inevitable that a few accidents may occur over a period of time. The following section provides details of the management of such laboratory accidents:

21.1 Needle stick injuries (including other sharps):

Wash the area immediately under running tap and water. Inform the infection control nurse for documentation and follow up of the about the accident. The exposed as well as the source shall be tested for all the blood borne viruses [HIV, HBsAg, and HCV] to know their baseline titers. The HICC Officer in coordination with the Casualty medical officer shall do the risk assessment of the exposed person and will decide on the requirement of combined immunization or PEP.

21.2 Eye wash station:

There shall be at least one eyewash facility per laboratory. Laboratory workers exposed to dangerous chemicals or infectious materials shall immediately use the eye wash to flush out the material. Hold the eyelids open while using the eye wash and let the water spray of for an extended period of time (15 minutes). Report about the incident to the laboratory manager for documentation of the same.

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21.3 Body shower station:

There shall be at least one body shower station facility per laboratory. Laboratory workers exposed to (splashes of large volumes) of infectious materials shall immediately use the shower facility for a minimum of 15 min. A mild disinfectant solution must be used to clean the area most exposed to infectious material. Report the incident to the Laboratory Manager.

22.0 Incident report:

Any accidental or negligent or untoward incidents occurring in the laboratory are documented in the institute incident report documentation form and will be filed in the incident report file.

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23.0 Fire safety:

Small bench-top fires are more common than large fires in labs. Labs, especially those using solvents in large quantities have a high potential for flash fires, explosion, rapid spread of fire and high toxicity of products of combustion.

23.1 Prevention:

23.1.1 Plan work:

- Majority of lab fires have resulted from menial staff or procedural errors or carelessness.
- Keep work area uncluttered and clean. Observe proper safety practices.
- Store solvents properly.
- Keep inflammable reagents in explosion proof cabinets.
- Wear proper clothing and personal protective equipment. Avoid working alone, whenever possible.
- Attend the training organized by the organization for use of emergency equipment (fire extinguisher.) when needed.

23.1.2 Emergency:

23.1.3 Know what to do - go by the emergency plan of the lab planned during the training sessions.

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23.1.4 Know where the things are - be aware of the closest fire extinguisher, hospital emergency services / maintenance department telephone number, emergency shower, first aid kit and exit(s).

23.1.5 Fire Procedure:

Notify - other occupants of the immediate space.

Evacuate- the immediate area of the fire if necessary.

If safe to do so- attempt to extinguish.

23.1.6 Fire Extinguishers:

(Note: an extinguisher is a first aid tool, do not expect it to control a big fire). **To use a portable extinguisher remember the acronym P.A.S.S.**

Pull the pin.

Aim extinguisher nozzle at the base of the flames

Squeeze trigger while holding the extinguisher upright

Sweep the extinguisher from side to side, covering the area of the fire.

23.1.7 Fire Training:

Training regarding fire safety is provided periodically to staff is necessary by the management.

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24.0 RECORDS:

All the records pertaining to the laboratory shall be maintained in the Laboratory as per the retention period and later will be forwarded to the Medical Record department after getting approval from the management for destruction of the same.

25.0 TRAINING OF TECHNICIANS :

25.1 Responsibility:

Primary Responsibility: Quality Manager

Secondary Responsibility: Laboratory Manager

25.2 Training Program:

The laboratory has defined a training program for the periodical training of the technical staff which will be documented.

25.2.1 All new joining staff shall be oriented to the department by the Laboratory Manager and will undergo induction training program at the end of which they will be assessed both for theory knowledge as well as practical performance.

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25.2.2 For those scoring less than 50% will, re-training will be conducted and will be assessed and even after the second session of training if they still score < 50%, the same will be communicated to the management for further action. Periodic training will be done once in 6 months.

25.2.3 Training needs of the staff is assessed by the head of the department based on the performance of staff.

25.2.4 Refer to Annexure -04 for topics for induction training program.

26.0 LIST OF EQUIPMENTS:

Refer to Annexure – 1

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27.0 ANNEXURES:

Sl. No.	Particulars
1	List of instruments in Microbiology Laboratory
2	Scope of microbiology services and Turn over time in Microbiology Laboratory
3	List of Staff and their Designation
4	Induction training program
5	Purchase Policy
6	Calibration of instruments

Annexure -1EQUIPMENT & INSTRUMENT LIST

Sl.no	NAME OF EQUIPMENT	QTY
1.	Refrigerator with Stabilizer	06
2.	VDRL Rotator	02
3.	Centrifuge	02
4.	Distilled water plant	02
5.	Hot air Oven	01
6.	Autoclave	03
7.	BOD Incubator	03
8.	Laminar flow	02

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9.	Physical balance	01
10.	Incubator	03
11.	Binocular Microscope	06
12.	BS Level II Laminar Air flow	01
13.	pH meter	01
14.	Serum Inspissator	01
15.	Anaerobic Apparatus	03
16.	Computer & UPS	03
17.	Water bath	01
18.	Digital balance	02
19.	Fully Automated ELISA with computer	01
20.	BACTEC Automated blood & body fluid culture system	01
21.	Deep Freezer(-20 ⁰ C)	01
22.	Candle Jar	02
23.	Finecare FIA machine	01

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ANNEXURE 2: Scope of Microbiology Services

Lists of tests for Microbiology and Serology:

Sl. No	NAME OF THE INVESTIGATION	SPECIFIC TEST PERFORMED	TEST METHOD	RANGE OF TESTING /LIMITS
1.	Urine/Swab/Sputum/ Fluids/Pus/ET aspirate	Direct Microscopy [Gram Stain]	Gram Stain [Hucker's Modification]	NA
2.	Urine/Swab/Sputum/Flu ids/Pus/ET aspirate	Direct Microscopy [Acid fast Stain]	Ziehl-Neelsen Staining	NA
3.	Serum	Determination of Rheumatoid Factor	Latex agglutination	≥ 8.0 IU/ml
4.	Serum	Determination of C-reactive protein	Latex agglutination	≥ 0.60 IU/dl
5.	Serum	Determination of ASO Titer	Latex agglutination	≥ 200 IU/ml
6.	Serum	Determination of antibodies to Salmonella typhi O, H and Salmonella paratyphi AH Antigen	Tube agglutination (Widal Test)	$\geq 1:20$ dilution
7.	Serum	RPR (Rapid Plasma Reagin)	Macro agglutination	Semiquantitative
8.	Urine (Mid-stream,	Culture	Semi quantitative culture (Modified	NA

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	Suprapubic & Catheter)		Mayo's method)	
9.	Blood	Culture	Standard Technique	NA
10.	Sterile fluid CSF, Synovial, Peritoneal, Pleural)	Culture	Standard Technique	NA
11.	Sputum	Culture	Standard Technique	NA
12.	Stool	Culture	Standard Technique	NA
13.	Fluids [CAPD, Ascitic fluid, etc.,]	Culture	Standard Technique	NA
14.	CVC Tip	Culture	Maki's Roll Plate method & Dilution plate method	NA
15.	Tracheal aspirate/ Broncho alveolar lavage/ Endotracheal tip	Culture	Semi quantitative culture	NA
16.	Pus	Culture	Standard Technique	NA
17.	Swab Culture	Culture	Standard Technique	NA
18.	Isolate identification	Biochemical tests	Standard Technique	NA

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19.	Semen	Culture	Standard Technique	NA
20.	Culture [colonies/growth]	Antibiotic Susceptibility	Modified Kirby Bauer Method	
21.	Oral scraping/Tissue/ nail clipping	Direct Microscopy	KOH wet mount	NA
22.	Serum/Plasma	HCV(rapid) qualitative detection of antibody to Hepatitis C virus	Rapid Immunochromatographic immunoassay	NA
23.	Serum/ Plasma	HBsAg (rapid) Qualitative detection of Hepatitis B surface Antigen	One step antigen capture(Sandwich) Immunoassay	≥5 ng/ml
24.	Serum/Plasma	HIV - Bioline	Immunochromatographi c assay	NA
25.	Serum/ Plasma/ Whole blood	Simultaneous detection of Dengue NS1 antigen and differential IgG/IgM antibodies to dengue virus	Immunochromatographi c assay	
26.	Serum/ Plasma	PCT, D- dimer, Trop I, NT Pro BNP	Fluorescent immuno assay	As per kit insert
27.	Whole blood	Detection of histidine rich protein II [HRP-II] specific to Plasmodium falciparum and Plasmodium lactate	Immunochromatographi c assay	NA

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		dehydrogenase [pLDH] pan specific to Plasmodium species.		
28.	Urine	Determination of human chorionic gonadotrophin [hCG] in urine	Qualitative , sandwich dye conjugate immunoassay	≥ 25 mIU/ml
29.	Serum	HBsAg	ELISA	
30.	Environmental Surveillance (OT Swabs,RO Water, Swabs)	Culture	Standard Technique	NA

Turnaround time

Sl. No	Investigations	Sample type	Processing Time	Expected Response Time
1	HIV Rapid Test	Serum 1-2 ml	1 hour	4 hours
2	HBsAg Rapid Test	Serum 1-2 ml	1 hour	4 hours
3	HCV Rapid Test	Serum 1-2 ml	1 hour	4 hours
4	ASO Titres	Serum 1-2 ml	1 hour	4 hours
5	Rheumatoid Factor	Serum 1-2 ml	1 hour	4 hours
6	C-Reactive Protein	Serum 1-2 ml	1 hour	4 hours

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7	Rapid Plasma Reagin Test	Serum 1-2 ml	1 hour	4 hours
8	Widal Tube Test	Serum 1-2 ml	24 hours	24 hours
9	Urine Culture (No growth)	Urine- Clean Catch Midstream urine	24 hours	24 Hours
10	Urine Culture and sensitivity(growth)	Urine- Clean Catch Midstream urine	48 hours	48 Hours
11	Pus/Swab Culture and sensitivity	Pus specimen	48 hours	48 Hours to 7 Days
12	BACTEC Culture and sensitivity	Blood 5 to 10 ml	24 hours to 5 days	24 hours to 5 days
13	Blood Culture and sensitivity	Blood 5 to 10 ml	48 Hours to 7 Days	48 Hours to 7 Days
14	CSF and Fluids Culture and sensitivity	CSF 1 ml	48 Hours to 7 Days	48 Hours to 7 Days
15	CVC Tip Culture and sensitivity	CVC tip in sterile container	48 Hours to 7 Days	48 Hours to 7 Days
16	Stool Culture and sensitivity	Stool in sterile container	48 Hours to 72 hours	48 Hours to 72 hours
17	Tissue Culture and sensitivity	Tissue specimen in sterile container without formalin	48 Hours to 7 Days	48 Hours to 7 Days
18	Surveillance	Swabs or Fluids	48 Hours to 7	48 Hours to 7

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	swabs/Fluids culture		Days	Days
19	RO water	Water sample as per guidelines	48 hours	48 Hours
20	Biological Indicators	Indicator tubes	48 hours	48 Hours
21	Gram Stain	Appropriate specimen	1 hour	4 Hours
22	Ziehl neelsen Stain for AFB	Appropriate specimen	1 hour	4 Hours
23	KOH Wet mount	Appropriate specimen	1 hour	4 Hours
24	Hanging drop	Stool specimen	20 mins	1 Hour
25	Negative staining for Cryptococcus	CSF/Fluids	20 mins	1 Hour
26	Fungal culture	Appropriate specimen	48 hours to 3 weeks	48 Hours to 1 month
27	Dengue ELISA	Serum 1-2 ml	8 hours	24 Hours
28	UPT	Urine 2 ml	30 mins	2 Hours
29	HBSAG ELISA test	Serum 1-2 ml	8 hours	24 Hours
30	MP Card	EDTA 2 ml	45 mins	2 Hours
31	MP Smear	EDTA 2 ml	45 mins	4 Hours

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TURN AROUND TIME FOR STAT

Policy

1. PCT, Troponin-1, D-dimer, nT-ProBNP, Gram's stain, ZN stain, negative staining and hanging drop will be processed and reported in 30 mins of receiving the samples.
2. All other stat microbiology samples will be processed and reported within 2 hours of receiving the samples.
3. Oral communication shall be given to the concerned clinician and documented.
4. The clinician requesting for emergency reporting need to mention as "stat samples" on the requisition form.
5. Only those samples labeled as "stat samples" on the requisition forms shall be processed immediately on emergency basis.

