Dr. Vithalrao Vikhe Patil Foundation's

Medical College & Hospital

Ahmednagar-414111

STANDARD OPERATING PROCEDURES (SOPs)

of

DEPARTMENT OF PATHOLOGY

DEPARTMENT OF PATHOLOGY SOPs

SOPs for Cytopathology

SOP RAPID PAP STAINING

Principle – Papanicolaou stain includes both acidic and basic dyes. Acidic dye stains basic components of the cell and the basic dye stains acidic components of the cell.

Procedure-

1. Hydration of smear- hydrate fixed smear for 3-5 minutes in tap water and blot out excess water from the slide.

2. Nuclear- staining – keep the slide on a staining rack and add few drops of nuclear stain rapid PAP (R1) to cover the smear. Wait for 60 seconds and wash in running tap water.

3. Developing – Add 3-5 drops of wash buffer (R7) and wash after 20 sec. Blot out excess water from the slide.

4. Dehydration- Dehydrate with RAPID- PAP dehydrate (R5) for 60 sec.

5. Cytoplasm Staining- Keep the slide on a staining rack and add few drops of working cytoplasm stain (R2A+R2B) to cover the smear. Wait for 60 sec.

6. Washing- Wash in tap water, blot out excess water from the slide.

7. If the smear required mounting, dehydrate with dehydrant (R5) for 60 sec and dry at air. Rinse with xylene (R6).

8. Mounting – Mount with cover glass using a drop of D.P.X (R4).

SOP MODIFIED LEISHMAN'S STAIN

Principle -

Two main components of all Romanowsky stains are an acidic dye (eosin y) and a basic dye (oxidized methylene blue)

- ➔ Basic or cationic dye- It is positively charged and binds to anionic sites and imparts blue violet color to nucleic acids, nucleoproteins and granules of basophils. E.g. Methylene blue, azure B.
- ➔ Acidic or anionic dye- It is negatively charged and binds to cationic sites and imparts orange red color to hemoglobin and eosinophil granules; it also binds to cationic nuclear protein E.g (eosin Y)

Procedure-

1. Place a drop of blood on slide and spread with a fine edge spreader.
2. Air dry the smear.
3. Cover the smear with leishman stain for 4 minutes.
4. After 4 minutes, add twice the volume of buffer to the stain and leave it for 7 minutes. A scum of metallic sheen forms on the surface.
5. Wash the stain away in a stream of tap water.
6. Wipe the back of slide clean with cotton wool and set it upright in the draining rack to dry.
7. Air dry the slide and mount it with DPX.

SOP H&E STAINING

Application -

H&E Staining in cytology is useful for microscopin analysis of cell cytology specifically nuclear details.

Solutions -

1. Harris hematoxylin solution
2. 1% eosin solution
3. 2% Aq. Lithium carbonate solution.

Procedure -

1. Fix the smear with biofix fixative.
2. Stain with hematoxylin for 1 min.
3. Wash in water.
4. Blue in lithium carbonate solution for 10 seconds.
5. Wash in water for 1/2 min.
6. Stain with eosin solution for 15 seconds.
7. Dehydrate in ascending grades of alcohol.
   - 70% alcohol – 5 dips.
   - 90% alcohol – 5 dips.
   - 100% alcohol- 10 dips.
8. Clear in xylene.
9. Mount in DPX.

SOP CYTOCENTRIFIUGE

Principle – In a liquid suspension, the particles whose density is higher than the liquid sink and the lighter particles float. The movement of the particles in the liquid media greatly depends on the density difference with the suspension liquid. Centrifugation technique replaces the gravity by a more powerful “Centrifugal force” to enhance the rate of sedimentation of suspended particles that are denser than the suspension liquid. This effective gravity increases depending on the radius of the arm of the centrifuge machine and the square of the rotational rate of the arms.

Relative centrifugal force = Mass x Radius of rotation (means, distance of particles from the axis) x (angular movement)^2

Procedure-

1. Program the machine at 900 rpm for 5 min.
2. Load the cytocuvettes with filter cards and slides into rotor.
3. Ensure the alignment of holes of cytocuvettes and filter card.
4. Pour the body fluid in cytocuvette with the help of pipette or dropper.
5. Sample volume should be generally 200 to 400 µl.
6. Ensure- 'No spillage' inside the rotor chamber.
7. Put the lids in place to prevent aerosols.
8. Balance the centrifuge on other side with empty assembly of cuvette, filter card and slide.
9. Close the lid and then press start button.
10. After completion of programmed cycle, it will give an alarm.

Applications-

1. Fluid cytology for malignant cells.

2. Retrieval of cells from pauci-cellular materials like CSF, Urine etc.

3. Liquid based cytology in cervical cancer screening.

Sample Volume-

1. Pleural, peritoneal, pericardial and synovial fluids = 200-400 µl.

2. Turbid fluid – 50-100 µl.

3. Hypo cellular fluids- 500 µl

4. Hemorrhagic fluid- first lyse the RBC's with 0.5% acetic acid solution.

5. Viscous fluids (Bronchial wash / Sputum, BAL etc) are treated with 5 % KOH before introducing them in cytocentrifuge.

SOPs for Histopathology

SOP RAPID H&E STAINING FOR FROZEN SECTION

Principle- The mordant used in alum hematoxylin is aluminium either potash alum (aluminium ammonium sulfate)

Initially, the nuclei become red after staining which turn blue or blue black when stained sections are washed in weak alkali. Tap water can be used for washing as it is alkaline enough to produce desired color change. Sometimes, alkaline solutions like Scott's tap water, saturated lithium carbonate or 0.05% ammonia in distilled water is used for this color change. This process of changing color from red to blue is called blueing.

Solutions -

1. Harris hematoxylin solution
2. 1% eosin solution
3. 2% Aq. Lithium carbonate solution.

Procedure -

1. Take the section to water
2. Stain with hematoxylin for 1 min.
3. Wash in water.
4. Blue in lithium carbonate solution for 10 seconds.
5. Wash in water for 1/2 min.
6. Stain with eosin solution for 15 seconds.
7. Dehydrate in ascending grades of alcohol.
   - 70% alcohol – 5 dips.
   - 90% alcohol – 5 dips.
   - 100% alcohol- 10 dips.
8. Clear in xylene.
9. Mount in DPX.

Advantage-

H&E differentiates and distinguishes the nuclei, cytoplasm and connective tissue.

Results:-

Nuclei – Blue

Cytoplasm connective tissue- shades of pink.

SOP H & E STAINING PROCEDURE FOR ROUTINE HISTOPATHOLOGICAL SECTIONS

Principle- The mordant used in alum hematoxylin is aluminium either potassium alum (aluminium potassium sulfate) or ammonium alum (aluminium ammonium sulfate). Initially, the nuclei become red after staining which turn blue or blue black when stained sections are washed in weak alkali. Tap water can be used for washing as it is alkaline enough to produce desired color change. Sometimes, alkaline solutions like Scott's tap water, saturated lithium carbonate or 0.05% ammonia in distilled water is used for this color change. This process of changing color from red to blue is called blueing.

Procedure-

1) Depararffinize the section in descending grades of alcohol for 30 sec in each.
    1) Alcohol
    2) 80% Alcohol
    3) 70% Alcohol
2) Then take the section to water to 2 min.
3) Dip the slides in Harris hematoxylin stain for 4-5 min
4) Wash it in water
5) Keep the slide in water for 3-4 min
6) Differentiate with 1% Acid Alcohol (2-3 dips)
7) Wash it in water
8) Wash briefly in water 3 dip in water for 10-15 min
9) Dip the slide in eosin stain for 30-60 sec
10) Wash it in tap water
11) Dehydrate in 95% Alcohol for 2 changes
12) Clear the slide in xylene 2 change dip 30 sec
13) Mount the section with DPX and cover with a coverslip

Block B stain kit

Formula for preparation of hematoxylin for routine use:

Harris Hematoxylin

1) Content of stain

Harris Hematoxylin (lexystals)- 5 gm

Absolute Alcohol- - 50 ml.

Ammonium or potassium alum- 100 gm

Distilled water - 950 ml.

Mercuric oxide - 1 gm.

G Acetic Acid - 40 ml.

Dissolve Hematoxylin in Alcohol 50^{c} temp in water bath

Distilled water 950 ml

Potassium ammonium Alum/ potassium alum - 100 gm.

Mix and heat

Take the hematoxylin

Mercuric Oxide - 1 gm.

Cool

Acetic acid - 40 ml.

Filter the solution

EOSINS

Eosin 10 gm.

Distilled water- 1000 ml.

Mix well

Use the process:-

1% Acid Alcohol

700 ml Alcohol + 300 ml Distilled water 1000 ml

1000 ml – 10 ml = 990 ml.

990 ml + 10 ml HCL add

Total- 1000 ml Acid Alcohol

Advantage-

H&E differentiates and distinguishes the nuclei, cytoplasm and connective tissue.

Results:-

Nuclei – Blue

Cytoplasm connective tissue- shades of pink.

PAS (PERIODIC ACID SCHIFF STAINING)

Principle-

PAS stain is a histochemical reaction in that the periodic acid oxidizes the carbon to carbon bond forming aldehydes which react with colourless Schiff reagent producing pink colour.

Preparation (Solutions and reagents) -

1. 0.5 % Periodic acid solution

- Periodic acid- 0.5 gm
- Distilled water- 100 ml

2. 1 N HCL Solution

- Hydrochloric acid – 83.5 ml
- Distilled water-916.5 ml

3. Schiff's reagent

- Basic fuschin – 1gm.
- Distilled water heat to 60^0C - 200 ml & bring to boiling point, cool and then add
- Potassium metabisulphite – 2gm
- 1 N HCL-10 ml

Let bleach far 24 hrs then

- Add activated carbon- 1 gm

➔ Shake for 1 minute, then filter through coarse filter paper. Repeat

filtration until the solution is colorless. Store in refrigerator.

Procedure-

1. Bring the tissue sections on slide.

2. Warm slide on lamp flame to melt wax.

3. Remove wax by 10-12 drops of xylene.

4. Remove xylene by adding isopropyl alcohol.

5. Bring section to distilled water and drain water well.

6. Add 8-10 drops periodic acid reagent on smear and wait for 5 min at R.T. and wash slide slowly with DI and let it dry.

7. Add 8-10 drops of schiff's reagent and wait for 15 min at R.T and wash the slide under tap water for 5 min.

8. Counterstain the smear with 8-10 drops of Hematoxylin stain and wait for 2 min and wash under tap water for 15-20 seconds and let it dry.

9. Mount the slide with DPX and examine under microscope.

Results -

- Glycogen, mucin and some basement membranes - red to purple.

- Fungi- red to purple.

- Nuclei – Blue.

ACID FAST STAINING (AFB) OR ZIEHL – NEELSEN STAINING (ZN)

Principle -: Acid fast mycobacteria contain mycolic acid in their outer membrane, making the cells waxy and resistant to staining with aqueous based stains such as the gram stain. The primary stain, carbol fuchsin is applied to the cells, and heat and phenol are used to allow the stain to penetrate into the waxy surface of acid – fast microorganisms. The excess stain is removed with treatment by acid alcohol (ethanol and HCl). A secondary stain, methylene blue, is then applied to the cells.

Reagents -:

1. Primary stain – 0.3% carbol- fuchsin

   (Dissolve 50g phenol in 100 ml ethanol/ methanol)

2. Decolorization solution-

   (Add 30 ml HCl to 1 L of 95% denatured alcohol)

3. Counterstain- 0.3% methylene blue

   (Dissolve 3g methylene blue in 1L distilled water)

Procedure for AFB staining:-

1. Fix the smear with biofix fixative.
2. Add carbol fuchsin (2 N stain)
3. Heat the slide. (Do not boil)
4. Keep the stain for 8 min.
5. Wash with tap water.
6. Decolorize with 20% H_2SO_4 for 2-4 min.
7. Wash with tap water.
8. Counter stain in methylene blue for 1 min.
9. Wash with tap water.
10. Clean, dry and mount.

Interpretation-:

Acid fast -: Bright red slightly curved rods occurring singly or in small groups.

Non-acid fast-: blue color

Background-: Blue.

ALCIAN BLUE STAINING FOR ACID MUCOPOLYSACCHARIDES

Principle- Alcian blue is a copper phthalocyanine basic dye that is water soluble and is colored blue because of its copper content. When used in a 3% acetic acid solution, Alcian blue stains both sulfated and carboxylated acid mucopolysaccharides and sulfated and carboxylated sialomucins.

Reagents required-

1. 3% acetic acid

   - Glacial acetic acid- 3ml

   - Distilled water – 97 ml

2. Alcian blue solution

   - Alcian blue 8G X -1gm

   - 3% acetic acid – 100 ml

3. Nuclear fast red (Kernechtrot) solution.

- 0.1 gm nuclear fast red in 100 ml of 5 % aluminum sulfate solution. Heat to boiling slowly, cool, filter and add a grain of thymol as a preservative.

Procedure-

1. Place in 3% acetic acid solution for 3 min.
2. Stain in alcian blue solution for 30 min.
3. Wash in running water for 10 min.
4. Rinse in distilled water.
5. Counterstain in filtered nuclear fast red solution for 5 min.
6. Wash in running water for 1 min.
7. Dehydrate and clear through 95% ethyl alcohol, absolute alcohol and xylene, 2 changes each, 2 minutes each.
8. Mount with suitable DPX.

Result - Weakly acidic sulfated mucosubstances

- Hyaluronic acid and sialomucins – Dark blue.

- Nuclei- red to pink

- Cytoplasm – pale pink.

Reticulin stain

Principle- Reticulin fibers have an affinity for silver and subsequently stained with ammonical solution.

Procedure-

1. Bring deparaffinized sections to water.
2. Oxidize with 1% potassium permanganate for 1-2 min.
3. Rinse in tap water.
4. Decolorize with 3% potassium metabisulfite for 1 min.
5. Rinse in tap water.
6. Sensitize in 2% iron alum for 1 min.
7. Wash for 2-3 min, then rinse in distilled water 2-3 changes.
8. Impregnate in silver solution for 3 min.
9. Rinse quickly in distilled water.
10. Reduce in 10% formalin in tap water for 3 min.
11. Wash in running tap water for 3-4 min, then rinse in distilled water.
12. Tone in 1:500 gold chloride for 5-15 min.
13. Rinse in distilled water.
14. Place in 3% potassium metabisulfite for 1 min.
15. Rinse in distilled water.
16. Fix in 3% sodium thiosulfate for 1 min.
17. Wash in water.
18. Dehydrate through graded alcohol.
19. Clear in xylene and mount in DPX.

Result -

Reticulin fibers – Black

Nuclei and cytoplasm- Grayish / shades of grey.

SOP FOR SPECIMEN COLLECTION

(In Accordance with the CAP guidelines)

A. Patient Identification and specimen labelling:-

1) Patient's identity is verified at the time of specimen collection and the specimen is labelled in the presence of the patient.

2) Specimen label contains at least 2 patient specific identifiers A) Full patient name B) Identification number of hospital C) Date of Birth.

3) Additional label elements that are present:

A) Age & gender B) Requisition number C) Ordering physician

D) Type of specimen.

B. Specimen transport:-

1) All specimens are placed in leak proof containers.

2) For routine specimens: 10% neutral buffer formalin is used as transport media 15-20 times the specimen volume.

3) For Frozen sections: Normal saline is used and the specimen is transported immediately to the lab.

C. Requisition form:-

1) The specimen is accompanied by a requisition form which is filled by the duty doctor.

2) The requisition form contains patient identifiers name of doctor -in- charge, procedure performed, clinical details and date and time of specimen collection.

D) Specimen reception:-

1) The specimen with the completed requisition form is received by the histopathology laboratory personnel on duty.

2) Patient identifiers are re- checked before accepting the specimens.

3) These received specimens are stored at a designated area in the grossing lab in an orderly fashion.

SOP SPECIMEN DISCARDING

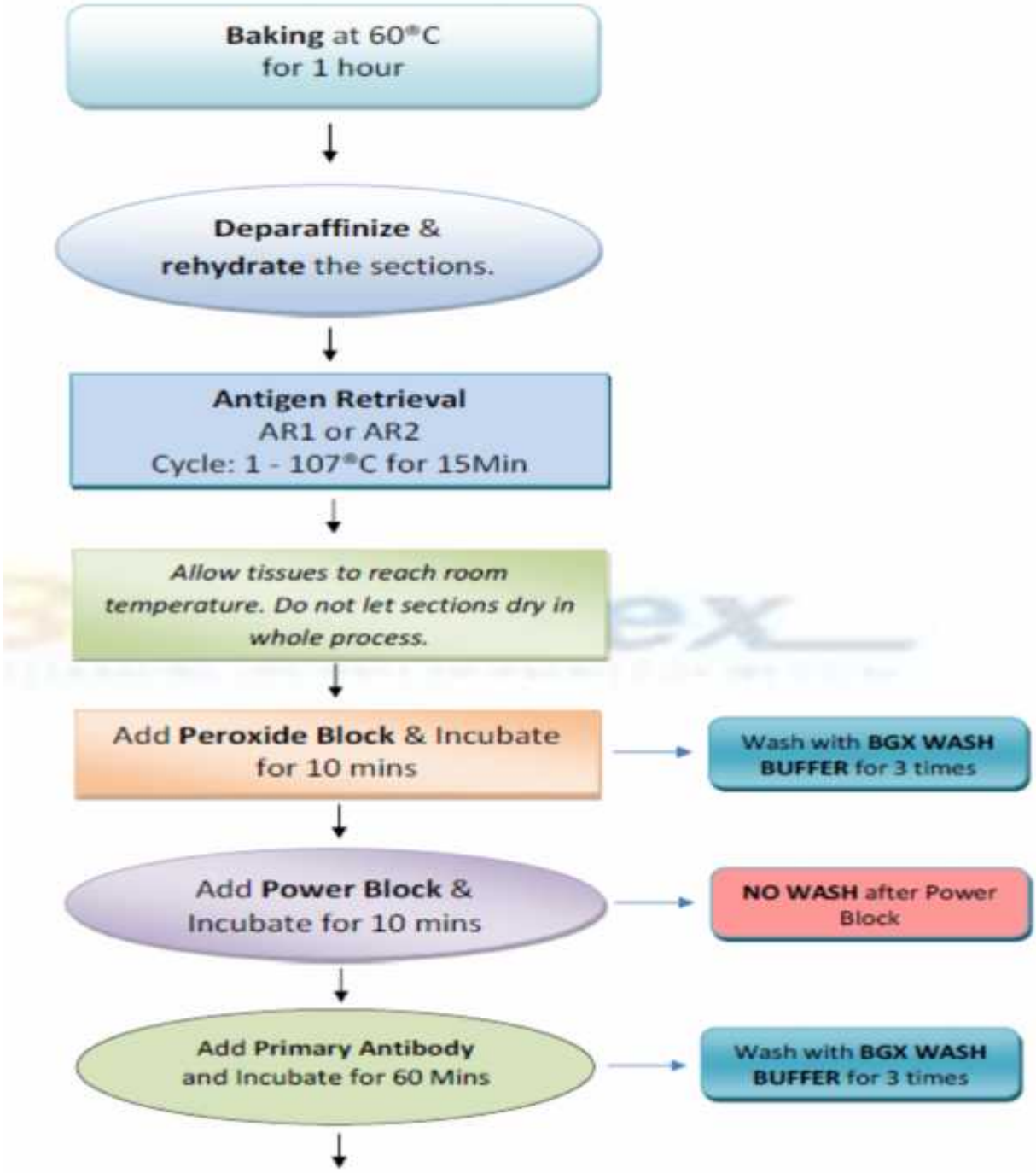
1) After a retention period of 6 months the grossed and reported specimens are segregated as museum specimens and those to be discarded.