The following are the tests that can be processed as STAT samples

Sl no.	Test	TAT
1.	PCT	30 minutes
2.	Troponin-1	30 minutes
3.	D-dimer	30 minutes
4.	nT-ProBNP	30 minutes
5.	Gram's stain	30 minutes
6.	ZN stain for AFB	30 minutes
7.	Hanging drop	30 minutes
8.	Negative staining	30 minutes
9.	HIV rapid test	1 hour
10.	HBsAg rapid test	1 hour
11.	HCV rapid test	1 hour
12.	ASLO titres	1 hour
13.	C-Reactive protein	1 hour
14.	RPR test	1 hour

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Annexure – 3 List of Staff and their Designation

Sr. No.	Name of the staff	Designation	Educational qualification	Experience		
				Present	Previous	Total
1.	Dr.Sangeetha.S	Professor and HOD	MD in Microbiology	10 yrs 1 month	8 yrs	18 yrs 1month
2.	Dr. Prakash R	Associate Professor and lab Manager	MD in Microbiology	2 years 2months	7 years 9 months	9 years 11 months
3.	Dr. Lakshminarayana S A	Assistant Professor and Section incharge, Bacteriology	MD in Microbiology	4 years	6 years 4 months	10 years 4 month
4.	Dr.Vishwajith (Quality manager)	Asst.Professor, Section incharge, Parasitology	MD in Microbiology	3 year 3 months	3 years	6 years 3 months
5.	Dr.Yashashwini MK	Asst.Professor and Section incharge, Mycology and Media	MD in Microbiology	2 years 9 months	3 years	5 years 9 months
6.	Dr. Santhoshini Vaijinath	Asst.Professor	MD in Microbiology	2 years 6 months	3 years	5 years 6 moth
7.	Dr. Archana Rao K	Asst.Professor	MD in Microbiology	2years 6 months	3 years	5 years 6 months
8.	Dr. Kanthishree	Asst.Professor	MD in Microbiology	2 year	3 years	5years
9.	Dr. Kirtilaxmi KB	Asst.Professor	MD in Microbiology	1 year	6years	7years
10.	Dr. Nandini L	Asst.Professor	MD in Microbiology	1 year 5months	4years	5years 5 months
11.	Dr. Archana BR	Asst.Professor	MD in Microbiology	2 year 2 months	4 years	6years 2 months

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Annexure 4: Induction Programme for freshers

1. Faculty

Fresh faculty will be posted to various sections for observation of work flow and procedures for a period of three months. They will be made authorized signatory for reports after this period under supervision by section heads.

2. Technicians

Technicians will be posted on rotation to various sections for observation of workflow and procedures for a period of 3 months. They will be allowed to conduct tests independently under supervision by technician in-charge of section.

3. Computer operator.

Computer operator will be posted on rotation to various sections for observation of work flow and procedures for a period of 1 month. After this period they will be allowed to type reports under supervision of senior computer operator.

4. Lab attenders

Lab attenders will be posted on rotation to various sections for observation of workflow and procedures for a period of 1 month and after this period under supervision by senior lab attenders.

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Annexure 5: Purchase policy

1. Equipment

Based on demand from clinicians increase in workload and to impart quality in generation of lab reports, a purchase request is placed to purchase departments. Equipment is purchased based on sensitivity, specificity, reduction of turnaround time and cost of the hospital.

2. Media kits and reagents

Minimum stock of one month is maintained in the department of microbiology.

Annexure 6: Calibration of instruments

Will be done on annual basis for all instruments in the department of microbiology under supervision by biomedical department and concerned section in charge.

Annexure 7: TURN AROUND TIME FOR OUT SOURCE SAMPLE

Sl. No	Test Code	Test Description	TAT
1.	AHCV	ANTI HEPATITIS C VIRUS-TOTAL (AHCV)	24-36 hours
2.	ASO	ANTI STREPTOLYSIN-"O"(ASO)	24-36 hours
3.	C3	COMPLEMENT 3 (C3)	24-36 hours

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4.	C4	COMPLEMENT 4 (C4)	24-36 hours
5.	CD4	CD4+T HELPER CELLS PERCENTAGES OF CD3	24-36 hours
6.	CM_AV	CYTOMEGALOVIRUS AVIDITY	24-36 hours
7.	CM_G	CYTOMEGALO VIRUS(CMV)- IgG	24-36 hours
8.	CM_M	CYTOMEGALO VIRUS(CMV)- IgM	24-36 hours
9.	CRP	C-REACTIVE PROTEIN (hsCRP)	24-36 hours
10.	EAG	HEPATITIS B ENVELOPE ANTIGEN (HBeAg)	24-36 hours
11.	AHAVIG M	ANTI HEPATITIS A VIRUS(HAV)-IgM	24-36 hours
12.	AHAVT	ANTI HEPATITIS A VIRUS- TOTAL ((HAVT)	24-36 hours
13.	HC_G	HERPES SIMPLEX VIRUS (HSV)- IgG	24-36 hours
14.	HC_M	HERPES SIMPLEX VIRUS (HSV)-IgM	24-36 hours
15.	HEVM	ANTI HEPATITIS E VIRUS (HEV)-IgM	24-36 hours
16.	HIVE	HIV (AG/AB)COMBO ASSAY	24-36 hours
17.	HS1G	HERPES SIMPLEX VIRUS I (HSV)-IgG	24-36 hours
18.	HS1M	HERPES SIMPLEX VIRUS I (HSV)-IgM	24-36 hours

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19.	HS2G	HERPES SIMPLEX VIRUS II (HSV)-IgG	24-36 hours
20.	HS2M	HERPES SIMPLEX VIRUS II (HSV)-IgM	24-36 hours
21.	IGA	IMMUNOGLOBULIN A (IgA)	24-36 hours
22.	IGG	IMMUNOGLOBULIN G (IgG)	24-36 hours
23.	IGM	IMMUNOGLOBULIN M (IgM)	24-36 hours
24.	LP_M	LEPTOSPIRA-IG M	24-36 hours
25.	RB_AV	RUBELLA AVIDITY	24-36 hours
26.	RB_G	RUBELLA (RUB)-IgG	24-36 hours
27.	RB_M	RUBELLA (RUB)-IgM	24-36 hours
28.	RFAC	RHEUMATOID FACTOR (RF)	24-36 hours
29.	SAG	HEPATITIS B SURFACE ANTIGEN (HBSAG)	24-36 hours
30.	TIGE	TOTAL IgE(TIGE)	24-36 hours
31.	TX_AV	TOXOPLASMA AVIDITY	24-36 hours
32.	TX_IGG	TOXOPLASMA GONDII(TOXO)-IgG	24-36 hours
33.	TX_IGM	TOXOPLASMA GONDII(TOXO)-IgM	24-36 hours
34.	WEST	WESTERN BLOT	24-36 hours
35.		TORCH ALL TEN	24-36 hours
36.		TORCH ALL EIGHT	24-36 hours

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**PATHOLOGY LABORATORY
SERVICES**

DEPARTMENT MANUAL

Doc. No. NABH/RRMCH/DM/Path/02

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Service Name :

QUALITY MANUAL

DEPARTMENT OF PATHOLOGY NABH/RRMCH/LAB/01

Date Updated :

05.02.2019

Approved By :

Medical Superintendent

Name : Dr.Govindaraj K M

Signature :

Issued By :

Head of the Department

Name : Dr. Sharmila P.S

Signature :

Responsibility of Updating :

Professor

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Technical Manager

Name: Mrs. Vani Bai, Mr.S.H Sathish, Mrs.Jomy John

Signature:



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AMENDMENT SHEET

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1	Section 5, Page No. 3	Department Hierarchy	Change of HOD and faculty		
2	Section 7, Page No. 5, 6	List of technicians including Blood Bank	New technicians staff joined		
3	Section 14.5.4.11, Page No. 29, 30	Disposal of Biomedical waste	Upgradation		
4	Section 13.1.4.11, Page No. 26	Retention period for Frozen Section and Immunohistochemistry	Upgradation		
5	Section 20.0, Page No. 34 -36	List of equipments	Upgradation		



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1.0 PURPOSE:

1.1 The objective of this document is to define the services that will be provided by Department of Pathology, RRMCH.

2.0 SCOPE:

2.1 The scope of this document is restricted to the services provided by RRMCH.
The following scope of services: Pathology.

3.0 ABBREVIATIONS:

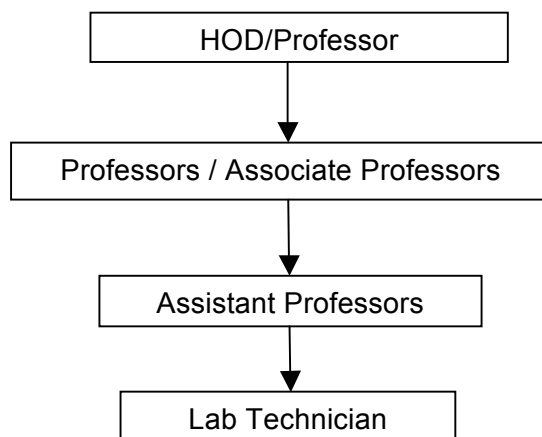
3.1 NABL: National Accreditation Board of Laboratories.

3.2 HOD: Head of the Department

4.0 RESPONSIBILITY:

HOD of Laboratory and Technicians

5.0 DEPARTMENTAL HIERARCHY:



6.0 COMPETENCY MATRIX:

Sr. No.	Name of the staff	Designation	Educational qualification	Experience		
				RRMCH	Previous	Total
1	Dr.Sharmila P.S	Prof. & HOD	M.D Pathology	13yrs 1mth	8yrs 2mths	21yrs 3mths
2	Dr.V.Mahanthachar	Professor	M.D Pathology	11yrs 4mths	9yrs	20yrs 4mths



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3	Dr.C.J.Prakash	Professor	M D Pathology	3yrs 4mths	30yrs	33 yrs 4mths
4	Dr.Jyothi A Raj	Professor	M.D Pathology	13yrs 8mths	4yrs 5mths	18yrs 3mths
5	Dr. Vamseedhar Annam	Professor	M.D Pathology	2yrs 4mths	13yrs 2mths	15yrs 6mths
6	Dr.S.Shweta Jayker	Assoc. Professor	M.D Pathology	6yrs 6mths	3yrs 7mths	10yrs 1mth
7	Dr.Shashikala.K	Assoc. Professor	M.D Pathology	6yrs 7mths	3yrs	9yrs 7mths
8	Dr.Nalini M	Assoc. Professor	M.D Pathology	4yrs 9mths	3yrs	7yrs 9mths
9	Dr.Sumitha M P	Asst. Professor	M.D Pathology	3yrs 7mths	3 yrs	6yrs 7mths
10	Dr.Anisha T S	Asst. Professor	M.D Pathology	3yrs 8mths	3yrs	6yrs 8mths
11	Dr.Latha.V	Tutor	DCP Pathology	14yrs 7mths	2 yrs	16yrs 7mths

7.0 Technicians List - Department of Pathology

Sl. No	Name	Designation
1	Mrs.Jyothilakshmi.N	Technician
2	Mr.Paramesha.T	Technician
3	Mrs.J.Vijayalakshmi	Technician
4	Mr.S.H.Sathish	Technician
5	Mrs.Sandana Mary	Technician
6	Miss.Vani Bai.B.N	Technician
7	Mrs.Kamala.L	Technician
8	Mrs. Jomy John	Technician
9	Mr.Shivaramu.N	Technician
10	Miss.Husna Banu	Technician
11	Miss.Sunitha.N.S	Technician
12	Mr.Manikantan	Technician
13	Mr. Hemanth Prabhu	Technician
14	Mr.Lokesh.M	Technician



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15	Mr.Pavan Kumar.M	Technician
16	Mrs.Poncy Shaji	Technician
17	Ms. Kavitha K M	Technician
18	Ms. Neelavva	Technician
19	Mr. Yatish K	Technician
20	Ms. Elavarsi	Technician
21	Mr. Huttresh M Lamani	Technician



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Blood Bank -Technicians List

Sl.No	Name	Designation
1.	Mr. Ramalingaiah	Technical Supervisor
2.	Mr. Shiva Kumar	Technical Supervisor
3.	Mr. Shivakumar Swamy	Technician
4.	Mrs. Manjula	Technician
5.	Mr. Siddappa	Technician
6.	Ms. Vijaya Nirmala	Technician
7.	Mr. Manjappa	Technician

8.0 ROLES AND RESPONSIBILITIES:

- 8.1 **Pathologists:** For technical management of Histopathology, Cytology, Clinical Pathology & Hematology sections of Pathology department. Has standing deputation of the department to perform administrative responsibilities of Chief Consultant in the latter's absence.
- 8.2 **Laboratory In charge:** Administration & Management of laboratory activities to meet the requirements commensurate with organizational objectives. Reviewing of existing tests/methodologies/equipments and authorizing for new ones. Laboratory resource planning/deployment/ utilization to meet the requirements. To resolve interdepartmental issues in consultation with the Senior Consultant and heads of divisions. To monitor and implement effectively Quality Assurance program. To implement this manual, as well as quality system procedures laid down in the Quality manual. Reviewing of functional modalities and to direct to implement Corrective/Preventive actions when anomalies observed.
- 8.3 **Laboratory Technicians:** Technical Management of Clinical Pathology & Hematology division of the department. To perform various kinds of laboratory investigations as per protocols/guidelines/instructions laid down in the documented procedure sheets/manuals. Daily/Weekly maintenance of equipments/apparatuses scheduled under preventive maintenance process or as per demands of the situation/instructions of divisional heads



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Calibration/verification of equipments/ methods as per approved procedures and protocols. Implement Quality Assurance procedures predefined. Clinical procedures shall be done: Collection, transportation and preservation of biological samples. To keep good housekeeping in the Lab commensurate with safety standards applicable assisted by Lab. attendants.