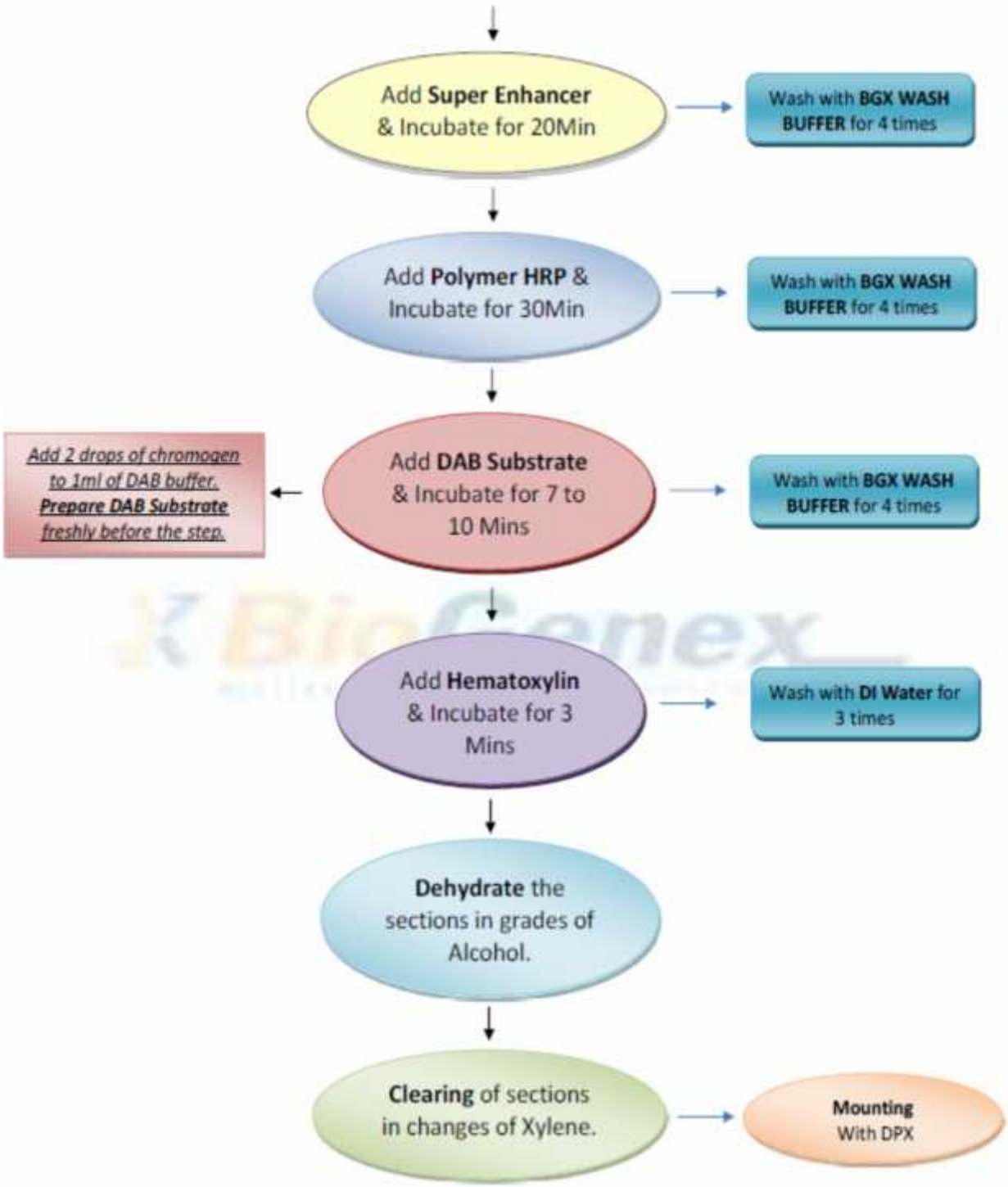
2) The museum specimen are mounted, labelled and displayed.

3) The specimens to be discarded are placed in colour coded (Yellow) biohazard container with a double bag which is disposed off in the hospital incinerator by the housekeeping supervisors.

SOP for Immunohistochemistry

Immuno Histochemistry Protocol




Add Super Enhancer & Incubate for 20Min
Wash with BGX WASH BUFFER for 4 times
Add Polymer HRP & Incubate for 30Min
Wash with BGX WASH BUFFER for 4 times
Add 2 drops of chromogen to 1ml of DAB buffer. Prepare DAB Substrate freshly before the step.
Add DAB Substrate & Incubate for 7 to 10 Mins
Wash with BGX WASH BUFFER for 4 times
Add Hematoxylin & Incubate for 3 Mins
Wash with DI Water for 3 times
Dehydrate the sections in grades of Alcohol.
Clearing of sections in changes of Xylene.
Mounting With DPX

IHC Markers Available

Sr. No	IHC Markers
1	Cytokeratin, High MW, Monoclonal (34bE12).
2	C-Erb B-2(Her-2/Neu) 6ml Bigenix
3	Anti-Humen progesterone Receptor 6ml
4	Estrogen Receptor 5 ml Biogenex
5	Ki 67 Antigen, proliferating cell, monoclonal (BGX-297), Mouse, IgG1”
6	Primary Antibody for paraffin section Desmin for IHC (6 ml)
7	Cytokeratin 7, Moniclonal (OV-TL 12/30), Mouse, Ig G1
8	Cytoleratin cocktail, Monoclonal (AE1 abd AE3), Mouse
9	S-100 Antibody 6 ml
10	Smooth muscle Actin (1A4)- 6 ml.
11	Chromogranin A, Monoclonal (LK2H10), Mouse. Igg1 (6 ml).
12	Synaptophysin, Monoclonal (snp88), Mouse, IgG3
13	CD (T Cell), Monoclonal (PS1), Mouse , IgG2a
14	Am430-5M CD5 Monoclonal, Mouse
15	Primary Antobody for Paraffin section CD 15 for IHC- (6 ml vial)
16	MIC-2/CD 99 Antobidy (6 ml).
17	CD-117 Antobody (6ml).

SOP for Museum specimen maintenance

Mounting - Jar size selection

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Specimen mounting

↓

Formalin filling/replacing- Upto level to ensure complete dipping of specimen into jar. Formalin in the jars is replaced as and when required.

↓

Specimen numbering -

1. All specimens are serially numbered
2. For specimens with same diagnosis, subsequent numbering is done as serial no. with alphabetical order
   [e.g 2, 2A, 2B, 2C…….]

↓

Labeling – All specimens are neatly labelled mentioning Diagnosis and number

[e.g Adenomyosis of uterus – 1]

↓

Specimen arrangement

- All mounted, well labelled specimens are arranged System wise in iron racks

↓

Discard- If autolysed

SOP for Death Audit

Introduction –

Death audit is carried out in all the hospitals to have complete knowledge about death of any patient in hospital setting, from admission of patient till the end.

Aim -

This is carried out to examine , the all the documented or non documented procedures, concerning with proper management of all patients till the demise, in selected cases, to determine any type of shortcomings, at any step from admission onward. Shortcomings if any, observed are conveyed to all concerned for its rectification and future guidance to all.

Frequency -

It is dove once a month with information to all concerned staff of hospital.

Selection of case -

Death cases to be discussed in death audit meeting are selected from one or more of following criteria

a) Death case to be discussed from death occurring in hospital in immediate last few months period.

b) Sudden death cases or death occurring within 24 hours of admission of patient.

c) Death cases of common ailments and rare disease cases from all specialties.

d) Academically interesting cases of death etc.

Procedure -

Death case to be discussed is selected from medical records department of hospital. All concerned are informed about date, time and place of death audit meeting. Generally HOD of Pathology and HOD of concerned specialty, with their available faculty members and all concerned PG students from both departments attend the meeting.

PG student from concerned specialty presents the case with all details from medical record of concerned death case. PG student from Pathology department present the cytological or histopathological reports, if done in that specific case.

There after all available details are discussed among all members, queries if any from anyone, is answered by concerned person. In nutshell all aspects of death case are analyzed critically in professional manner, regarding overall management of case during hospitalization period. Observations or shortcomings if any are conveyed to all for future guidance as continued learning process.

Documentation-

All significant details of death case discussed are documented for maintaining record.

SOP for Mentorship

1) First we made groups of 10 students (UG, PG, Interns) & for each group one mentor was allotted.

2) Mentor has been provided with mentorship diaries of each student.

3) Mentor filled all the diaries about the details of students like his academic, personal, hostel and psychological details.

4) Mentors also have taken meetings with students quarterly and whenever their parents visited the college, meeting with parents also has been taken.

5) During lockdown period, online meeting regarding their knowledge about corona infection and prevention measures and their area status and psychological status were taken.

6) Any problem related to students, all mentors have discussed it and solved the problems whenever possible.

7) Record of their online Zoom meeting is kept with me as I am mentorship in charge.

8) I have taken the meeting of all mentors regarding their difficulties to connect with the students.

SOP for Cultural Club

We have formed cultural club in our college which includes all cultural activities during the academic year under the able guidance of teachers.

We arrange annual cultural meet during which all cultural events such as singing, dancing, debate, poetry and anchoring activities are arranged. For the music our own students play some instruments and singing also is done by our students only. We have taken inter-college classical dance competition in which many colleges of our foundation had participated.

We also arrange poetry as well as debate competition in which personal poems as well as other poems of good poets had to be read. There was a huge response for both the competition. For debate, recent topics were chosen for that particular year.

At the end of social annual meet we distribute prizes to winners ever year.

As a cultural club I/C, I distribute all the work under the able guidance of teachers. We make student I/C for each subgroup and they co-ordinate with each other and teachers also.

We also arrange fine arts competitions which includes posters, rangoli, mehendi, sketching, and various days such as rose day, school day, cartoon day, mismatch day, halloween day etc.

The prizes for annual social gathering for which we have given name as ' Antarang' & every year we celebrate 'Ganesh festival' also which includes Ganesh murti sthapana, arti, decoration and prasad vatap everyday for 10 days. This is all arranged by students under the guidance of teachers and management. During this festival also we arrange few competitions. The prizes for which are distributed during the end of annual social meet. We also arrange 'Mahaprasad' & 'Satyanarayan' on day before the 'Visarjan of Bappa Ganpati'.

Members-

1) Dr. S.H.Khaparde- I/C	5) Dr.Sangita Patil- Member
2) Dr. Surekha Jadhav- CO – I/C	6) Dr. Pritish Raut- Member
3) Dr. Prachi Anchawale- Member	7) Dr. Swami Amrut- Member
4) Dr.Shradha Gunjal- Member	

Dr.Vikhe Patil Memorial Hospital & Medical College

STANDARD OPERATING PROCEDURES

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Amendment Sheet

S. No.	Date & Revision No.	Reason for amendment	Authorised By

Prepared By Approved By

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Standard Operating Procedure for Internal Communication Procedures

Purpose	The laboratory communicates effectively with the patient with regards to the services
Scope	It covers all communication in the laboratory.
Responsibility	Director - Lab, Quality Manager and Deputy Quality Manager

Procedure:

1 Enquiries: Enquiries by the patient are handled at the reception counters.

2 Customer Feedback: Patients are encouraged to give their feedback.

3 The internal communication is done through following means:
- a. Team / individual briefing and meetings
- b. Notice boards
- c. Review meetings
- d. Circulars and memos Presentations
- e. Verbal/ written instructions
- f. Work procedures
- g. Checklists
- h. Telephone

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Standard Operating Procedure for Handling of Human Specimens

Purpose	To establish a procedure to ensure that human specimens and remains are properly handled and treated according to legal requirement and good laboratory practice.
Scope	This applies to all samples handled in the laboratory from receipt to disposal as per government laws. While in possession handling should prevent or minimize chemical & biological activities within the sample to derive at accurate results.
Responsibility	Director - Lab, Quality Manager and Deputy Quality Manager
Policy	All specimens are handled with care irrespective of cast, creed or religion and disposed off in proper manner as per law.

Procedure:

1. All samples are handled with dignity and respect.
2. Samples are identified with the person to whom the sample belong with patients details as per registration slip.
3. Transfer the sample to Laboratory for processing and testing.
4. Processing of all sample with same dignity and care
5. Ensure proper storage conditions are maintained before the samples are processed and after processing to avoid any deterioration in results if repeat test is done / required.
6. Post testing all samples are stored as per the storage conditions and retention period defined in procedure for sample storage in Sample Collection manual.
7. After requisite storage period has lapsed, the samples are disposed off as per biomedical waste disposal procedure detailed in Gen-SOP-10.
8. All staff are given training on the handling of specimen with respect, wear proper personnel protective equipments [PPE] while handling the samples and also take care of cross contamination of samples, deterioration, spill, etc.

Prepared By Approved By

SOP / 03 / R 00 / Dt.: 01.07.2018

Standard Operating Procedure for Pre-Examination Handling, Preparation & Storage of Samples

Purpose To establish the appropriate and effectiveness systems for handling of specimens during pre-examination, preparation and storage i.e. till the samples are kept in the laboratory so that there is no deterioration in it besides the natural changes in analytes due to time.

Scope It covers all specimens / samples handled by the laboratory.

Responsibility Director - Lab, Quality Manager and Deputy Quality Manager

Policy The laboratory aims to handle the samples in most appropriate manner as deemed fit for it so that it preserve the analytes from abnormal deterioration during the period of their storage in laboratory.

Procedure:

1 The phlebotomist ensure that the samples are taken in appropriate containers as deemed fit for the analytes under test.

2 All containers are uniquely identifiable by means of bar code of respective customer as per the registration slip issued.

3 Care is also taken at the time of drawing the samples and transferring in the vials that the order of draw is followed.

4 Depending upon the test requirement, the blood samples are centrifuge immediately for plasma and kept for 1/2 - 1 hour where serum is required for testing. Where whole blood is used the sample is transported to that department for processing.

5 Technicians also checks that the time lapsed between the sample drawn and received in lab is not more than the prescribed norms for the respective test and are kept at appropriate temperature - for samples collected outside the lab i.e. in customer's place.

6 Proper centrifuge procedure is followed so that the plasma / serum is appropriate for testing

7 During handling the vials are kept in test tube stand and transported carefully to avoid and spillage /

8 It is ensured that there is no cross contamination while preparing the samples. Special attention is given to recapping so that the caps do not get interchanged.

9 **Storage period of examined specimen**

The examined specimens to be stored for re-examination and/or additional tests for a minimum period as specified bellow:

Clinical Biochemistry: Min. one day at 2 - 8° C

Haematology: Complete Blood Counts Min. One day at 2 - 8° C

Stained Slides: One Week

10 **Retained sample test for the stored specimen**

The repeat test on the stored specimens is performed to verify the storage conditions, numbering system and deterioration of the specimen during storage. The frequency for the repeat test is as follows:

Biochemistry: Samples for one analyte once in a week.

Haematology: The repeat test is done monthly for the stored sample.

Acceptability Criteria: The percentage difference between the two results refer to SOPs 16 A

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Procedures for Use of NABL Symbol

Purpose: To define the procedure for use of NABL symbol

Responsibility: Director - Lab, Quality Manager and Deputy Quality Manager

Reference: NABL 133 guidelines

Procedure:

Wherever NABL symbol is used it is NABL Logo with the certificate number underneath as follows

Cert. No. M-0XXX

NABL symbol is used on the letter head which is used for report printing. However the tests not covered under the scope has " * " mark in front of the test and a note written at the bottom of the page **"The tests and/or calibrations marked with an "*" are not accredited by NABL"**.

Procedures for Testing During Instrument/Equipment Failure.

Purpose	To define the action for Laboratory Testing During Instrument/Equipment Failure.
Scope	Covers all the samples which have to be tested on equipment when in-house machine is down.
Responsibility	Dir-Lab, Quality Manager & Technicians.

Procedure

- Samples are collected which have to be tested on equipment and incase it is breakdown.
- Call service engineer for checking the equipment.
- Fill the requisition forms provided by referral laboratory for each patient and entries are made in 'Outsourced Test Register.
- Samples are handed over to the courier from the referral laboratory with the requisition form & proper cold chain is maintained.

- Inform at reception and place a notice in bilingual language that machine is breakdown.
- Stop sample collection for the tests to be performed on failure equipment.

Standard Operating Procedure for Prevent Cross Contamination / Separation of Incompatible Tests

Purpose	To segregate the work area and make procedures in order to avoid cross contamination of samples.
Scope	It covers all samples handled and tests performed in the laboratory in various fields
Responsibility	Director - Lab, Quality Manager and Deputy Quality Manager
Policy	Adequate care is taken in designing the work area to maintain effective separation between incompatible processes and avoid cross contamination while working.

Procedure:

1. The entire lab is segregated in various work area which effectively separate the incompatible activities of the lab to ensure safety of the samples and staff.
2. Where available and commercially feasible, disposable material (e.g.. Needle, syringe, tips, cups, culture plates, slides, etc) are used to avoid cross contamination.
3. Separate area are assigned for performing tests on infectious material / samples
4. In sample collection: gloves are changed after collecting each sample / cleaned with hand sanitizer / disinfectant.
5. Regular cleaning of each work table, place and decontamination of equipments is done with 1% sodium hypochlorite.

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Standard Operating Procedure for Verification of Examination Procedures

Purpose To ensure that the procedures followed for examination of samples are as per the defined manner and appropriate for testing of samples i.e. these are as per kit inserts / equipment manual / standard book and the documented test procedure.

Scope It covers all examinations done in the laboratory.

Responsibility Director - Lab, Quality Manager and Deputy Quality Manager

Policy Only appropriate and standard method as per the equipment, kit insert or ones give in standard books to be followed at all time in the lab for testing of specimens.

Procedure:

1. All existing test procedures are verified by the Director - Lab / Technical Manager / Consultants for their appropriateness and use atleast once in a year or whenever there is change in the method.
2. They verify that the examination method being followed in actual is as per the one written in the equipment manual or kit insert for those tests performed on equipments. If this method is also same as the one written for the respective test.
3. The manual method are verified annualy with the kit insert or the standard book used to prepare the initial written procedures.
4. The technician takes care and verify whenever a new kit is opened that the method & Biological reference interval mentioned in the kit insert is the same as the one followed earlier. In case of any difference, it is brought in the notice of concern consultant for their verification.
5. Authorised Signatories also reviews the method whenever there is any suggestion / complaint from the user of the service and if appropriate the procedures are modified.
6. Authorised Signatories also takes care to follow the best and most reliable procedures suitable for the equipment in use to arrive at accurate test results for improved customer care.
7. Post review and verification of the examinatio procedures, the Director-Lab / Technical Manager / Consultants sign on the existing procedure copy as an evidence that the procedure has been reviewed and there is no change in it. In case of changes, the procedure is revised and revised issue is printed and approved and records maintained.

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Standard Operating Procedure for Storage & Disposal of Specimens

Purpose To define the procedure for storage of specimens after testing and its disposal thereafter.

Scope Covers all specimens received in laboratory for testing

Procedure:

Storage of Specimens / Samples

Haematology Specimens

a. Keep the EDTA tube in the rack (ensure all tubes are capped)
b. Keep the specimen in the fridge and write the date on the tube holder / stack
c. All Haematology specimens to be stored for one day.

Biochemistry Specimens

a. Transfer the serum / plasma in the aliquot which are marked with same ID as per the specimen being transferred and in tube if gel separated tubes are used
b. Keep the aliquots / gel vacutainer in the rack
c. Keep the specimen in the fridge and write the date on the rack
d. All Biochemistry specimens to be stored for one day.

Disposal of Specimens / Samples

Every day in the evening dispose Haematology & Clinical Biochemistry stored samples of previous day in RED Bag as per BMW policy.

Note:

All samples / specimens after testing should be stored in fridge within 2 hours of testing

Standard Operating Procedure for Bio Medical Waste Segregation

Purpose To define the system of waste disposal and prevent it's re-use.

Scope Details of the procedures for proper disposal of waste generated.

Procedure:

The medical waste disposal is becoming an important area of concern. Lab has entered into a contract with a government approved waste disposal agency. This agency ensures that all medical waste is destroyed to prevent its re-use.

The segregation of waste type – All waste is classified in four categories and are segregated at the place of generation itself for ease of disposal. [Ref.: BMW notification dt. 28-03-2016 and amendment dt.: 18-03-2018]

Bio Medical Waste Segregation

Colour	Waste Description
Yellow Bag	Cotton swabs. Used urine reagent strips. Discarded Microbiology culture plates after autoclaving. Histo samples.
Red Bag	Syringes (without needle) Used Gloves. Vacutainers after recapping properly. Reaction vessels, cuvettes, Hitachi cups, RIA vials, used pipette tips, urine containers after discharging the urine.Stool samples in plastic containers after recapping properly & centrifuge tubes that have been used for sample processing Plastic empty reagent containers/cassettes.
White Puncture Proof Container	All metal sharps including Vacutainer needles and syringe needles.
Card board Box with Blue marking	All glass sharps including slides, and broken glass bottles Empty glass QC/PT/reagent vials
Black Bag	Non infectious waste including paper, plastic bags vacutainer needle covers etc.

• Biomedical waste is collected from lab and timely packaging and labeling in correct order color coded bags is insured.

• Disposbal of used needle is done in puncture proof container in Sample Collection Room. Which is discarded within 48Hrs.

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Standard Operating Procedure for Bio Medical Waste Segregation

Disposal of Remnants of Specimens in the Laboratory

• Urine - Pour the remnant in the sink and flush with plenty of water and discard the containers in Red bin.
• Stool - Close the lid tightly and discard in Red bin

Disposal Blood & Serum Sample-

• Place the Blood and serum sample tubes in autoclavable bag after affixing small strip (indicator strips in autoclave).
• Switch on the supply.
• Give 15 pounds pressure, 121°C temperature for 60 minutes,
• If Temperature is 120°C then for 90 minutes
• put it off and let it cool.
• Check indicator strips for effective sterilization.
• And collect the waste in the Red plastic bag and seal it.

Final Disposal

Care should be taken to reduce the waste as much as possible before it is finally disposed. Valid agreement with operator of common biomedical waste facilities (CBWTF) authorized by MPCB for collection transportation, treatment & disposal of the bio-medical waste in Maharashtra.