8.4 Laboratory Attendants: To carryout daily Housekeeping / waste management activities. To assist Lab. Assistants for the collection, transportation and preservation of biological samples. To ensure un-interrupted supply of consumables/re-usable as per demand of the work flow. To provide items for reuse after recommended washing, cleaning and drying.

8.5 Phlebotomist: The phlebotomist represents the laboratory and should uphold the quality standards of Laboratory. He / she should always bear in mind that his conduct and actions on duty towards the patient and Doctor directly reflects the quality assurance standards given by the Laboratory. Principal responsibility includes Patient preparation, specimen collection, specimen storage and specimen dispatch. Additionally an efficient and courteous handling of queries, clear communication about specimen requirements, test schedule, report delivery time must be done in proper steps to minimize confusion and delay of these services.

9.0 DEPARTMENT WORKING HOURS:

9.1 Each shift duty shall have the following staff on duty.

Sl. No	Designation	Working hours	Shift timings
1	Pathologist	7 hours	9.00AM to 4.00PM
2	Lab Incharge	7hours	9.00AM to 4.00PM
3	Lab Technician	7 hours	9.00 AM to 4.00 PM
		6 hours	2.00 PM to 8.00PM
		13 hours	8.00 PM to 9.00AM
4	Cleaning Staff	8 hours	8.00AM to 4.00PM

10.0 REFERENCE TO NABH STANDARDS:

S.No	Chapter	Relevant NABH Standard / Objective Element



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1.	Access assessment and continuity of care	The organization has a well defined registration and admission process AAC.2. A – E.
2.	Access assessment and continuity of care	Laboratory services are provided as per the scope of services of the organization AAC 6. A – H.
3.	Access assessment and continuity of care	There is an established laboratory quality assurance programme. AAC 7. A – E.
4.	Access assessment and continuity of care	There is an established laboratory safety programme. AAC .8. A – E.
5.	Access assessment and continuity of care	Patient care is continuous and multidisciplinary in nature AAC.13. A – F.
6.	Patient rights and responsibility	A documented procedure for obtaining patient and / or family's consent exists for informed decision making about their care. PRE .4 A – H.
7.	Hospital infection control	Proper facilities and adequate resources are provided to support the infection control programme HIC.5. A – D.
8.	Hospital infection control	Statutory provisions with regard to Bio medical waste (BMW) management are complied with HIC.8.A – F.
9.	Continuous Quality Improvement	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tool for continual Improvement. CQI.3.
10.	Continuous Quality Improvement	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tool for continual improvement CQI.4.
11.	Responsibility of Management	The service provided by each department are documented ROM.3.

11.0 POLICIES:

11.1 Scope of Services:

11.1.1 Laboratory service for outpatients & inpatients in different sections of Department of Pathology:



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11.1.2 Hematology.

11.1.3 Clinical Pathology.

11.1.4 Cytology.

11.1.5 Histopathology.

11.2 General Procedure:

11.2.1 The Department of Pathology, RRMCHospital is performing various lab investigations.

11.2.2 All the tests are done as per the protocol of standard test procedures which are available.

11.2.3 The individual samples are processed as per standardised test procedures by manual, semi-automated and automated techniques.

11.2.4 All the results of the laboratory investigations are available for the physicians or patients as per the time frame according to the laboratory test schedule.

11.2.5 All the critical results and the results of Emergency Departments like ITU, ICU and Casualty are intimated immediately to the concerned physician, ward Medical officers or the ward in-charge.

11.2.6 The investigations which are not available in the department are sent to the NABL Accredited Laboratories, which are maintaining Quality Assurance Procedures. The outsourced to Anand diagnostics Laboratory.

11.2.7 Samples are sent in a safe and secure manner as per QA protocol.

12.0 PROCEDURES:

12.1 Sample collection Procedure:

12.1.1 **Purpose:** To provide guidelines on sample collection.

12.1.2 **Scope:** Applicable to all laboratory divisions.

12.1.3 **Responsibility: The responsibility of Phlebotomist:** The phlebotomist shall be qualified and trained personnel. He / she should always bear in mind that his conduct and actions on duty towards the patient and Doctor directly reflects the quality assurance standards given by the Laboratory. Principal responsibility includes Patient preparation, specimen collection, specimen storage and specimen dispatch. Additionally an efficient and courteous handling of queries, clear communication about



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specimen requirements, test schedule, report delivery time must be done in proper steps to minimize confusion and delay of these services.

12.1.4 Labeling the samples: No sample / specimen should be collected or allowed without proper labeling. The tests requested on the Requisition Form should be verified before proceeding with the collection. In case of any doubt or incomplete requisition form received then, the referring doctor may be contacted for further clarification. The request form shall have the following information:

12.1.4.1 Name of the patient. Age & gender. OP number. Date. Consultant's name. Investigations required. Clinical history of the patient.

12.1.4.2 The phlebotomist should check for the following information before sample collection: Specimen requirement and quantity. Special collection instructions like preservatives & sterile containers to be used.

12.1.5 Allotting Lab ID & Labeling: After receiving request form, check whether the bill was raised properly for the required tests or not. Enter the bill number, patient details and test particulars in the reception register and allot an individual Lab ID for the specific patient sample. Note down the time of specimen collected / received. Note down the type of patient, i.e., Outpatient or Inpatient. Label the vacutainers and other collection vials with the Lab ID allotted and specimen type. Collect appropriate specimen and quantity so as to avoid redraws and inconvenience to the patient. If the patient required investigations with Urine, Stool and other specimens, label the required container with proper Lab ID and ask the patient to collect the sample in that particular container.

12.1.6 Basic steps for drawing a blood specimen:

12.1.6.1 Check and confirm with the patient details given on the Requisition Form. Assemble the vacutainers, collection vials, spirit swab, and tourniquet etc, required for phlebotomy. The phlebotomist should select the appropriate type of needle based on patient's physical characteristics and amount of blood to be drawn. The patient should be made to sit comfortably in a chair and should position his arm on a slanting armrest, extending the arm straight from the shoulder without bending at the elbow. If the



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patient wants to lie down, let the patient lie comfortably on the back. The patient should extend the arm straight from the shoulder.

- 12.1.6.2 **Selection and preparation of vein site for blood collection:** For most vein puncture procedures on adults, veins located on the arm are used. The median cubital vein is most commonly used.
- 12.1.6.3 **The following conditions should be avoided while selecting a vein:** Vein from area having extensive scarring. Phlebotomy must not be performed on any size of hematoma. Blood should not be collected from the arms having intravenous site.
- 12.1.6.4 **Locating Veins:** To locate veins it is necessary to palpate and trace the path of the vein several times with index finger.
- 12.1.6.5 **Alternate site:** Site such as dorsal wrist or hand and ankles or lower extremities may be required for patients with difficult veins.
- 12.1.6.6 **Applying a tourniquet:** A tourniquet is used to increase venous filling. This makes the vein more prominent and easier to enter. Wrap the tourniquet around the arm 3 to 4 inches above the vein puncture site. The tourniquet should never be left on the arm for more than 2 minutes, because it prevents blood from flowing freely. After blood has been drawn, the patient should release the fist and the tourniquet is also released and then the needle is withdrawn from the vein with simultaneous application of cotton at the vein puncture site.
- 12.1.6.7 **Cleaning of the vein puncture site:** The puncture site must be cleansed to prevent microbiological contamination of the specimen and infection at the vein puncture site. A cotton ball should be soaked in the spirit, excess should be dripped away. The cleaning should start from the vein and move out in circular motion towards the outer surface. Once disinfected, this site should not be touched with bare hands.
- 12.1.6.8 **Preventing Hematoma during vein puncture:** The tourniquet should be released after no more than one minute. Local stasis can occur with hemoconcentration and the possible formation of a hematoma due to infiltration of blood into tissue. Remove the tourniquet before removing the needle. Puncture only the uppermost wall of the vein. Use the major veins. Do not make partial penetration with the needle. Apply a small amount of pressure to the area with cotton after blood collection.



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- 12.1.6.9 **Collection of blood from pediatric patients:** Pediatric collections should be done with the help of scalp vein needle.
- 12.1.6.10 **Procedure to be followed post blood sample collection:** A cotton ball is held firmly over the vein puncture site as soon as the needle is removed. After checking that there is no blood flow, the patient is given a cotton ball to be held at the site of vein puncture that has to be removed after 5 minutes. In case continuous bleeding, apply pressure to the site with a cotton ball and ask the patient to keep it for 15 minutes.
- 12.1.6.11 **Urine collection for routine Exam:** First voided mid stream specimen is the best specimen for examination. Patient must be instructed to void directly into the container provided. During the collection the initial portion of the urine stream is allowed to escape, while the mid stream portion is collected.
- 12.1.6.12 **Sputum sample collection:** Sample is collected by the nursing staff in OPD or bedside and dispatched immediately to the laboratory.
- 12.1.6.13 **Collection of Body Fluids (Pleural fluid, ascitic fluid, peritoneal fluid, Synovial fluid and CerebroSpinal fluid):** Sample is collected by the clinician in OPD or bedside and dispatched immediately to the laboratory.



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12.1.6.14 Containers to be used for testing specimen in Pathology:

Specimen	Type Of Containers to be used
Cerebro Spinal Fluid	Sterile screw cap plastic container
Ascitic Fluid	Sterile screw cap plastic container
Pleural Fluid	Sterile screw cap plastic container
Synovial Fluid	Sterile screw cap plastic container
Peritoneal Fluid	Sterile screw cap plastic container
Bronco Alveolar Lavages	Sterile screw cap plastic container
Urine / Stool / Sputum	Sterile screw cap plastic container
Blood	3-5 ml of blood in EDTA or plain vacutainers.
Biopsy specimen	In adequately sized containers with sufficient quantity of formalin or other fixative.

12.1.6.15 Receiving the biopsy specimen and fixed smears for pathological study: While receiving the biopsy specimen and smears, verify the following details: The test requisition form must have the patient details, Type of specimen, site of specimen, clinical history and diagnosis. The specimen container should have the details of patient and nature of specimen. Verify the specimen or slides whether it was kept in proper fixative or not. Enter all the details in the Histopathology register including date and time of specimen received. Give the proper information to the patients or patient attendants regarding reporting date.

12.1.6.16 Fixatives used for Pathology study:

12.1.6.16.1 Isopropyl Alcohol - To fix smears for cytology study.

12.1.6.16.2 10% formalin - To keep biopsies.

12.1.6.16.3 Bouin's fluid - To keep bone marrow biopsies.

12.1.6.16.4 Note: the fixative must be 10 to 20 times more the volume of the specimen.



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12.1.6.17 Anticoagulants for various investigations:

Investigations	Specimen type
Hematological testing (cell counts)	EDTA Blood
E S R	EDTA Blood
PT & APTT	Buffered 3.2% Tri- Sodium Citrate solution. (1 part citrate + 9 parts blood)
Out sourced lab investigations	According to the concerned lab procedures

12.1.6.18 Transporting samples to the Main Lab: The samples collected in the wards shall be placed in the Sample collection box provided and carry to the Pathology Laboratory. Do not carry the samples or sample containers without collection boxes. Before sending to the Main lab, all the specimens must be rechecked for proper labeling and Lab ID given. Kept the specimens in the sample collection box and handover in the Main lab along with TRF & Bill. After receiving the sample, label the vial with lab ID and name of the patient enter in the register. Handover to the concerned technician and take his/her signature. After receiving report enter report status and reporting date in the register.

12.1.6.19 Dispatching Laboratory Reports: After completion of the investigations in the laboratory, get the typed reports. Signed by technical in-charge and Consultant - Lab. Note the test results in the Lab Main Register. For outpatient reports ask the patient / patient attendant to show the copy of the receipt and check the reports by comparing the bill number and issue the reports and get signature in the report dispatching register. For In patient reports, enter the ward / room number, name of the patient and time of issuing report in the Report Dispatching Register. Handover the reports to the concerned ward in charge / staff and get the signature. For the patients newly admitted, enquire about ward / room number from casualty and confirm by contacting the ward in charge, then handover the reports to the concerned person. For the reports of Outsourced tests, Special tests like Tumor markers, Biopsy reports and get the receivers signature in the particular register.

12.1.6.20 Turn Around Time: For the time of reporting, Please refer the table of TAT for the laboratory test reporting. It is the time from sample collection to report ready for dispatching.



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I) HISTOPATHOLOGY

Test Name	Duration (in working days)
1) Biopsy small	3 days
2) Large surgical specimen	6 days
3) Immunohistochemistry	7 days
4) Frozen Section	< 1hr

II) CYTOLOGY

Test Name	Duration(in working days)
1)FNAC a) Palpable mass	1 day
b) Under image guidance	1 day
2) Pap smear	1 day
3) Body fluid cytology	4-6 hours
4) Intraoperative cytology	30 mins -1 hr.

III) HEMATOLOGY

Test Name	Duration (in working days)
1) CBC	Same day within 6 hours
2) HB	Same day within 6 hours
3) TC	Same day within 6 hours
4) DC	Same day within 6 hours
5) ESR	Same day within 6 hours
6) Platelet Count	Depending on the criticality, 4-6 hours
7) Reticulocyte count	1 Day
8) Peripheral smear	1 Day
9) Complete hemogram	1 Day
10) Bone marrow	1 Day
11) PT& APTT	4 hours
12) BT &CT	30mins

IV) CLINICAL PATHOLOGY

Test Name	Duration (in working days)
1) Urine analysis	
Routine	6 Hours



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BS, BP	
Ketone bodies	
2) Semen analysis	12.□.□.□ day

12.1.6.21 Rejection criteria for unacceptable samples: The samples must be rejected for the following reasons: Insufficient quantity of the sample. If the specimen quality is not acceptable (hemolysed /clotted/ lipemic / etc.). Incorrect specimen type, test name and labeling. If the test cancelled either on request of the patient or doctor. In case of INVALID RESULTS got for various technical reasons. (A repeat, fresh sample will be collected and sent for testing). In the event of unforeseen circumstances like non-availability of kits, failure of test runs, instrument break down, etc. In case the biopsy specimens are not collected in adequate formalin.

12.1.6.22 Critical Tests:

12.1.6.22.1 Purpose: To ensure immediate reporting of critical values / results to appropriate care providers to enable provision of timely, appropriate treatment to the patient.

12.1.6.22.2 Scope: All critical cases.

12.1.6.22.3 Responsibility: All laboratory Technicians.

12.1.6.22.4 Definition: A critical test is defined as a stat test with critical values/ results or other results that are determined by the laboratory to be critical to the patient's subsequent treatment decisions.

12.1.6.22.5 Procedure: All critical results and critical values must be called immediately to the Consultant or attending physician (Medical officer) or ward in-charge. Documentation of the call including time and date and who received the critical value/result must be made as a permanent part. All shall be recorded in critical report intimation register properly.

12.1.6.23 Critical values:

Test	Patient Age	Critical Value	
		High	Low
Hematology			
Hemoglobin	All	> 20 gm/dL	< 6 gm/dL
Leucocyte count	All	>50,000 cells /mm ³	< 1000 cells /mm ³



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APTT	All	> 50 seconds	NA
PT, INR	All	≥ 30 sec	NA
INR		> 6.5	NA
Platelets	All	> 10 Lakh cells /mm ³	< 50,000 cells /mm ³
Falciparum malaria	All		Positive
Cytology & Histopathology			
Malignancies	All		Positive

12.1.6.24 Outsourcing Tests: Purpose:

12.1.6.24.1 To establish Standard Operating Procedures for Outsourced Laboratory Tests.

Scope: Some of the tests that cannot be performed by the laboratory are outsourced to outside Laboratories and diagnostic centers. The hospital has recognized the Laboratories and diagnostic centers as per their quality assurance program such as NABL accreditation for Laboratories.

12.1.6.24.2 Responsibility: All consultants and Laboratory management.

12.1.6.24.3 Definition & abbreviations: NABL: National Accreditation Board for Laboratories.

12.1.6.24.4 Procedure: Samples to be sent to outsourced laboratories are registered in the same way as other tests performed in-house and the bill was generated. Laboratory samples are either collected by the outsourced Laboratory or sent to them. Specimens are transported in special leak proof boxes are used for transportation. These boxes shall prevent any breakage or damage to the specimen container.

13. Laboratory Quality Assurance Programme:

13.1 Purpose: The Quality Assurance manual for clinical Laboratory performing Clinical Pathology, Hematology, Serology, Cytology, and Histopathology tests provides the details of quality assurance practices followed in the Laboratory.

13.2 Scope: These guidelines, Policies and Procedures describe quality assurance activities that laboratories shall follow to ensure its competency, quality and integrity of its reports. The scope of the manual extends to the tests performed in the Laboratory Medicine Units – Hematology, Clinical Pathology, Serology, Histopathology and Cytology



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13.3 Responsibility: HOD and all laboratory Technicians.

13.4 Definitions & Abbreviations: As used in these guidelines, the following terms have the meanings specified: **Audit** is an inspection used to evaluate, confirm, or verify activities related to quality. **Calibration** is a set of operations that establish, under specified conditions, the relationship between values provided by a measuring instrument, measuring system, and a known material or known values. **Control samples or known samples** are test materials whose identity, type, or values have been established are used to assess the performance of a laboratory or an individual(s). **Quality assurance** is the system of management activities designed to ensure that a process item, or service is of the type and quality needed, this includes monitoring activities that are intended to verify whether practices and test results are providing reliable and relevant information. **Quality control** is a mechanism or laboratory activity intended to verify whether test conditions are functioning appropriately to yield reproducible results. **Quality manual** is a document stating the quality policy, quality system, and quality practices of an organization. **Validation** is a process by which a procedure is evaluated to determine its efficacy and reliability for analysis.

13.5 Procedure:

13.5.1 Organizations and Management: Medical Team: consists of consultant Pathologist. Technical Personnel includes Laboratory in-charge, technicians and Assistants. Refer Annexure for Job description and specification of Laboratory technical and Assistant. Refer Annexure for Job description and specification of Laboratory In-charge. The HR department maintains the records on the relevant qualifications (including college transcripts), training, skills, and experience of all technical personnel. All the personnel have been trained and department maintains a documented program to ensure technical and continuing education programmes. All personnel are evaluated annually through performance appraisal.

13.5.2 Documentation Requirement: It is important for the hospital to maintain control over the distribution, updating, and storage various documents. This is to make sure that the staff receive and use proper and the latest systems and procedures and related material. An effective document control will result in reduced costs by helping eliminate wasted effort and material due to the use of improper documents.



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It will also ultimately result in increased business due to customer satisfaction from getting expected services. The following are the four levels of documents introduced as part of Quality Management System and being implemented and controlled: Quality Assurance Manual. Laboratory Safety manual. Standard operating procedures and Policies for each test. Work instructions.

1 Document Approval and Issue: To avoid using documents that are incorrect, inadequate, or unauthorized, it is the hospital's policy that authorized personnel always reviews these documents for adequacy and approves them prior to issue. The pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed, and obsolete documents are promptly removed from all points of issue or use.

2. Sample collection manual: This manual is collection of SOPs, which establishes guidelines for collection of various specimens, based on site of collection of specimen, type of container, identification, Handling and transportation of the specimen. This manual is available in work area and reviewed annually.

3. Standard procedures for all tests: SOPS, which define test performance, reference ranges; specimen acceptability, reagent preparation, QA calculations and reporting of the tests are available in work area and reviewed annually. Required elements include: Step by step performance of the procedure, including test calibrations and interpretation of results. Preparation of slides, solutions, calibrators, controls. Reagents, stains and other materials used in testing. Calibration and calibration verification. The reportable range for test results: Quality control procedures. Corrective actions to taken when calibration or control results fail to meet the laboratory's criteria for acceptability. Limitations in the test methodology, including interfering substances. Reference intervals. Imminently life threatening test results (critical values). The system for reporting imminent life threatening results (critical values). Critical results are intimated



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immediately to the concerned personnel. Procedure manuals may be in hard copy or electronic format (**Ref. Department wise SOPs**).

13.5.3 Quality Management System: The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies evaluates and resolves problems.

13.5.3.1 Pre-analytical system: Test requests and patient identification. Samples are marked with unique identifiers. See sample collection manual. Documentation of sample identity, receipt, storage, and disposition is maintained. Criteria for specimen acceptance: No sample / specimen shall be allowed into the Laboratory without proper TRF. **While receiving the specimens into the laboratory, check for the following information.** Each specimen must have the corresponding TRF and Bill. Nature of the specimen & Quantity of the specimen required. Check for the proper labeling and Lab ID allotted. In case of any doubt, the referring doctor may be contacted for further clarification. Separate and distribute the samples to the sections according to the tests required. **Identification of tests required:** Note down the test details in the Lab Work Registers provided in the sections. Note Lab ID, Name of the patient, Patient type (OP or IP), Ward number if IP and the tests required for the patient. Note down the Time of sample received into the Laboratory.

13.5.3.2 Analytical system: Procedure manuals.

- a) **Test systems:** Test systems are selected by the Laboratory. Test systems must be performed following the manufacturer's instructions and in a manner that provides test results with in the laboratory's stated performance specifications.
- b) **Calibration and calibration verification procedures of Equipments:** The laboratory uses equipment suitable for the methods employed. The laboratory identifies shall have a documented program for calibration and,



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when appropriate, monitoring instruments and equipment. The frequency of the calibration is documented for each instrument requiring calibration which is maintained by Bio medical Department of RRMCH.

- c) Verification and validation of performance specifications:** The laboratory compares patient test results for consistency with patient age, sex, diagnosis or pertinent clinical data, and relationship with other test parameters. For each test system, the clinical laboratory has established a control procedure to monitor the accuracy and precision of the complete analytic process. At a minimum, the quality control process will detect: Immediate errors and errors occurring over time. Errors occurring due to test system failure. Environmental condition changes. Operator performance.
- d) External Quality Assurance Programme:** External quality control materials are used to monitor the accuracy and precision of the test system. The laboratory is enrolled with All India Institute of Medical Sciences, New Delhi for Histopathology and Hematology and Christian Medical College, Vellore for coagulation studies.
- e) Internal Quality Assurance Programme:** For each quantitative procedure, two levels of quality control material are used (Normal & Pathological), for which values are already known. Calibrators of different lot numbers and concentration are used to calibrate the system.

13.5.3.3 Postanalytic system: Test reporting: The laboratory maintains written procedures for generating and maintaining documentation for tested samples. The laboratory maintains written procedures for the release of tested sample information. The laboratory maintains the following examination documentation: Analyst / technician - generated notes, to include identity of person generating notes. Date and time of analysis completed. **Review of reports:** The laboratory follows written procedures for technically reviewing all tested samples information and results. The technical review is conducted by a technically qualified individual other



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than the preparer of the report, notes, data and other documents under review. All the laboratory reports are verified and signed by qualified Pathologist. The histopathology slides and blocks will be issued to the patient on request to the pathologist. Normal ranges where appropriate are provided. Errors in patient's reports will be corrected in timely fashion.

Complaints about lab investigations: The laboratory has a system in place to ensure that it documents all the complaints and problems reported to the laboratory. **Corrective and Preventive actions:** The laboratory follows procedure for corrective action whenever analytical errors and / or proficiency testing discrepancies are detected. The laboratory maintains documentation for the Corrective & Preventive actions.

13.5.3.4 Retention period for Specimen, Registers, Reports:

13.5.3.4.1 Hematology:

1. Complete blood count – 24 hours at 2 to 8° C
2. Coagulation screening test – 6 to 8 hours at 2 to 8° C
3. Bone marrow aspiration and biopsy – slides and blocks - 5 years.

13.5.3.4.2 Clinical Pathology:

1. Semen analysis slides – 1 week.
2. Urine routine – < 24hrs.
3. Stool for occult blood - <24hrs.

13.5.3.4.3 Cytology:

1. Body fluids – 24 hours at 2 to 8° C.
2. Slides (FNAC, Body fluids and PAP smears, smears Imprint) – 5 years.

13.5.3.4.4 Histopathology:

1. Specimens: Small biopsies - 1 month



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Large biopsies - Benign lesions - 3 months

Malignant lesions – 6 months

2. All Histopathology slides [including IHC slides] and blocks – 5 years

13.5.3.4.5 Autopsy:

1. Specimens – 2 years
2. Slides and blocks – 5 years.

13.5.3.4.6 Registers and Reports:

Retention of test reports histopathology and cytology - 5 years

Hematology and clinical pathology and other outsourced tests
– 1 year



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14. Laboratory Safety Programme:

14.1 Purpose: To follow good laboratory practices (GLP) to reduce the risk of occupational exposure to infectious agents, hazardous chemicals and to avoid accidents (eg. fire) in the laboratory.