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Standard Operating Procedure for Handling of Critical & Alert Range of Result

Critical values are test results that are so abnormal that they generally indicate severe illness and require immediate medical intervention. For this reason, these values must be communicated to the attending physician / customer immediately. On observing that a parameter is lying in the critical range, the technician need to inform the doctors and subsequently to the customer or their clinician over phone within 30 minuts. The record of the communication is maintained in the critical value information record. (Note the date, time and the name of person informed)

Critical Values

Test Parameter	Result	
Albumin	Children	< 1.7 and > 6.8 gm/dL
Bilirubin	New Born	> 15 gm/dL
Urea	Adult	> 171.2 mg/dL
	Children	> 117.7 mg/dL
Calcium	Children	< 6.5 or > 12 .7 mg/dL
	Adult	< 6.0 or > 13 .0 mg/dL
Creatinine	Adult	> 5 mg/dL
	Children	> 3.8 mg/dL
Glucose	Adult	< 40 or > 450 mg /dL
	Children	< 46 or > 445 mg /dL
	Newborn	< 30 or > 325 mg /dL
Potasium	Adult	< 2.8 or > 6.2 mEq/L
	Newborn	< 2.8 or > 7.6 mEq/L
	Children	< 3.4 or > 9.5 mEq/L
Sodium	Adult	< 120 or > 160 mEq/L
Uric Acid	AdulT	> 13 mg/dL
	Children	> 12 mg/dL
Total Protein	Children	< 3.4 and > 9.5 g/dL
Hemoglobin	Adult	< 7 and > 20 gm%
	New Born	< 10 and > 22 gm%
T.L.C	Adult	< 2000 and > 30,000/cumm
	New Born	< 2000 and > 43,000/cumm
PCV / HCT	Adult	< 20 and > 60 %
	New Born	< 33 and > 71 %
Platelets	< 40,000 and > 10,00000 / cumm	
Malaria Tests	Positive	
P/S	Presence of Blast & Drepanocytes - presence of sickle cells.	

Clinical Pathology

Ketone bodies in urine	Positive
Hanging drop preparation	Positive

Referance: Fundamentals of Clinical Chemistry, Teitz 6th Ed. Page 872 & 873, Henry's 22nd Ed.

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Standard Operating Procedure for Repeat testing

Purpose To define the conditions under which the repeat tests are performed.

Scope It covers all tests undertaken in the laboratory

Responsibility Quality Manager, Technician

Procedure

Under following conditions repeat tests are performed :

1. When the results are beyond the linearity limit, sample is tested in appropriate dilution / concentration.

2. Highly abnormal results are retested for confirmation.

3. When the results do not correlate with other results.

4. On request of clinicians / customer.

In case of 1st, 2nd & 3rd point mentioned above, if the result is within the close tolerance (within 10%) then the first reading is given in the report and both reading are recorded in Repeat Test Record file.
However, if the variation is more than 10% then the test is performed for the third time and the average of the two readings within 10% is reported.
In 4th case the repeat test is performed and the result is compared with the original report and the fresh report is given with the current reading. The records of these repeat tests are maintained in repeat test register.

Standard Operating Procedure for Reporting of Results

Purpose To format the report form with it is to be communicated from the lab to the user of lab services (clinicians).

Responsibility Authorised signatories and technicians.

Procedure

- The reporting of results is done by authorized signatories in the laboratory.
- The report is entered in the computer and a print out is obtained.
- The printed report is legible, error free and is laid down in the standard format which includes the following :

i. Name of the laboratory with address which is printed on top of the report.
ii. Name of the test.
iii. Unique identification of patient (Lab No.)
iv. Date & Time of sample collection and Receiving.
v. Date & Time of release of report.
vi. Result of examination.
vii. Biological reference interval, where applicable.
viii. Interpretation of result where applicable.
ix. Other comments as necessary.
x. Signature of the authorised signatory.

Reporting of Result : Authorised Signatories manually sign the reports.

- If the report is prepared with the knowledge that the primary sample received might have compromised the result, it is mentioned on the report. However, as a general practice unsuitable samples are not accepted for testing.

- The results are transcripted in the LIS for manual tests. The detailed report is stored as soft copy in computer. The back-up report is maintained in the main lab register.

- As a standard practice, if the result of a test is in alert range, then the clinician/patient is immediately informed on telephone, a record of which is entered in the main lab register.

- The examination for which the in-house facility is not available or at the time of breakdown of equipment, the tests are performed by the external laboratory that is ISO 15189 (NABL) accredited. The report from this laboratory is given in original to the patient and the copy is maintained for record.

- In case any interim report is released during emergency hours, the same is reviewed and authenticated by the authorised signatory the next day.
- In case a report is released and later we came to know that the report was wrong, the old report is called back and the new correct report is issued. The record of the wrong report and the reason for changes are documented.

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Standard Operating Procedure for Reports Delivery

Purpose	To establish and maintain a procedure for delivery of reports and its preservation.
Scope	The procedure applies to all medical laboratory reports and maintenance of report records.
Responsibility	Reception Staff

Procedure

A. Once the reports are finalised they are printed and signed by authorised signatories.

B. Reports can also emailed on customer's request

C. Printed reports are packed in envelop and kept on reception

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Standard Operating Procedure for Emergency & Injury Management

Purpose To define the actions to be taken in case of any injury or an emergency.

Scope Give brief of the activities under various circumstances.

TYPE OF INJURY	DO'S	DON'TS
Needle stick Cuts Abrasions	• Remove protective clothing. • Liberal washing in water. • Apply skin disinfectant. • Protective first-aid dressing	• Do not suck wound
Eye injury	• Wash thoroughly with clean water for atleast 15 minutes. • Refer to nearby hospital casualty.	• Do not rub the eye.
Burns & Scalds	• Reduce the heat and quench the flame. • Cool tissues with water. • Remove smouldering clothes and smother flames by whatever means possible. • Immerse the burnt part in water. • Gently clean and dry the part. • Remove rings, bracelet, belts etc. • Lightly cover by sterile dressing. • Ensure adequate fluid intake.	• Do not apply lotion, ointment and oil based dressings.
Chemical and corrosive burns / injuries	• Flush area with abundant amount of water. • Remove contaminated clothing. • Refer immediately to nearby hospital.	
Injuries due to inhalation of smoke / fumes	• Remove the person from the danger area. • Transfer urgently to nearby hospital.	• Do not keep the patient in sitting position.
Vasovagal attacks during phlebotomy	• Lie down the patient with head down and turned to one side. • Call the doctor immediately.	• Do not keep the patient in sitting position.
Insect bite	• Call the doctor immediately. • Check pulse and blood pressure. • Inject intravenously hydrocortisone and antihistamine if needed.	

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Standard Operating Procedure for Inter-Laboratory Comparison

Purpose : To define the systems of quality assurance activities for inter laboratory comparison.

Scope : Give details of the activities for performing the quality assurance and inter lab proficiency testing in normal and non-conforming conditions.

General – Quality assurance is a very important function in medical diagnostic laboratory. The final test results will be different for different patient hence to check and ensure the accuracy of measurement is very critical. Internal quality is measured by using standard controls and external accuracy by participating in EQAS and through inter-laboratory comparison. For ILC only NABL accredited laboratories are selected.

Inter-Laboratory Comparison – Random samples are sent to external NABL accredited laboratory under various conditions:

i) As general quality assurance - The tests which are not covered under EQAS, a schedule for inter-lab comparison with NABL accredited lab is prepared. The specimens are sent for these tests to referral lab as per the planned schedule and the result is compared with the internal results. If they are within close tolerance that indicates that our systems are OK and the result is accurate. In case of substantial deviations (Refer to Gen SOP 16 A), the specimen is sent to second referral lab and the results compared. If required necessary steps are taken to set our systems.

ii) For repeat test for patient satisfaction – in some cases when the customer has doubt and wants us to repeat the test, the sample is sent to referral lab and the report compared with our report. This is done to satisfy the patient that our methodology and systems are OK and the results provided are accurate.

iii) Internal quality check – in case of some doubt on our system, the specimen can be sent to referral lab to verify that our results tally with the other NABL accredited lab.

iv) If any analyte in EQAS is beyond the acceptable limit after rerun, the sample is sent for the ILC for that parameter and results compared

In case of any variations beyond the acceptable range, the systems, quality control data, equipment maintenance, reagents and other parameters which may effect the result are checked & reviewed. In case every thing looks OK, the sample, if available, is sent to second referral lab for confirmation. Subsequently the actions are taken as appropriate.

Acceptance Criteria: Refer to SOP 16 A

Standard Operating Procedure for Acceptable Limit Performance

Purpose: To define the acceptance limits for the inter laboratory comparison and for Internal QC purpose for Inter equipment comparison, inter technician comparison, repeat test acceptance.

Scope : It covers various quality control acceptance limits - Inter Laboratory Comparison, Inter Equipment Comparison, Inter Technician Comparison, Repeat Test Acceptance, Retained Sample Acceptance, Kit Verification Using Patient Sample and any other type of quality control activities.

CLIA Rules for Quality System

The tables below contain information on CLIA proficiency testing criteria for acceptable analytical performance, as printed in the Federal Register February 28, 1992;57(40):7002-186. These guidelines for acceptable performance can be used as Analytical Quality Requirements.

Haematology		
Sr. No.	**Test or Analyte**	**Acceptable Performance**
15	Cell Identification	90% or greater consensus on identification
16	Erythrocyte Count	Target ± 6%
17	White Cell Differentiation	Target ± 3 SD based on percentage of different types of white cells
18	Haematocrit	Target ± 6%
19	Haemoglobin	Target ± 7%
20	Leukocyte Count	Target ± 15%
21	Platelet Count	Target ± 25%

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Sr. No.	Test or Analyte	Acceptable Performance
	Routine Chemistry	
1	Albumin	Target value ± 10%
2	Alkaline Phosphatase	Target value ± 30%
3	Aspartate aminotransferase (AST)	Target value ± 20%
4	Calcium, total	Target value ± 1.0 mg/dL
5	Cholesterol, total	Target value ± 10%
6	Cholesterol, high dens. lipoprotein	Target value ± 30%
7	Creatinine	Target value ± 0.3 mg/dL or ± 15% (greater)
8	Glucose	Target value ± 6 mg/dL or ± 10% (greater)
9	Potassium	Target value ± 0.5 mmol/L
10	Sodium	Target value ± 4 mmol/L
11	Total Protein	Target value ± 10%
12	Triglycerides	Target value ± 25%
13	Urea Nitrogen	Target value ± 2 mg/dL or ± 9% (greater)
14	Uric Acid	Target value ± 17%
15	Bilirubin, total	Target value ± 0.4 mg/dL or ± 20% (greater)

Standard Operating Procedure for External and Internal Quality Assurance

Purpose	To define the system of quality assurance activities including external proficiency testing methodology.
Scope	Give details of the activities for performing the quality assurance and external proficiency testing in normal and non-conforming conditions. .
Responsibility	Director - Lab, Quality Manager and Deputy Quality Manager

General – Quality assurance is a very important function in medical diagnostic laboratory. The final test results will be different for different customers hence to check and ensure the accuracy of measurement is very critical. Internal accuracy is measured by using standard controls and the external is by participating in external proficiency testing programme.