14.2 Scope: Applies to all patients who give specimens in the Clinical laboratory.

14.3 Responsibility: Head of Department and All lab staff.

14.4 Definition & Abbreviations: NIL.

14.5 Procedure:

14.5.1 Handling of Specimen:

a. Wearing Gloves: Wear gloves and laboratory coats (Aprons) at all times when handling and processing patient specimen, decontaminating instruments and cleaning. Apply Bandage to open cuts and scratches on the hand and then wear gloves. Wear gloves when performing phlebotomy and handling actual blood specimens. Wash hands immediately after gloves are removed, after a task that involves heavily contaminated matter and before leaving the laboratory.

b. Specimen Transportation: Always transport specimens to the laboratory in leak proof containers. Do not accept grossly soiled or contaminated specimens.

c. Using syringes and needles: Use needle-locking syringes or plastic disposable syringe-needle units. Never bend the needles after use, do not recap. Discard them in the sharps container. Secure blood culture bottles before inserting needles into the bottle (eg., place bottle in support rack).

d. Handling test tubes: Always carry test tubes in the racks provided. Use plastic tubes when possible. Do not use the glass tubes that are broken or damaged. Discard such tubes into the sharps container.

e. Using Centrifuges: Centrifuge tubes must be intact and properly balanced during Centrifugation. Do not place table top centrifuges in the biological safety cabinets. Clean the centrifuge once daily after use, to remove any contaminating material on the inner side of the centrifuge. Do not open lid during centrifugation process.

f. Hand washing: Frequent hand washing after removing gloves, before leaving the laboratory are absolutely essential. Use non irritating soap for routine washing. Use antiseptic soap or an alcohol based hand disinfectant followed by thorough hand washing for accidental skin contamination.



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14.5.1.1 Handling Chemicals: Wear appropriate PPE when handling hazardous chemicals.

Label all reagents with their chemical names and appropriate hazard warnings provided from their Material Safety Data Sheets

(MSDS). Keep MSDS for all chemicals either in the laboratory or in the office near by. Store all hazardous chemicals, including chemicals, reagents and dyes, below eye level.

14.5.1.2 Avoid or minimize the activities associated with transmission of infectious agents.

Designate the CLEAN and CONTAMINATED work areas. Clean and disinfect (see section on decontamination) all surfaces after spills and at the end of each work shift. Keep all work areas neat and uncluttered. Do not store personal items in the work area. Do not bring food or beverages into the laboratory area. Remove coats before leaving the laboratory. Dispose all contaminated materials in appropriate colour coded & closed bags.

14.5.1.3 Decontamination: Routine decontamination and cleaning of the work environment is the responsibility of all laboratory workers, particularly of the house keeping staff. To accomplish this work area should be uncluttered, with clean and unclean materials clearly demarcated and separated.

Procedures for Decontamination:

a. Usage of 1% Sodium Hypochlorite solution: Prepare fresh solution daily. Dispense in wide mouthed large plastic containers. The containers should be only half full. Place the containers in the designated areas.

b. Decontamination of Work Surfaces: Work surfaces have to be decontaminated at least twice daily, before the work begins and at completion of work. Use a paper towel or a soft cloth soaked with the disinfectant (1% sodium hypochlorite solution). Wipe the work surface going over each area at least twice. Allow to air dry with a minimum contact time of 5 -10 min.

c. Decontamination of Equipments: Follow the same procedure as for work surfaces after consulting the supervisor that the disinfectant is compatible with the equipment surface. The periodicity of decontamination for the above mentioned equipment has to be decided by the supervisors in each section of the laboratory based on the use of equipment. **Note:** Do



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not use Alcohol on equipments which are close to open flames (burner). Do not use Sodium hypochlorite on metal parts because they may cause rusting. Do not use Aldehyde based disinfectants as general surface disinfectants.

d. Cleaning of Spills: Evacuate the area or room and alert all personnel regarding the spill and take care not to breathe in aerosolized material. The staff cleaning the spill should ensure that they use the appropriate PPE (disposable aprons, gloves and mask etc). Use disposable absorbent pads to wipe off the liquid in the spillage and discard the absorbent pads into the zip seal bag. Cover the entire spillage area with disposable pads and pour the disinfectant on the pads. Wait for 20 mints. After 20mints dispose the pads in the Zip seal bag. The treated area should be wiped with paper towels soaked with tap water and allow the area to dry. The disposable pads, gloves and other material used for cleaning should be discarded in a yellow color plastic cover and then immediately discard in to the yellow container. Wash hands with soap and water.

14.5.1.4 Disposal of Waste: Proper waste disposal and management of biohazardous wastes is essential to limit the risk of infections to the health care workers. Spill management will be done according to the Hospital Infection Policy. Hospital wastes include infectious and non- infectious items that have to be disposed using the following steps: Segregation; Transport; Temporary storage; Final disposal. While the laboratory may not be directly involved with step 4, segregation of wastes at source and proper timely transport of the wastes to the terminal area will remain a responsibility of the laboratory.

1. Segregation: Segregation of wastes generated in the laboratory is the responsibility of every laboratory worker. The house keeping staff is responsible for ensuring that every section of the laboratory has disposal containers with all the bags as mentioned below. The following colour code has to be strictly followed while the wastes are segregated: 1 Yellow coloured non-chlorinated plastic bag. 2. Red coloured non-chlorinated plastic bag. 3. White puncture proof container. 4. Puncture proof and leak proof boxes or container with blue coloured marking.

SR. NO.	CATEGORY	TYPE OF WASTE



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1	Yellow coloured nonchlorinated plastic bags	a) Human anatomical waste: Human tissues, organs, body parts and foetus below the viability period b) Animal Anatomical Waste: Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses. c) Soiled Waste: Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and bags containing residual or discarded blood and blood components. d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc. e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants. f) Discarded linen, mattresses, beddings contaminated with blood or body fluid routine mask and gown. g) Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of micro- organisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures. *Note- Autoclaving of Microbiology, Biotechnology and other clinical laboratory waste before disposal into yellow bags
2	Red coloured nonchlorinated plastic bags	Contaminated Waste (Recyclable)-Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.
3	White Puncture proof, Leak proof, tamper proof containers	Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes used, discarded and contaminated metal sharps.
4	Puncture proof and leak proof boxes or container with blue colored	a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.



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marking	b)Metallic Body Implants

Note:

Biomedical waste 2018 amendment:

- Cardboard box with blue lining for glassware – changed into puncture proof and leak proof boxes or containers with blue coloured marking.
- Phase out use of chlorinated blood bags and replaced with nonchlorinated bags.

2. Transport: Transportation will be done in closed cartwheel bins separately.

3. Temporary Storage: The waste will be stored in proper segregation storage room.

4. Final Disposal: All the biomedical waste of the organization has to be collected for final disposal / treatment by **M/s Maridi**, which is authorized and is having biomedical waste treatment facility.

14.5.1.5 Laboratory Areas: The laboratory shall have designated areas for laboratory work and access to such areas shall be limited to the laboratory employees. **1. Visitors in laboratory areas:** Children under 12 years of age shall not be permitted into laboratory. Each laboratory supervisor is responsible for the safety of adult visitors to the laboratory. **2. Hazard warning signs and labels:** The following four symbols may be used by the laboratory to communicate the extent of risk in the laboratory. **NOTICE** - states a policy related to safety of personnel or property but not a physical hazard. **CAUTION** - indicates a potentially hazardous situation, which may result in minor or moderate injury. **WARNING** - indicates a potentially hazardous situation, which may result in death or serious injury. **DANGER** - indicates an imminently hazardous situation that if not avoided, will result in death or serious injury.

14.5.1.6 Laboratory Accidents: Though the laboratory provides all facilities to avoid accidents, it is inevitable that a few accidents may occur over a period of time. The following section provides details of the management of such laboratory accidents: **1.**



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14.5.1.7 Needle stick injuries (including other sharps): Wash the area immediately under running tap and water. Inform Hospital Infection Control nurses about the accident. The hospitals' policy of Post exposure prophylaxis will have to be followed and the appropriate prophylaxis instituted as early as possible. All incidents shall be documented properly for further management. Patient shall be assessed for any communicable disease like HIV/AIDS, Hepatitis B & C etc.

14.5.1.8 Eye wash station: There shall be at least one eyewash facility per laboratory. Laboratory workers exposed to dangerous chemicals or infectious materials shall immediately use the eye wash to flush out the material. Hold the eyelids open while using the eye wash and let the water spray of for an extended period of time (15 minutes). Report about the incident to Ophthalmologist.

14.5.1.9 Body shower station: There shall be at least one body shower station facility per laboratory. Laboratory workers exposed to (splashes of large volumes) of infectious materials shall immediately use the shower facility for a minimum of 15 min. A mild disinfectant solution must be used to clean the area most exposed to infectious material. Report the incident to the laboratory incharge.

14.5.1.10 Incident report: While it may not be possible to alert the supervisor about the Laboratory accident immediately, the laboratory worker should ensure that the supervisor is informed about the incident at the earliest. The supervisor is duly advised to prepare a report of the incident, using the incident report work sheet and the HOD has to be informed. The laboratory In charge will have to ensure that the appropriate treatment has been followed.

14.5.1.11 Fire safety: Small bench-top fires are more common than large fires in labs. Labs, especially those using solvents in large quantities have a high potential for flash fires, explosion, rapid spread of fire and high toxicity of products of combustion.
CODE RED

14.5.1.11.1 Prevention: Plan work. Majority of lab fires have resulted from mental or procedural errors or carelessness. Keep work area uncluttered and clean. Observe proper safety practices. Store solvents properly. Keep inflammable reagents in explosion proof cabinets. Wear proper clothing



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and personal protective equipment. Avoid working alone, whenever possible. Attend the training organized by the organization for use of emergency equipment (fire extinguisher.) when needed.

14.5.1.11.2 Emergency: Know what to do - go by the emergency plan of the lab planned during the training sessions. Know where the things are - be aware of the closest fire extinguisher, hospital emergency services / maintenance department telephone number, emergency shower, first aid kit and exit(s).

14.5.1.11.3 Fire Procedure: Notify - other occupants of the immediate space. Evacuate- the immediate area of the fire if necessary. If safe to do so- attempt to extinguish.

14.5.1.11.4 Fire Extinguishers: (Note: an extinguisher is a first aid tool, do not expect it to control a big fire). To use a portable extinguisher remember the acronym P.A.S.S.

14.5.1.11.4.1 Pull the pin.

14.5.1.11.4.2 Aim extinguisher nozzle at the base of the flames.

14.5.1.11.4.3 Squeeze trigger while holding the extinguisher upright

14.5.1.11.4.4 Sweep the extinguisher from side to side, covering the area of the fire.

14.5.1.11.5 Training: Training regarding fire safety is provided periodically to staff is necessary.

15.0 QUALITY OBJECTIVES:

15.1 To ensure compliance of the turn-around-time for all tests.

15.2 To ensure timely communication and documentation of the critical test values.

15.3 To ensure minimum reporting errors.

15.4 To ensure minimum re-dos of tests.

15.5 To ensure compliance of test results with the patient diagnosis.

15.6 To ensure compliance with the quality assurance programme.



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15.7 To ensure compliance with safety programme.

15.8 To ensure compliance with the biomedical waste management techniques.

16.0 QUALITY INDICATORS:

S. No	Performance indicator	Numerator	Denominator	Standardization factor
1	Number reporting errors per 1000 investigations	Number of reporting errors picked up before dispatching of report	1000 investigations	1000
2	Percentage of Re-dos – laboratory	Number of Re-dos in Pathology	Total number of investigations	100
3.	Percentage of Re-dos – laboratory	Number of Re-dos in Haematology	Total number of investigations	100

17.0 DATA INFORMATION:

17.1 All the quality indicators are monitored at appropriate interval as defined in the policy.

17.2 The report shall be submitted to the Quality department or NABH coordinator.

17.3 Improvements on the quality care indicator shall be discussed in the Quality Assurance Committee.

17.4 Appropriate corrective and preventive actions shall be taken and the documentation done of the same.

18.0 TRAINING:

18.1 All new joining staff shall be oriented to the department by the Head of the department.

18.2 Training needs of the staff is assessed by the head of the department based on the performance of staff.

18.3 The following are the training schedules :

18.3.1 **Newly appointed personnel will be oriented to Hematology – Clinical Pathology for 1 month.**

18.3.2 **They will be put on night duties after completion of 1 month.**

18.3.3 **After 6 months, they will be trained in cytology by rotation.**

18.3.4 **Persons found suitable will be trained in histopathology after 2 years.**

19.0 LIST OF EQUIPMENTS:



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HEMATOLOGY

1. AUTOANALYSER - SYSMEX XN 1000 – TRANSASIA (6 part)	2
2. UPS - 3KVA WITH EXTERNAL BATTERIES	2
3. COMPUTER WITH MONITOR – SAMSUNG & ACER	2
4. LASER PRINTER – HP Laser jet 1020 & 1007	2
5. INCUBATOR	1
6. CENTRIFUGE (REMI)	1
7. KC4 Delta	1
8. SAHLI'S HEMOGLOBINOMETER	2
9. NEUBAUER'S CHAMBER	1
10. WINTROBE TUBE (GLASS)	2
11. WINTROBE STAND (STEEL)	1
12. ESR DISPOSABLE TUBE STAND	1
13. MICROPIPETTE- 5 – 50 microlitre	1
100 – 1000 microlitre	1
14. WHIRLPOOL REFRIGERATOR – 165 LITRE CAPACITY	1
15. STABILIZER FOR REFRIGERATOR	1
16. REFRIGERATOR Double door, Samsung (with Stabilizer) – 245 Ltrs	1
17. BOROSIL GLASS 1ML PIPETTE	1
18. HEMOGLOBIN TUBE	1
19. WBC PIPETTE	1
20. RBC PIPETTE	1
21. BLOOD CELL COUNTER WITH KEYS	2
22. MULTI THERMOMETER WITH PROBE FOR REFRIGERATOR	1
23. MICROSCOPES (Monocular)	



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HISTOPATHOLOGY

NAME OF EQUIPMENT

NO.

1. TISSUE PROCESSOR- LEICA TP 1020	1
2. ROTARY MICROTOME- LEICA RM 2245	2
3. YORCO ROTARY MICROTOME	2
4. TISSUE CAPSULES	150
5. WAX EMBEDDING STATION (THERMOSCIENTIFIC)	1
6. ALUMINIUM SLIDE CARRIERS – large size	15
small size	1
7. MICRO SLIDE CABINET (5000 capacity)	2
8. PARAFFIN BLOCK CABINET (20,000)	2
9. MICROSLIDE CABINET (20,000 CAPACITY)	1
10. CRYOSTAT MICROTOME AUTOMATED (Leica)	1
11. TISSUE FLOTATION BATH	1
12. WATER BATH (THERMOSCIENTIFIC)	1
13. INCUBATOR	1
14. ELECTRIC STOVE	1
15. PRESSURE COOKER FOR IHC (PathNSitu)	1



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GROSSING ROOM

1. GROSSING STATION	2
2. SCISSORS	2
3. MEASURING SCALE	1
4. FORCEPS	2
5. BP - SCALPEL	1
6. BRAIN CUTTING KNIFE	2
7. WEIGHING SCALE	1
8. BONE CUTTING SAW	1

CYTOLOGY

1. CYTOCENTRIFUGE- CYTOSPIN 4- (THERMOSCIENTIFIC)	1
2. MICRO SLIDE CABINET (20000 CAPACITY)	3
3. MICROSLIDE CABINET (5000 CAPACITY)	1
4. FNAC GUN	1
5. TEST TUBE RACKS (PLASTIC)	1
6. COPLIN JARS	17
7. FORCEPS	1
8. HEMOCYTOMETER	1
9. SYRINGE & NEDDLE DESTROYER	1
10. HOT AIR OVEN	1

COLLECTION CENTRE

1. SYRINGE NEEDLE DESTROYER	3
2. MEASURING SCALE	1
3. PLASTIC TEST TUBE HOLDER	1

REPORTING ROOM

1. BINOCULAR MICROSCOPES	10



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AMENDMENT SHEET

S.no	Section no & page no	Details of the amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority
1	8.1	3 Professors	Promoted from Associate		
2	8.1	2 Associate Professor	Promoted from assistance		
3	24	List of equipments	New usg machine added		
4.	21	Training toic addition	upadation		
5.	21	Infarct to acute	updated		
6.	7	Faculty list	updated		
7.	5	HOD	updated		
8.	3/1.2.4	SIX USG Machine	update		



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CONTROL OF THE MANUAL

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable.

The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

HOD – Radiology department is responsible for issuing the amended copies to the copyholders, the copyholder shall acknowledge the same and he /she shall return the obsolete copies to the HOD.

The amendment sheet, to be updated (as and when amendments received) and referred for details of amendments issued.

The manual is reviewed once a year and is updated as relevant to the hospital policies and procedures. Review and amendment can happen also as corrective actions to the non conformities raised during the self assessment or assessment audits by NABH. The authority over control of this manual is as follows:

Preparation	Approval	Issue
HOD, Radiology Department	Medical Superintendent, RRCMH Hospital	NABH coordinator

The procedure manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy'.

Distribution List of the Manual:

Sr. No.	Designation
1	NABH Coordinator
2	HOD, Radiology Department



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**IMAGING SERVICES
DEPARTMENT MANUAL**

**RAJARAJESWARI MEDICAL COLLEGE & HOSPITAL
BANGALORE**

Service Name :	IMAGING SERVICES MANUAL IMAGING SERVICES/NABH / RRMCH / IMGSM / 01
Date Updated :	30.01.2019
Approved By :	Medical Director Name : Dr. D.L Ramachandra Signature :
Issued By :	Medical Superintendent Name : Dr. Govindaraju Signature :
Responsibility of Updating :	Head of the Department Name : Dr. Pravin.G.U Signature :



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1.0 INTRODUCTION:

- 1.1 The Radio-imaging department was started along with the inauguration of the hospital on 2003
- 1.2 The department is today equipped with the following facilities:
 - 1.2.1 6 fixed X-ray units with 2 IITV.
 - 1.2.2 6 Portable X-ray units.
 - 1.2.3 128 slice CT scan machine
 - 1.2.4 Six USG machine with Doppler. (2 portable)
 - 1.2.5 One 1.5T MRI

2.0 PURPOSE:

- 2.1 Medical imaging services supports investigation of patients that provides imaging information of diseases and the treatment.
- 2.2 The imaging modality caters to both Out-patients and In-patients of the hospital.

3.0 SCOPE:

- 3.1 The scope of the Department is:
 - 3.1.1 Computerized Radiography.
 - 3.1.2 Conventional Radiography.
 - 3.1.3 Ultrasound and Color Doppler.
 - 3.1.4 CT scan.
 - 3.1.5 Mammography.
 - 3.1.6 Intervention Radiology.
 - 3.1.7 MRI

4.0 ABBREVIATIONS:

- 4.1. CT scan : Computed Tomographic Scan
- 4.2. CMO : Chief Medical Officer
- 4.3. MRI : Magnetic Resonance Imaging



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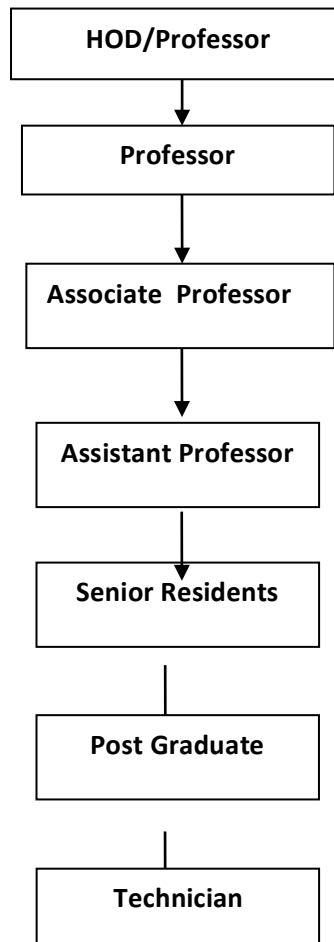
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5.0 RESPONSIBILITY:

- 5.1 Radiologist,
- 5.2 Radiation safety officer,
- 5.3 Radiography technicians,

6.0 DEPARTMENTAL HIERARCHY:





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7.0 COMPETENCY MATRIX:

Sr. No.	Name of the staff	Designation
1.	Dr. J. Ravi Prasad	HOD/ Professor
2.	Dr. Anil Kumar Shukla	Professor
3.	Dr.Pravin G.U	Professor
4.	Dr. Nagesh	Professor
5.	Dr. Parthsarathy.A	Asst. Professor
6.	Dr.Gautam .M	Asst. Professor
7.	Dr.Sindhu	Asst. Professor
8.	Dr. Jagatheshwari	Senior Resident
9.	Dr. Padma	Senior Resident
10.	Dr.Nitish	Senior Resident
11.	Dr. Swaroop	Senior Resident
12.	Mr. Victor	Senior Technician
13.	Mr. Suresh	Senior Technician
14.	Mr. Chinnbasappa	Senior Technician

7.0 ROLES AND RESPONSIBILITIES:

7.1

Head of the Department: They are responsible for smooth and efficient functioning of the department. They are responsible for all the medical staff working in the department. They are also responsible for deployment and utilization of services of medical and clerical staff working under them. They are responsible maintaining the functional status of all equipment under their department and will promptly ensure that this equipment function smoothly / repaired and without lengthy downtime. They will keep liaison with the company maintaining the machine. They are responsible for proper segregation and collection of hospital waste in the department as per guidelines issued by CPCB and other authority from time to time. They will assign duties to various Heads of Units working under them from time to time. They will ensure that all records relating to patients especially the MLC cases are in order complete and kept in safe



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custody. They will be responsible for the upkeep, sanitation. Cleanliness and availability of supplies in the department.

- 7.2 **Consultant Radiologist:** Perform and report the modalities assigned to CT/ USG. Shall monitor patient examinations, patient preparation wherever required, interpreting images and maintain the quality of images. Any adverse reaction of contrast to be treated and log of the same to be maintained.
- 7.3 **Chief Radiographer:** Prepare duty roaster for all radiographers. Ensure availability, storage and utilization of consumables - like films, chemicals, drugs, etc. Preparation on leave roster. They maintain records in X-ray department. They are responsible for quality control and also look after the safety measures of patients and people who are working there. They are responsible for general maintenance including preventive maintenance with the help of maintenance engineer.
- 7.4 **Radiographers In X-Ray Room:** Always to be present in the radiography room. Receiving the patient and verification of patient Name, MR No., ID Bands. Checking the investigation – according to the consultant's advice and the side to be investigated. Explaining the procedure and reassuring the patient. Preparing the patients and obtain written consent for the special procedure like IVU or any IV contrast administration. Positioning and performing the investigation with proper care and with optimum exposure factors. Taking care of the machine by handling with proper care, warming up, doing periodical calibration and Log book maintenance. Operating x-rays equipments and processing exposed images. Assessing the diagnostic quality of the radiograph. Assisting the radiologist during specific procedures, assisting patients while in your care.
- 7.5 **Radiographers In CT :** To be present in the investigation room as per the duty schedule. Receiving the patient & verifying the Patient's particulars. Perform complex specialized tasks associated with the operation of CT scanners and related equipment in accordance with prescribed radiation safety procedures. Position patients for CT scans using immobilization and protective equipment as necessary. Assist radiologist with the imaging procedures, starting IV's and injecting contrast, if applicable. Assist radiologist with interventional CT procedures. Evaluate CT scans for technical quality, collate processed images in sequence of exposure and appropriately label. Schedule patients for procedures: assist with clerical functions. Dispense



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oral contrast to patients for CT scans. Load and operate power injections for contrast media administration. Maintain accurate patient records. Provide orientation and training to new CT technologists. Provide care for psychological and physical needs of patients for CT scans. Perform other related duties incidental to the work therein.

- 7.6 Duties of the Night Duty CT Technologists:** Performing all CT investigation as per requisition, taking all precautions. IV contrast to be administered only if there is duty doctor. Position patients for CT scans using immobilization and protective equipment as necessary. Evaluate CT scans for technical quality, collate processed images in sequence of exposure and appropriately label. Maintain accurate patient records. Perform other related duties incidental to the work therein.

8.0 DEPARTMENT WORKING HOURS:

- 8.1** Each shift duty shall have 8 hours on duty.

Sl. No	Designation	No. of staff	Working hours	Shift timings
1.	HOD & Professor	1	8 Hrs	08.00 AM – 04.00 PM
2.	Professors	4	8 Hrs	08.00 AM – 04.00 PM
3.	Associate Professor	3	8 Hrs	08.00 AM – 04.00 PM
4.	Assistant Professor	2	8 Hrs	08.00 AM – 04.00 PM
5.	Senior Resident	5	8 Hrs	08.00 AM – 04.00 PM
6.	Chief Radiographer	2	8 Hrs	08.00 AM – 04.00 PM
7.	Radiographer	10	8 Hrs	08.00 AM – 04.00 PM
8.	Nurses	3	8 Hrs	08.00 AM – 04.00 PM

9.0 REFERENCE TO NABH STANDARDS:

S.No	Chapter	Relevant NABH Standard / Objective Element
1.	Access assessment and	Documented policies and procedures are used for registering



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	continuity of care	and admitting patients. AAC.2. A – E.
2.	Access assessment and continuity of care	Imaging services are provided as per the scope of services of the organization. AAC 9. A – I.
3.	Access assessment and continuity of care	There is an established Quality assurance programme for imaging services. AAC 10. A – E.
4.	Access assessment and continuity of care	There is an established radiation safety programme. AAC.11. A – G.
5.	Access assessment and continuity of care	Patient care is continuous and multidisciplinary in nature AAC.13. A – F.
6.	Patient rights and responsibility	A documented procedure for obtaining patient and / or family's consent exists for informed decision making about their care. PRE .4 A – H.
7.	Hospital infection control	The organization provides adequate and appropriate resources for prevention and control of Healthcare associated infections (HAI). HIC.5. A – D.
8.	Hospital infection control	Biomedical waste (BMW) is handled in an appropriate and safe manner. HIC.8.A – F.
9.	Continuous Quality Improvement	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tool for continual Improvement. CQI.3.
10.	Continuous Quality Improvement	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tool for continual improvement CQI.4.
11.	Responsibility of Management	The service provided by each department are documented ROM.3.