Internal Quality Control – Is achieved by following means

a. Proper maintenance of equipment,
b. Use of quality reagents and methods
c. Regular running of controls.

The laboratory has entered into AMC with all major equipment suppliers, which ensures that the equipments are serviced by competent and authorised agencies only. Besides this, specially trained personnel operate the equipment.

The laboratory procures reagents and consumables from authorised and reliable sources only. Large number of reagents are proprietary in nature hence are sourced from the company directly or through their authorised dealers / distributors.

The controls are run as per planned schedule (Ref: Schedule for Controls: Gen SOP-18) for various equipments. This is done to check the performance and accuracy of equipment. The data are recorded and plotted to check the variations and the coefficient of variance and standard deviations are calculated. The aim is that the CV % is as low as possible. In case the controls are out of range, if available, calibrator is run to set the equipment.

Dir-Lab/Quality manager keep verifying the lab mean shift periodically. If any trend is observered CAPA is initiated.

Actions to be taken in case of non-conforming results i.e. non compliance to Westgard QC rules –

Criterion for rejection of controls

The laboratory shall follow the multi control QC rules as described below:

The rules to follow when one level QC material is used:

Reject QC if:

a. it is outside 3 SD (1_3s)
b. two consecutive values obtained are outside 2 SD on the same side but within 3 SD (2_{2S})
c. ten consecutive values are above or below the mean, but within 2 SD (10x)

Standard Operating Procedure for External and Internal Quality Assurance

The rules to follow when 2 level QC materials are used:

Reject QC if:

a. either QC values is outside 3 SD (1_{3S})

b. both QC values are outside 2 SD on the same side, but within 3 SD (2_{2S})

c. difference between both QC values is >4 SD i.e. one level QC is > 2 SD and other level QC is <2SD (R_{4S}).

d. ten consecutive values of the same level QC are >/< the mean, but within 2 SD (10x).

e. five consecutive values of one level QC and five consecutive values of other level QC are >/< the mean but within 2 SD (10x)

- LJ charts are maintained where the option is available in the instrument software.
- For instrument where on board LJ charts are not available, IQC data records are maintained in requisite controlled formats and LJ charts are prepared on excel and are regularly reviewed.
- Wherever possible, lab defined means and standard deviations are calculated.
- In situations where the QC frequency or technical limitations preclude calculation of lab defined means and standard deviations, the company provided means and standard deviations are used for evaluating QC data.

During running of controls, if the result is not within the QC rules, following actions are taken:

i) Check the control that it is OK & there is no visible evidence of microbial growth. Check the reagents wheather is OK or detoriated.Then repeat run is made. Even after the repeat if the results are wrong, Calibrate the parameter & new control is run. If the result is still wrong, the service engineer is called for checking of the equipment.

ii) If the equipment gives correct results when new control is used, the first control is discarded and the results of new control are recorded.

iii) Only after the confirmation of equipment performance, it is used for testing of samples.

External proficiency testing programmes – Lab participates in external proficiency programme by : Biorad & AIIMS-Delhi. The specimens are received monthly for Biochemistry and quarterly for Haematology. The specimen are analysed at the lab and the result is sent to the EQAS agency. They review and analyse the result and send us a report giving the indication of the performance of our laboratory.

This report gives our rating with respect to participating laboratories. Thus if the rating is good, it indicates that our lab results are close to the target values.

External Proficiency result evaluation and actions taken – Lab tests the samples received from these agencies and record the results. The results are filled-up in the appropriate format and send back to them.

On receipt of their report, the scoring is checked, which the lab strives to be as "Excellent" or minimum good. Each test parameter is check and compared with results and the variations observed. If the variances are more for a test, then the reason for the same is analysed and an appropriate action is taken so that the same problem is not repeated in future.

In case of doubt, the correspondence is made with the agency for explanation of poor rating and correction of their calculation / typographical errors.

When any outlier is observed in EQAS, following is done:

Standard Operating Procedure for External and Internal Quality Assurance

a. Internal QC data and LJ Chart for the period when EQAS test were run is checked.
b. Any maintenance / breakdown on equipment during this period.
c. The expiry of reagents used & its kit validation records.
d. Any abnormal happening during that period in the lab.
e. If all above are OK.
f. Run the retained sample of EQAS kept in freezer.
g. If the result is within the range of corresponding analytes, it can be assume random error. The results of next cycle to be checked.
h. If the rusult of retained EQAS is not with in the range, Send a sample for ILC.
i. If ILC result are OK wait for next cycle result.
j. If ILC result variation result is more then acceptable limit call service enginer to rectify the problem and after that send one more sample for ILC.

Acceptable Limits

ILC: Refer to Gen SOPs 16 A.

Split / Repeat sample: Refer to Gen SOPs 16 A.

Retained Sample : Refer to Gen SOPs 16 A

Schedule For Controls, Calibratior, ILC & Inter Analyst Comparison

A. Schedule for Control

S. No.	Parameter	Frequency
1	• Clinical Biochemistry all parameters	Two levels - Once a day
2	• Clinical Biochemistry for rare parameters	The QC will be run on that day when the test is requested
3	• Hematology all parameters	Two Levels - Once a day
4	• Electrolytes	Two levels - Once a day
5	• Urinalysis: Single level control is run daily. Manual methods are used for cross checking all parameters that test positive on the Reagent strip	One level - Once a day

B. Schedule for Calibrator

S. No.	Parameter	Frequency
1	Clinical Biochemistry All parameters on Automated analyser	Whenever the lot is changed or Control is outlier or equipment is repaired
2	Automated Electrolyte	Automatically 8 hourly
3	Automated Cell Counter	Once in a Year

C. Inter-Analyst Comparison

S. No.	Parameter	Frequency
1	Urine, Stool Microscopy, Occult Blood.	Once in three months Inter Pathologist Comparison
2	Paps, Semen, Peripheral Smear, Differential & Malaria parasite	Once in three months Inter Pathologist Comparison

D. Inter-Laboratory Comparison

S. No.	Tests	NABL accredited Lab
1	Inter-laboratory comparison for the tests which are outlier in EQAS after rerun as CAPA	As required

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Dr.Vikhe Patil Memorial Hospita &
Medical College

SOP / 19 / R 00 / Dt.: 01.07.2018

Standard Operating Procedure for Housekeeping

Purpose To establish and maintain a procedure for effective housekeeping.
Scope The system applies to all area of the laboratory.
Responsibility Technician, Helper
Procedure

- The floor of the entire laboratory is mopped with Lysol / phenyl / disinfectant.
- The table tops (of Lab) are cleaned with 1 % Hypochlorite.
- The toilets are cleaned twice a day and also as and when requested by customer. It is also taken care that soap is available.
- The Lab aid ensures availability of drinking water and disposable glasses for the customers.
- The dustbins are cleaned and the waste collected in the bags as per bio medical waste disposal norms.
- Place the proper colour bags in the dustbins.
- All workers involved in cleaning are trained on handling of bio-medical waste and its disposal norms.

Incase of Spillage

a) Spread blotting paper on the surface (wear the gloves).
b) Spread 1% hypochlorite on spilled area.
c) Leave for 20 min.
d) Pick up the wet blotting paper.
e) Discard in yellow bag.
f) Clean the area with soap and water.
g) If it has sharp glass pieces use broom / brush and discard glass pieces in sharp container.

Spillage Kit Contains

1. Gloves.
2. Absorbant Paper.
3. Face Mask.
4. 1% Sodium Hypochlorite.
5. Dust Pan
6. Tongs
7. Yellow waste disposable bag.

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SOP / 20 / R 00 / Dt.: 01.07.2018

Standard Operating Procedure for Washing

Purpose To define the procedure for washing of containers reused in the laboratory.

Scope It covers all washing activities for containers meant for re-use in the laboratory.

Responsibility Technician, helper

Procedure

1. Wear gloves
2. Remove the slides & tubes from Hypo Chlorite solution.
3. Wash the slides with brush .
4. Rinse in running water.
5. Dry in hot air oven.
6. Wash beaker and bucket with water and soap.
7. Discard gloves in red bin.

Precautions

a. Use gloves and goggles while handling the containers & slides
b. Ensure that the specimen and detergent are properly removed.

NOTE: As far as possible use only disposable items.

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Standard Operating Procedure for Training

Purpose To establish and maintain a uniform approach to identify the training needs and define a system of training of all employees.

Scope This procedure applies to all training conducted or arranged by the laboratory, which has effect on the quality system.

Procedure

1 Laboartory maintains the employee records & Competency assessment of their training attended by them.

2 Identifying training needs for in-house or external training with reference to:
- Perceived emerging changes in technology.
- For improvement in operational performance.
- Development of individuals.
- Refreshing training for operation of machines and its features.

3 Identifying training needs of:
- New entrants before assigning them job responsibility.
- For existing staff – training requirement for additional new responsibilities.

4 Recording conduct of training, trainee's sign and trainer's sign.

Verifying effectiveness of training by either one of the following
- By interviewing.
- Assessing their performance.
- Written examination.

5 Criteria for Verbal Competency Assessment :
90 % to 100 % - Excellent
89 % to 80 % - Very Good.
79 % to 70 % - Good.
69 % to 60 - Average.
Less than 60 % - Retraining to be done.

6 Post Training assessment is done by written test after training and verbal technician assemment for the work performance is done once in a year

7 The training schedule is prepared for the One Year period and is followed. Care is taken to train the staff in quality management system requirement as well as operational system.

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Standard Operating Procedure for Lab Safety

Purpose To establish and maintain a procedure for lab safety.

Scope The system applies to all area of the laboratory.

Procedure

All members have been instructed to adhere to the general lab safety precautions in the lab. The aim is to protect the staff from getting any infection or injury while working and also to protect the user of the lab services.

General lab safety precautions are:

- Wear personal protective equipment such as gloves and lab coats or aprons while working in lab.
- Wear gloves while servicing parts of the instrument that have contact with body fluids such as serum, plasma, urine or whole blood.
- Wear facial protection when splatter or aerosol formations are possible.
- Keep your hands away from your face.
- Cover all superficial cuts and wounds (if any) before starting any work.
- Dispose of contaminated materials according to your laboratory's biomedical waste disposal procedures.
- Keep your work area disinfected.
- Do not eat, drink, smoke, or apply cosmetics or contact lenses while in the laboratory.
- Do not mouth pipette any liquid, including water.
- Do not put pen or any other items in your mouth.