10.0 POLICIES:

10.1 Scope Of Services:

10.1.1 Computerized Radiography.



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- 10.1.2 Conventional Radiography.
- 10.1.3 Ultrasound and Color Doppler.
- 10.1.4 CT scan.
- 10.1.5 MRI.
- 10.1.6 Mammography.
- 10.1.7 Intervention Radiology

10.2 Regulatory Compliances:

- 10.2.1 AERB / BARC approval for imaging unit shall be obtained after inspection and the licenses shall be displayed in their respective areas to prove compliance on these issues.
- 10.2.2 RSO shall be appointed for checking the radiation levels and to ensure the safety
- 10.2.3 All the workers of the imaging services shall be provided with TLD badges for monitoring of their individual exposures to radiation
- 10.2.4 Regular monitoring of these badges shall be outsourced and a record for the same shall be maintained in the Radiology department, RRMCH.
- 10.2.5 Proper sign posting has been done in the Radiology department.
- 10.2.6 Patients shall come with the requisition slip for the required investigation from the treating Doctor.
- 10.2.7 For MLC cases, Police will accompany the patient along with the requisition slip from the court.
- 10.2.8 Requisition slips from other Hospital Doctors are also accepted for CT scan services.
- 10.2.9 For **Contrast studies** a date shall be given for the same.
- 10.2.10 Training of department staff.

- 10.3 Ultra Sound Scan Registration policies for Antenatal scans:** Ultrasound Machine Purchased will be registered with PNDT act. Form B shall be issued by the health department after registration. A Registration number shall be allotted to the radiology department in form B. Statutory requirements are as follows: Form B shall be displayed in the ultrasound scan



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room. Posters from the Health department (in local language) shall be displayed in the ultrasound scan room. Contents of the display are as follows: "Sex determination is illegal" board shall be displayed in English & local language in OPD and in the department. Scanned Patient details shall be preserved for 2 years from the date of Scan. PNDT act copy to be kept in the department. Consent forms F shall be taken from the Patient before doing Antenatal checkup. Total number of Antenatal Scans done shall be sent to the following every month on or before 5th through post /E-Mail to DH&FWO.

10.4 Identification of patients:

10.4.1 RRMCH shall ensure that all the patients are identified prior to carrying out their investigations. The patients are checked for their Name, Hospital ID, Age, Sex. The radiographer checks the patient details and then proceeds for imaging.

10.5 Transportation of patients:

10.5.1 Stable patients shall be transported with the help of attenders in wheel chair.

10.5.2 Unstable patients shall be transported with requisite restraints and will be accompanied by the attenders.

10.6 Turn-Around-Time for tests:

10.6.1 The turn-around-time for all the tests done by each section shall be defined, documented and displayed.

10.7 Critical Test Result Intimation:

10.7.1 Critical results shall be intimated to concern physician/ surgery by telephone and the report shall be given later.

10.7.2 The below Mentioned Diagnosis (Critical Reports) will be informed to the treating doctor immediately after the procedure:

10.7.3 Ectopic Pregnancy.

10.7.4 Burst Abdomen.

10.7.5 Deep Vein Thrombosis.

10.7.6 Perforation.

10.7.7 Incomplete Abortion.

10.7.8 Hemorrhage.

10.7.9 Acute.



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10.7.10 Multiple Fractures.

10.7.11 Pneumothorax

10.7.12 Abdominal Obstruction.

10.7.13 Vascular/Visceral Injury.

10.8 Format of Reports:

10.8.1 There shall be uniformity in the formats in which the reports are generated. The report, at the least, shall include: The name of the Hospital. The patient's Name, Age, Sex with the Unique Identification Number. The name and Signature, Date, time, Reg.No of the person reporting the test result. All reports from the outsourced imaging centre shall incorporate these features and the hospital shall not alter / modify anything in the report.

10.9 **Outsourcing of tests:** All outsourced investigations shall be listed. There shall be an MOU /Agreement for the same.

10.10 **Radiology Quality Assurance:** Imaging department shall follow Internal and external quality assurance programme as follows: Internal quality checks – By surveillance, checks of the output of investigations, assessment of competence of personnel, assessment of calibration, maintenance and performance parameters of equipments. Quality of services shall address safety of staff and patients, timeliness of results, accuracy and validity of results. All investigation reports shall be perused and signed by the Radiologist. Surveillance – Radiologist / Supervisors shall carry out activities connected with surveillance of test results. External quality check – Random films of imaging shall be sent to outside Hospital once every three months for reporting to carry out comparison. Periodic calibration and maintenance of all test equipments is to be carried out as per manufacturers guidelines (where available). Imaging department shall maintain a register documenting all corrective and preventive actions consequent to investigation of non-conformity. Records for all the above activities shall be maintained. **Key characteristics:** Quality Assurance programme of radiology is focused on following key characteristics. These key characteristics shall meet the specified acceptance criteria / norms. These key characteristics are monitored on weekly basis to ensure that they meet the acceptance criteria. A record for this is maintained in quality



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assurance register of the department. Departmental coordinator shall be vigilant about these key characteristics. Based on the observation, every week departmental coordinator shall record his / her remark against the key characteristics as to whether the key characteristics meet the acceptance norms or not. Specific comments for the key characteristics may also be written. These records shall be reviewed by Quality Assurance committee every week.

11.0 PROCEDURES:

- 11.1 **Procedure for Identification of patient:** The staff responsible for transfer of patient from inpatient, Emergency areas and those who need assistance from outpatient unit. Wheel chairs and stretchers have been provided in all the areas of the hospital for transporting such patients. Care must be taken to prevent patient fall. Those patients who are serious shall be accompanied by a staff nurse to the radiology department. Patients are verified by the radiographers / doctors in the radiology department by their repose to their name and MR. no and from patient relatives / attendants before shifting to the radiology department.
- 11.2 **Handling of Inpatient Request:** Request for imaging is given by the treating physician. Patient Name, age, sex, MR.no and the requesting doctor name is written in the investigation form for imaging.
- 11.3 **Processing of results:** The radiographer shall process and prepare the films, check the identification, label the films, enter the details in the appropriate register and provide films to the Radiology Consultant for preparing report. The Radiology Consultant views the films and interprets accordingly with the patient condition and provides the result.
- 11.4 **Monitoring of patients before / during / after procedure:** All patients, depending upon the type of the procedure that has to be performed under X-ray, CT scan, MRI & Ultrasound are prepared accordingly. Patients are made comfortable. Vitals are checked and monitored continuously. Relevant consent is duly filled and signature is obtained from patient / patient attendant. For all IV contrast examinations, patients are observed and monitored for any contrast reaction.
- 11.5 **Reporting of results:** The results are reported in printed form with the patient name, age, sex, MR.no, date, along with the reporting consultant name and signature.



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- 11.5.1 X-Rays:** All X-rays taken before 1 P.M will be dispatched after 5.00P.M on the same day. All X-ray taken after 1.00 P.M will be dispatched after 10.00 A.M on the next day. Emergency X-rays of patient will be dispatched within ONE hour.
- 11.5.2 Ultrasound:** All USG done before 12.00 P.M will be dispatched after 2.00P.M on the same day. All USG done after 1.00 P.M will be dispatched after 4.30 P.M same day. Emergency USG reports of patients will be dispatched within one hour.
- 11.5.3 CT & MRI:** All CT done before 1.00 P.M will be dispatched after 2.00P.M on the same day. All CT done after 1.00 P.M will be dispatched after 4.30 P.M same day. Emergency CT reports of patients will be dispatched within one hour. CT & MRI done after 3.30 P.M will be dispatched by 10.00A.M next day.
- 11.6 Procedure for reporting of Critical results: Intimation of the critical reports to the concerned personnel:** Critical values followed by the department: General radiography: Ischemic bowel. Massive pleural effusion. Pneumoperitoneum. Pneumothorax. **CT scan:** Pneumothorax, Pneumoperitoneum. Hemothorax, Hemoperitoneum. Ischemic bowel. Acute Appendicitis. Critical coronary artery stenosis. Cardiac tamponade. Large infarcts with mass effect. Subarachnoid haemorrhage. Acute trauma to abdomen. Pulmonary embolism. Aneurysms with subarchnoid haemorrhage. **Ultrasound:** Appendicitis. Post traumatic organ damage. Ectopic pregnancy. Massive pleural effusion. Hemoperitoneum. Acute arterial occlusions. DVT. Any critical report shall be informed to the concerned clinician by telephonic call and later the writer/ printed report shall also be given.
- 11.7 Turnaround time:** X-ray - 4 hours. Ultrasound scans - 4 hours. CT scan (Routine) - 3 hours. CT Angio - 4 hours. Investigations done afternoon session, the reports will be given at 10.00 am on the next day.
- 11.8 Patient education on: 8.1 Contrast studies: IVU:** Patient is informed for overnight fasting by the radiologist. Laxatives 2 tablets are advised for previous night. Gas absorption tablets (T.DIMOL 2 tablets 3 times or its equivalent). Patient is instructed to report at 8 A.M in the morning to the radiology department. Patient to come with reports of blood urea / S.Creatinine. **8.2 Barium Studies: Barium meal:** Patient is informed to be in fasting for overnight. **Barium enema:** Bowel preparation – Patient need admission. Preparation will be decided by the radiologist. Oral Peglec as per recommendation given by the previous day



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(Or) Soap water enema is given to the patient on previous day and plain water enema on the day of procedure. Patient needs to come to the department at 8 A.M in fasting. Other contrast studies like – Sinogram, fistulogram, urethrogram, MCU does not require any fasting. Prophylactic antibiotics to be given before procedure in case of MCU and ascending urethrography.

- 11.9 **Handling of Drug reaction:** If it is Mild reaction reassurance of patient, Anti histamine is given. Moderate Reaction – Reassurance of patient based on the condition following drug may be administered: Steroids (Hydrocortisone). Broncho dilators. Oxygen support will be provided if required. Admission if required in case of out patients, which will be decided by Radiologist in consultation with clinician. **Severe Reaction:** Check for ABC. Airway securing. Adrenaline support if required. Isotopic support if required. Patient to be shifted to ICU for further treatment. All the adverse reactions will be documented and records are maintained in the radiology department. Corrective and preventive actions will be taken in the Quality Assurance committee.
- 11.10 **Procedure for Contrast Administration: Contrast Policy:** IV contrast in CT are used depending on clinical situation. **For contrast administration:** Blood urea and creatinine to be checked. If values are increased, contrast administration to be done only based on Nephrologist or Physician's advice. Previous H/O allergies documented. CT / MRI room will have crash cart and all emergency medication. Log to be maintained regarding any contrast reaction.
- 11.11 **Procedure for handling of General Radiography: Patient information:** Patient is explained about the procedure. All metallic objects are removed from the part being examined. Patient is instructed about the breath holding. Date of LMP is checked in female patients of child bearing age group. Charts are displayed to inform to the Technologist / Radiologist if the patient is pregnant or doubtful about the pregnancy. **Guide lines:** Main switch on (wall mounted). Switch on sub main – (1) (green button). Control panel switch on. Set factors – (check voltage / MA) as mentioned in the chart. Arrange the cassette, position the patient.
- 11.12 **Guide lines for C- arm:** Connect 'C' arm to monitor socket. Connect the main cable from the monitor to the stabilizer. Connect the stabilizer to the mains. Switch on stabilizer, initialize. Switch on 'C' arm mains in the monitor unit. Position 'C' arm for usage.



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11.13 Patient information for CT scan procedure: Patient is briefed about the procedure. Patient is instructed not to move. For all body scans the breathing instruction is explained. For all intravenous and oral contrast studies patient is instructed to be on nil per oral 2 to 3 hours prior to the examination. Serum Creatinine value is checked prior to the injection of intravenous contrast. Written consent is explained & signed by the patient / patient attendant. Test dose of intravenous contrast is given, patient is observed for any contrast reactions. If the patient doesn't develop any reactions. Then the entire dose of contrast is injected. All patients who undergo intravenous contrast study are kept under observation and encouraged to drink plenty of fluids to excrete the contrast medium. In case if patient develops contrast reactions relevant drugs are used to suppress the reactions and the patient is shifted to emergency room for further management. **Guidelines:** Switch ON the main power in the machine in the morning at 5.30 am. In the main menu select the scan mode. Scan mode option select the warm up and do warm up, as per machine alerts. In the scan mode select the New patient. Enter the patient data. Then select the protocol and do the scan. End exam, take the patient out.