Precautions when using electrical appliances:

- Not to touch naked wire or the electrical point with wet hand, electrical shock can occur.
- DO NOT attempt to gain access to parts of the instruments while it is ON
- Service and repair can only be performed by authorized and qualified personnel.
- Should one of the instrument circuit breaker or fuses "blow" DO NOT attempt to operate the analyzer before contacting the service engineer.

Chemical safety precaution

- The operator is responsible for taking all necessary precaution, against hazards associated with the use of clinical laboratory chemicals.
- Used cassettes contain residual amounts of reagents. Disposal of all waste material should be in accordance with waste disposal procedure.
- Proper storage of reagent as specified on the containers.
- All hazardous chemicals / reagents (acids, alcohol, etc) should be stored at separate hazardous material storage area.

Standard Operating Procedure for Ethics in Laboratory

Purpose To establish and maintain a procedure for lab ethics.

Scope The system applies to all area of the laboratory.

1. General

The professional personnel of a medical laboratory are bound by the ethical codes of their respective profession.

2. General principles

The general principle of healthcare medicine is to insure patients well being and welfare. The laboratory responsibility is to ensure that the patients' welfare and interest are the first consideration. There is no discrimination between the patients

3. Collection of information

The laboratory collect information for the proper identification of the patients which helps in the requested examination and other laboratory procedures to be carried out. The patients should be aware of the information collected. Information should be collected for communicable diseases wherever possible. Billing purposes, financial audit, resource management and utilization are also legitimate management concerns for which information may be collected.

4. Collection of primary samples

All procedures carried out on patients require the informed consent of the patient. For most routine laboratory procedures, consent can be inferred when the patient presents him – or her-self at a laboratory with a request form and willingly submits to the usual collection procedure. For invasive procedures written consent should be taken.

Adequate privacy during reception and sampling should be available and appropriate to the type of primary sample being collected and information being requested.

Adequate privacy during reception and sampling should be available and appropriate to the type of primary sample being collected and information and the referring physician notified.

5. Performance of examination

All laboratory examination should be carried out according to appropriate standards and with the level of skill and competence expected of the profession.

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Standard Operating Procedure for Ethics in Laboratory

6. Reporting of results

Results of laboratory examinations that can be attributed to a specific patient are confidential unless discussers is Authorized Results will normally be reported to the requesting physician and may be reported to other parties with the patient's consent or as required by low. Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

Decisions concerning implies consent for the reporting of results to other parties should be made cautiously, taking local customs into account. Laboratories have written procedures detailing how various requests are handled and this information be made available to patients on request.

In addition to the accurate reporting of laboratory results, the laboratory has an additional responsibility to ensure that, as for as possible, the examinations are correctly interpreted and applied in the patient's best interest. Specialist advice with regard to the selection and interpretation of examinations is part of the laboratory services.

7. Storage and retention of medical records.

The laboratory should ensure that the information is stored such that there are reasonable safe guards against loss, unauthorized access or tampering and other misuse.

The retention of medical records can be defined by various statutory and legislative requirements and these requirements will need to be considered together with guideline issues by relevant professional bodies.

Local customs, particularly the reliance of clinicians on laboratory records as opposed to their own records, also need to be taken into account.

Concern regarding legal liability for certain types of procedures may requires the retention of certain records or materials for much longer periods than for other records for samples.

Laboratory has defined the protocols for the retention of records, indicating the time various examination results are to be retained.

8. Access to medical laboratory records.

The laboratory records are accessible only to the authorised personnel on need to know basis. The records can be provided as per protocols addressing the handling of different requests in accordance with local laws and customs.

9. Financial arrangements

Medical laboratories should not enter into financial arrangements with referring practitioners or funding agencies where those arrangements act as an inducement for the referral of

Standard Operating Procedure for Ethics in Laboratory

examinations or patients or interfere with the physician's independent assessment of what is best for the patient.

Where possible, rooms used fro primary sample collection should be completely independent and separate from referring practitioner's rooms, but where this is not possible, financial arrangements are to follow normal commercial practice.

Laboratory tries to avoid situations that give rise to a conflict of interest. Where this is not possible, the interest should be declared and steps taken to minimize the impact.

Standard Operating Procedure for Decontamination

Purpose To define the procedure for decontamination of equipment.

Scope The procedure applies to all equipment in the laboratory.

Procedure

Decontamination is the process of rendering soiled medical devices safe for handling for processing and / or maintenance. It includes the reduction of infectious organism and other contaminants from the equipment and the area where the person may need to access.

The purpose of decontamination is to make devices safe for handling and prevent the transmission of disease.

Important step in decontamination is thorough cleaning, rinsing by performing timely maintenance and regular cleaning thus the contamination is prevented.

In general the decontamination process before giving the equipment for servicing are:

a. Clean the machine from outside with 1% Sodium Hypochlorite
b. Remove all infectious material i.e. specimen
c. Ensure all sample racks are empty
d. All sample racks are cleaned with 1% Sodium Hypochlorite
e. Liquid waste cans in machines are emptied and cleaned

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Standard Operating Procedure for Lab Information System

Purpose To define the various features of the laboratory information system, the method of its operation, uses, back-up and contigency plan.

Scope Give details of the centralised laboratory information system and its operations.

Procedure

General

In view of meeting its aim of providing accurate, reliable and quick service to its valued customers, the specially developed laboratory information software installed in the laboratory thus reducing the paper work substantially, at the same time provides accuracy in data transfer, control, retrieval, monitoring etc.

Security

The laboratory information system provided complete security for the efficient operation of the organisation. Authorised people have been provided with password, which is used to access/enter the information in the system. Software can only be operated through individual password which is available only to authorised people. Permanent record like biological reference intervel, test method, Interpretation etc. is only permitted by password which is available with consultant Pathologist or Authorised signatory only.

Information

The various informations to execute the work efficiently and quickly are stored in this laboratory information system and can be accessed by click of a button.
Some of the informations are:

- List of tests
- Cost of each test
- The biological referance intervel for each test

This helps every one to access the required information instantaneously, thus improving the overall work efficiency and no wastage of time in information retrieval.

Registration

At the time of sevice agreement cum registration the laboratory information system screen displays the various fields which needs to be filled, this helps the billing staff to quickly enter the necessary information.
As the tests are entered, the system automatically adds the cost and display the total cost of diagnosis. The system automatically enters each customer / patient under a unique serialised registration number. The customer's / patient's information can be accessed only by the authorised person.

Control and recording of test results and its verification.

After the test is performed the data is entered by technician with specific password provided against respective patient . Results are printed and verified by pathologist with equipment printout. This eliminates the possibility of human errors. Results are then signed by consultant Pathologist or Authorised signatory.

Standard Operating Procedure for Lab Information System

Training

LIS training is given by either Dir-Lab or Quality Manager.

LIS Operating Procedure

Customer agreement cum registration

- Click the icon of LIS.
- Enter User name and password.
- Enter Lab operation.
- Choose add option to add customer details.
- Fill details : Name, Age, Sex, Phone number in fields.
- Enter Panel/Company name in Panel/company field.
- Enter Referring Doctor's name in field.
- Select test for customer.
- Select bill/receipt option to print the agreement cum booking slip.
- Issue agreement cum booking slip to customer.

Manual Result Entry:

- Select result option to enter result/Value.
- Fill all field.
- After filling all the required field select save option to save the value in LIS.
- Select print option to print the report.

Interfacing:

- Select result option to enter result/Value.
- Select interfacing.
- After checking with equipment printout select update report to save the value in LIS.
- Select print option to print the report.

Contingency plan for Laboratory Information Service

The laboratory has specially developed lab information software for service agreement cum registration of patients. The laboratory has networking tecnicians who are competent to resolve any breakdown within half hour.

Incase of any breakdown of laboratory information system, urgent reports if requested by our valued customer. Type the report manually in microsoft word document .

Once the reports are typed and printed it has to be verified by authorised signatories by equipment printout/data.

Authorised signatories sign the report and report is dispatched.

Standard Operating Procedure for Lab Information System

1. Result Verification:

Result verification is done by consultant Pathologist or Authorised signatory after checking the equipment printouts.

2. Alteration in Reports can only be done by consultant Pathologist or Authorised signatory in following cases with their own specific Password.

- Typographical error
- Mix-up in the results which comes to light after re-verification of the base data
- Report not correlating with other test results and the consultant has asked for the repeat test and the result is different than the one entered earlier.
- Any other finding which calls for alteration in report

3. Alteration in Report Format:

- Alteration in Report Format shall be done by consultant Pathologist or Authorised signatory after Review of examination provided i.e. changes in Biological Reference Interval, Method.
- Alteration in Report Format shall be communicated to the Referring consultants by consultant Pathologist or Authorised signatory.

Back-up system

Automated back-up is recorded in server.

Standard Operating Procedure for Calibration of Parameters

Purpose To define the systems for running the calibrator for calibration of respective analytes.

Scope It covers all analytes.

Procedure for respective machines is as follows:

Automated Clinical Biochemistry Analysers

i) Whenever a new lot is put in use.

ii) After major repair of the machine.

iii) When control is repeatedly out.

Automated Electrolyte Analyser

i) Automated Calibration 08 hourly when analyser is ON

Hematology cell counter is calibrated once a year by the service provider.

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Standard Operating Procedure for New Reagent Verification

Purpose To define the systems and criteria for new kit verification.

Scope The scope of this SOP covers the policy for verification of new kit/reagent lots used at the laboratory.

Biochemistry :

- New kit same lot : Run QC and Known sample prior to testing patient samples. Process samples only if QC and known sample is within acceptable limits as defined in SOP 16 A.
- New kit new lot: Calibrate the kit and then run QC. Process samples only if QC is within acceptable limits.

Clinical Pathology:

- New kit new lot : 01 day before finishing of old kit, open the new kit and then process same patient sample both with old kit and new kit. Check for result.

Hematology:

- Run QC or known sample after replacing diluents.

Leishman's stain:

3 - 4 days before finishing of old kit (Geimsa and Leishman's powder), open the new kit and then stain the slide both with old kit and new kit. Check for result.

Use of Control : Run the control for the analyte for which the new kit has been put in use. Record the value of the control in the new reagent verification record and also record the reading in the control sheet and preserve the printout, if available. Plot the values in the LJ chart.

Acceptance Criteria: Plot the values of the control in LJ chart and ensure compliance of Westgard Rules.

Use of sample run on previous kit: Repeat the patient sample run on the previous kit on this new kit. Record the reading of the previous and new kit values in the New Reagent Verification Record.

Acceptance Criteria: The % variation in the two values Refer to CLIA guidelines as per Gen SOP 16A.

Parameter not covered in CLIA: The % variation in the two values shall be less than CV %.

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Standard Operating Procedure for New Reagent Verification

Purpose To define the systems and criteria for new kit verification.