11.14 Patient Information for Ultrasound Scan: For all abdomino-pelvis ultrasound scan patient is instructed to the on fasting for minimum of 3 to 4 hours and with full urinary bladder. For antenatal scan Form G / F consent is obtained.

11.15 Imaging Quality assurance:

11.15.1 Monitoring and maintenance: A routine quality control monitoring and maintenance system is done for producing better quality results.

11.15.2 Monitoring of film processing: C.R. System: An index of speed. An index of contrast. Base plus fog. Film artifact identification.

11.15.3 Basic performance characteristics of the x-ray unit: 12.3.1

11.15.3.1 Fluoroscopic x-ray units: Tabletop exposure rates. Centering alignment. Collimation. kVp accuracy and reproducibility. mA accuracy and reproducibility. Reproducibility of x-ray output. Focal spot size consistency.

11.15.3.2 Image intensifier systems: Resolution. Focusing. Distortion. Glare. Low contrast performance. Physical alignment of camera and collimating lens.



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11.15.3.3 **Radiographic x-ray units:** Reproducibility of x-ray output. Linearity and reproducibility of mA stations. Reproducibility and accuracy of timer stations. Reproducibility and accuracy of kVp stations. Accuracy of source-to-film distance indicator. Light/x-ray field congruence. Focal spot size consistency.

11.15.4 Cassettes and grids:

11.15.4.1 **For cassettes: For C.R. System:** Screen condition. Cassettes condition. Artifact identification.

11.15.4.2 **Grids:** Alignment and focal distance. Artifact identification.

11.15.5 **View boxes:** View box surface conditions.

11.15.6 Specialized Equipments:

11.15.6.1 **Computerized Tomography:** Precision (noise). Contrast scale. High and low contrast resolution. Alignment. The maintenance program shall include both preventive and corrective aspects.

11.16 Preventive and Corrective Maintenance:

11.16.1 **Preventive maintenance:** Preventive maintenance shall be performed on a regularly scheduled basis with the goal of preventing breakdowns due to equipment failing without warning signs detectable by monitoring. Such actions have been found effective if responsibility is assigned inspection of the mechanical and electrical characteristics of the x-ray system covering such things as: Checking conditions of cables. Assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom. Listening for unusual noises in the moving parts of the system. Following the manufacture's recommended procedures for cleaning and maintenance of the equipment. Regular inspection and replacement of switches and parts that routinely wear out or fail.

11.16.2 **Corrective maintenance:** For maximum effectiveness the quality assurance program shall make provision for ascertaining if potential problems are developing. If potential or actual problems are detected corrective maintenance shall be carried out to eliminate them before they cause a major impact on patient care. **Standard for**



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image quality: Standards of acceptable image quality shall be established. Ideally these shall be objective e.g. acceptability limits for the variations of parameter values, but they may be objective e.g. the options of professional personal in cases where adequate objective standards cannot be defined. These standards shall be routinely reviewed and redefined as needed.

11.17 Evaluation: The facility quality assurance program shall include for two levels of evaluation:

11.17.1 On the first level, the results of the monitoring procedures shall be used to evaluate the performance of the x-ray system's to determine whether corrective actions are needed to adjust the equipment so that the image quality consistently meets the standards for image quality. This evaluation shall include analysis of trends in the monitoring data as well as the use of the data to determine the need for corrective actions on a day-by-day basis. Comparison of monitoring data with the purchase specifications and acceptance testing results for the equipment in question is also useful. The facility quality assurance program shall also include means for evaluating the effectiveness of the program. Possible means of including studies are the rejection rate and the cause of the repeated radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiograph being produced. Occurrences and reasons for complaints by radiologists, and analysis of trends is the results of the monitoring procedures such as sensitometric studies. Ongoing studies of the reject rate and its causes are often most useful and may provide information of value in the first level of evaluation. Such studies shall be used to evaluate the improvements to make corrections, and to determine whether the corrective actions were effective. The number of reject shall be recorded daily or weekly, depending on the facility's analysis of its needs. The reasons for the rejection shall also be determined and recorded.

11.17.2 Manual: The content of the manual shall be determined by the facility staff, but the following items are suggested as providing essential information: A list of the individuals responsible for monitoring and maintenance. A list of the parameter to be monitored and the frequency of monitoring in accordance with the equipment manual. A description of the standards, criteria of quality, or limits of acceptability which have



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been established for each of the parameters, monitored. A brief description of the procedures to be used for monitoring each parameter. A description of procedures to be followed when difficulties are detected to call these difficulties to the attention of those responsible for correcting them. A list of the publications in which detailed instructions for monitoring and maintenance procedures can be found. Copies of these publications shall also be readily available to the entire staff, but they shall be separate from the manual. A list of the records (including sample forms) that shall be kept. The facility staff shall also determine and note in the manual the length of time each type of record shall be kept before discarding.

- 11.18 **Training:** The program shall include provisions for appropriate training for all personnel with quality assurance. The training shall be specific to the facility and the equipment. This shall include both training provided before the quality assurances are assumed and continuing education to keep personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors, either in the facility or in a special program is the most desirable of training. The use of self teaching materials can be an adequate substitute for supervised instruction, especially in continuing education programs, if supervised instruction is not available.
- 11.19 **Review:** The quality assurance committee and/ or the practitioner in charge shall conduct the review. The items suggested for inclusion in the review include: The reports of the monitoring and maintenance techniques to ensure that they are being performed on scheduled and effectively. These reports shall be reviewed at least quarterly. The standards for image quality to ensure that they are consistent with the state-of the-art and the needs and resources of the facility. The standards shall be reviewed at least annually. The results of the evaluations of the effectiveness of the quality assurance actions to determine whether changes need to be made. This determination shall be made at least annually. The quality assurance manual shall also be reviewed at least annually to determine whether revision is needed.
- 11.20 **Maintenance of Equipment: Maintenance of Equipments:** Daily checking of equipments. Error log to be maintained for all equipments. **Maintenance of Equipment: X-ray:** Periodic inspection and preventive maintenance service is done by in-house biomedical engineers. CT, MRI and Ultrasound: Preventive maintenance service is done once in 4 months by the



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authorized service from GE MS. A detailed service reports is submitted to the HOD regarding the status of the machine.

11.21 **Radiation Safety Programme:** Refer to Hospital policy **NABH / RRMCH / AAC / 11**.

11.22 **Procedure for Mammography:** The patient is asked to stand in front of the X-ray machine. The radiologic technician (usually females) places the breasts one at a time, between an X-ray plate and a plastic plate. These plates are attached to the mammogram machine and compress the breasts to flatten them. This spreads the breast tissue out to obtain a clearer picture. The patient will feel pressure on their breasts for a few seconds and can cause some discomfort for few seconds. Most often the pictures are taken of each breast one from the side and one from above. A screening mammogram takes about 20 minutes from start to finish. **Few guidelines:** Advise patients not to undergo Mammogram during menstrual periods. Advise patients to inform the radiology technician if they have any breast implants. Advise the patient to avoid any perfumes, lotion, deodorant which may cause shadows in mammogram. Who is going to perform the procedure. A trained Radiology technician (usually females). **Advantages of doing the procedure:** Mammography is not painful. Some women feel a light and momentary discomfort only due to the delicate pressing system for the breast, which is necessary in order to obtain clear and precise images. Early detection of breast cancer with screening mammography means that treatment can be started earlier in the course of disease, possibly before it has spread. The cost of conventional mammogram is relatively inexpensive compared to other higher investigations. Mammography is helpful in identifying cysts; calcifications and tumors within the breast. **Disadvantages:** Even though screening mammogram, can detect malignant tumors that cannot be felt, treating a small tumor does not always mean that a women's life will be saved. A fast growing on aggressive cancer could have already spread to other parts. **False negative results:** False negative results occur when mammogram appear normal even though breast cancer is present. The reason for this is high density of breasts. **False positive results:** False positive results occur when radiologists decide mammogram are abnormal but no cancer is actually present. It can lead to anxiety and other form of psychological distress in affected women. The additional testing required to rule out cancer can also be costly and time consuming and can cause physical discomfort. **Over diagnosis and over treatment:** Screening mammograms



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sometimes can find cases of Ductal carcinoma in situ (DCIS) that need to be treated. But some of the DCIS will never cause symptoms or threaten women's life and treatment for such women exposes unnecessarily to the adverse effects associated with cancer threats. Radiation exposure. Mammogram require very small dose of radiation and repeated X-rays have the potential to cause cancer. **Materials used for carrying out the procedure:** A mammogram unit is a rectangular box that houses the tube in which X-ray are produced. The unit is used exclusively for X-ray exams of the breast with special accessories that allow the breast to be exposed to the X-rays. Attached to the unit is a device that holds and compresses the breast and positions it so images can be obtained at different angles.

12.0 QUALITY OBJECTIVES:

- 12.1 To ensure conformance to all statutory regulations and licenses.
- 12.2 To ensure minimum waiting time of the patients in the department.
- 12.3 To ensure the adherence to the turn-around-time for all investigations.
- 12.4 To ensure the timeliness, completeness and accuracy of all reports.
- 12.5 To ensure the completeness of all consent forms.
- 12.6 To ensure minimum number of re-dos.
- 12.7 To ensure that all staff, patients and relatives adhere to the safety precautions necessary.

13.0 QUALITY INDICATORS:

S.no	Performance indicator	Numerator	Denominator	Standardization factor
1	Number of reporting errors per 1000 investigations	Number of reporting errors	Total number of tests reported	
2	Percentage of re-dos	Number of films wasted	Total number of films used	100
3	Percentage of reports correlating with clinical diagnosis	No. of reports correlating with clinical diagnosis	Total no. of diagnosis done	100
4	Percentage of adherence to safety precautions by employees working in diagnostics	No. of employees adhering to safety precautions	Total no. of employees in the departments	100

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14.0 DATA INFORMATION:

- 14.1 All the quality indicators are monitored at appropriate interval as defined in the policy.
- 14.2 The report shall be submitted to the Quality department or NABH coordinator.
- 14.3 Improvements on the quality care indicator shall be discussed in the Quality Assurance Committee.
- 14.4 Appropriate corrective and preventive actions shall be taken and the documentation done of the same.

15.0 RECORDS:

- 15.1 All the below mentioned records shall be maintained for one year in the OPD unit and destruction shall be done by the Medical record department after getting approval from the management.

16.0 TRAINING:

- 16.1 All new joining staff shall be oriented to the department by the Head of the department.
- 16.2 Training needs of the staff is assessed by the head of the department based on the performance of staff.
- 16.3 The following are the training topics:
 - 16.3.1 Induction training
 - 16.3.2 Radiology safety
 - 16.3.3 BLS
 - 16.3.4 Needle stick injury.
 - 16.3.5 Mercury spill management.
 - 16.3.6 BMW.
 - 16.3.7 Disposal of contrast & adverse reaction.
 - 16.3.8 PPE

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17.0 LIST OF EQUIPMENTS:

S. No.	Equipment	NOs	Equipment Code	
1	Ultra sonogram	06 nos	RRMCH/RAD/USG/01-01	SAMSUNG
			RRMCH/RAD/USG/01-02	PHILIPS-HD7
			RRMCH/RAD/USG/01-03	PHILIPS-HD 11
			RRMCH/RAD/USG/01-04	SIEMENS
			RRMCH/RAD/USG/01-01	SONASITE
			RRMCH/RAD/USG/01-05	SONASITE
2	Magnetic Resonance Imaging	01 nos	RRMCH/RAD/MRI/01-01	AVANTO
3	Mammography	01 nos	RRMCH/RAD/MAMO/01-01	Planmed sophie classic
4	X-Ray machine	12 nos	RRMCH/RAD/X-RAY/01-01	300MA-GE
			RRMCH/RAD/X-RAY/02-02	500MA-GE
			RRMCH/RAD/ X-RAY /03-03	300MA-SIEMENS
			RRMCH/RAD/ X-RAY /04-04	500MA-SIEMENS
			RRMCH/RAD/ X-RAY /05-05	GE - 60MA
			RRMCH/RAD/ X-RAY /06-06	ALLENGERS-60MA
			RRMCH/RAD/ X-RAY /07-07	MEDICO-100MA
			RRMCH/RAD/ X-RAY /08-08	MEDICO-100MA
			RRMCH/RAD/ X-RAY /09-09	60MA SHIMADZU
			RRMCH/RAD/ X-RAY /10-10	1000 MA SHIMADZU
			RRMCH/RAD/ X-RAY /11-11	60MA – MEDITRONICS
			RRMCH/RAD/ X-RAY /12-12	800MA-ALLENGERS
5	Computerised Tomography	01 nos	RRMCH/RAD/ CT/01-01	SOMATOM 128 PERSPECTIVE