Scope The scope of this SOP covers the policy for verification of new kit/reagent lots used at the laboratory.

Biochemistry :

• New kit same lot : Run QC/Known sample prior to testing patient samples. Process samples only if QC is within acceptable limits.

• New kit new lot: Calibrate the kit and then run QC. Process samples only if QC is within acceptable limits.

Biochemistry (Electrolyte):

Run QC/Known sample with new reagent lot. Process samples only if QC is within acceptable limits.

Clinical Pathology:

• New kit new lot : 01 day before finishing of old kit, open the new kit and then process same patient sample both with old kit and new kit. Check for result.

Hematology:

• Run QC or known sample after replacing diluents.

Leishman's stain:

3 - 4 days before finishing of old kit (Geimsa and Leishman's powder), open the new kit and then stain the slide both with old kit and new kit. Check for result.

Use of Control : Run the control for the analyte for which the new kit has been put in use. Record the value of the control in the new reagent verification record and also record the reading in the control sheet and preserve the printout, if available. Plot the values in the LJ chart.

Acceptance Criteria: Plot the values of the control in LJ chart and ensure compliance of Westgard Rules.

Use of sample run on previous kit: Repeat the patient sample run on the previous kit on this new kit. Record the reading of the previous and new kit values in the New Reagent Verification Record.

Acceptance Criteria: The % variation in the two values Refer to CLIA guidelines as per Gen SOP 16A.

Parameter not covered in CLIA: The % variation in the two values shall be less than CV %.

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Standard Operating Procedure for Alteration of Reports

Purpose To define the conditions under which the reports are altered and its handling.

Scope It covers verification of results.

Responsibility Director Laboratory

Procedure

As a policy alteration in the reports is avoided. However, if the alterations have to be made it is approved by the Dir-Lab or Consultant present .
The conditions of making alteration in reports are:

A. Prior to release of report

1. Typographical error
2. Mix-up in the results which comes to light after re-verification of the base data
3. Report not correlating with other test results and the consultant has asked for the repeat test and the result is different than the one entered earlier.
4. Any other finding which calls for alteration in report.

B. After release of report.

1. Initial report was issued with the knowledge that the primary sample was defective and on request of the clinician the repeat test is being performed.
2. Repeat test has been performed on request of the clinician or customer and the variation in the results of repeat tests is more than acceptable limit defined in Gen SOP 16 A.
3. It was found that the equipment / reagent / process was defective and the result reported is different than the actual one.

Action to be taken :

1. The corrections are made in the report by specific password protected ID provided to authorised signatories
2. Fresh report is printed after corrections

a. Prior to release of report – fresh report is released with no comments about the alteration of report
b. After release of report - The fresh report is issued as amended report and the remark "AMENDED REPORT" is mentioned on top of the report

3. A record is preserved whenever such amendments are made and appropriate CAPA are taken to reduce / eliminate such errors in future.

Standard Operating Procedure for Preparation of Hypochlorite

Purpose To define the procedure for dilution of Hypochlorite for lab use

Scope It covers preparation of various level of dilution

Responsibility Technician, helper

Procedure

1. Wear gloves.
2. Take the concentrated Hypochlorite solution and check its concentration.
3. Take the empty container in which the solution is to be prepared
4. Follow these table for dilution

Final Hypochlorite concentration	1%	1%
Available Conc. of Hypochlorite	4%	5%
For 1 Ltr solution (1000 ml)		
Hypochlorite	250 mL	200 mL
Tap water	750 mL	800 mL

Precautions

a. First take water in the container and than add Hypochlorite
b. Prepare fresh diluted solution every day and keep in bottle with cap.

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Standard Operating Procedure for Protection of Confidential Information

Purpose To define the system for protecting confidential information of the patient

Scope It covers all patients / customers and their reports

Responsibility: Dir-Lab, Quality Manager, Consultants and Technicians

Procedure:

1. Access to the data captured in the computer system is restricted to the members by password.
2. All manual records are kept in the lab and its photocopy or carry it outside the lab is not allowed
3. Got the confidentiality agreement signed by all members and strict action is taken for any breach.
4. For working normally the unique lab ID is used
5. Verbal report is permitted only for critical result communication and that too with proper verification of the patient / customer.
6. All records are shreded after the preservation period is over under direct supervision of Dir-Lab cum Quality Manager.

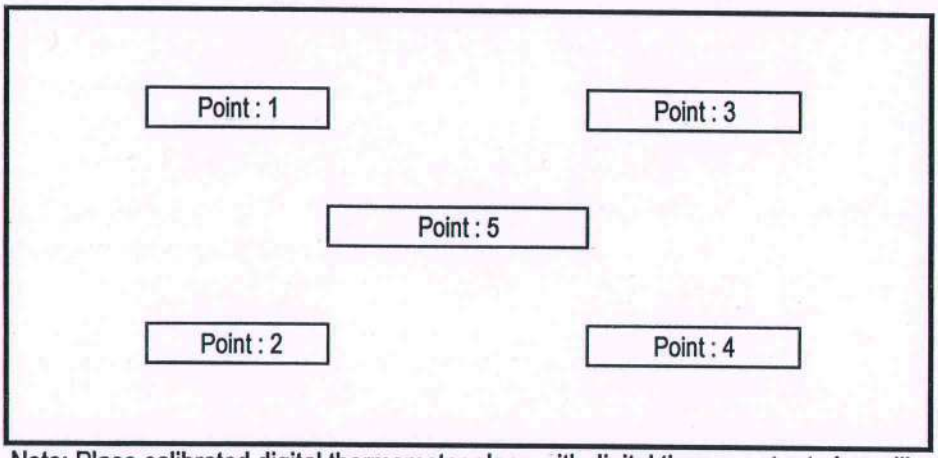
Standard Operating Procedure for Equipments Calibration

Purpose	To define the procedure for calibration of laboratory equipment / instruments.
Scope	It covers all equipment / instruments used in the laboratory thus ensuring that only properly calibrated equipments re used which will result in giving accurate test results
Responsibility	Director-Lab, Quality Manager, Lab Supervisor and Technicians
Policy	All equipments / instruments must be calibrated as per the defined procedure and frequency as specified in the respective equipment maintenance manual.

Procedure:

1. Quality manager prepares the calibration schedule of all equipment and instruments for the year as per the NABL 112 guidelines and respective equipment manuals.
2. The details when last calibration was done and next calibration is due with correction factor (if any) is affixed on respective equipment and the technician checks the same thus ensuring that the equipments are calibrated within the due dates.
3. The calibration procedure where provided in the equipment manual is followed by the service engineers and all necessary records are made and kept in the equipment file. The detail process is checked in the manual every time when the equipment is to be calibrated.
4. The calibration procedure for the equipments / instruments (e.g. pipettes, thermometer, centrifuge, etc) which are calibrated by NABL accredited agency is followed by them and we only maintain the calibration certificate and their associated traceability as provided by the calibration agency.
5. Each calibration certificate is verified by the quality manager for its fitness for use. If the equipment is OK, the calibration certificate sticker is fixed and if not OK the instrument is removed from service.
6. When any test equipment is repaired after breakdown / preventive maintenance / calibration the quality manager or technician checks the fitness for use of the equipment either by running of control and verifying the compliance to Westgard Rules or repeat running of the patient sample which was run prior to service and checking the difference in results are within the acceptable limits. Only if the equipment is judged as OK it is put in service.
7. Digital temperature indicators and temperature-humidity meters are calibrated once a year or after repair or if any doubt on the actual temperature.
   The procedure for Inhouse calibration is as follows:
   Take digital thermometer indicator calibrated from external NABL accreditated Laboratory– Check that the calibration of thermometer is valid as on date.

1. The refrigerator is kept in 'ON' condition.
2. Both probs of digital thermometer and thermometer to be calibratedare kept at the five points in the fridge as indicated in the box below.
3. Keep the probe for 15 minutes at each point and record the temperature.

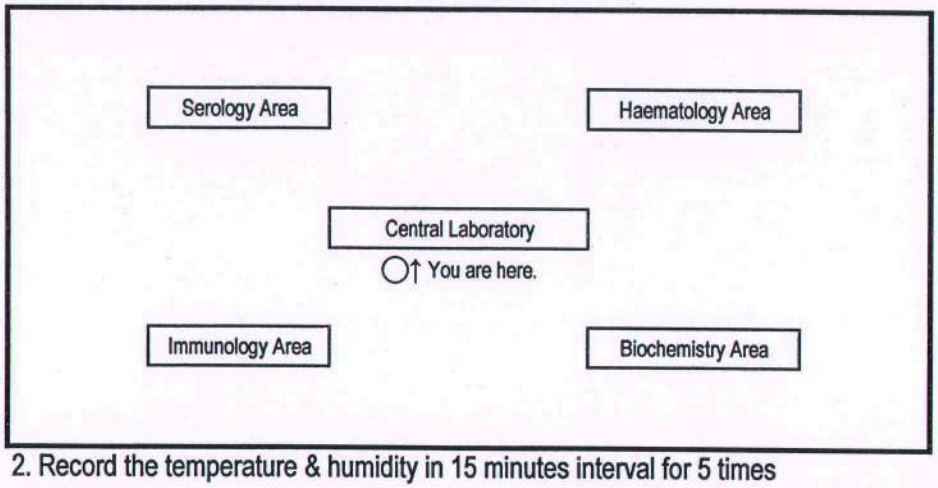


Note: Place calibrated digital thermometer along with digital thermometer to be calibrated.

4 Note the temperature reading on the Calibrated thermometer and on the digital thermometer in 15 minutes. Time intervel 5 times.
5.The data is recorded in the in-house calibration sheet (Gen-FR-02).
6. Calculate the variation observed in °C.
Acceptable uncertainity : ± 0.10°C

Digital Temperator & Hygrometer -

1. Place calibrated Digital Temperator-Hygrometer & Digital Temperator - Hygrometer which has to be calibrated in five different area of Laboratory.



2. Record the temperature & humidity in 15 minutes interval for 5 times
3. Note the temperature & Humidity reading on the Calibrated thermometer and on the digital thermometer in 15 minutes time intervel 5 times.
4.The data is recorded in the in-house calibration sheet (Gen-FR-02).
5. Calculate the variation observed for temperature in °C. and humidity in %.
Acceptable uncertainity : Temp ± 0.10°C/ Humidity ±1.8 %

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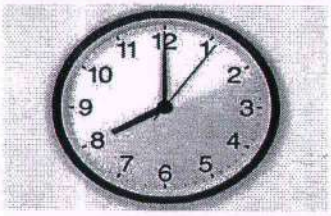
In-house calibration of digital timer: (Performed with computer time)

1. Place the timer in front of computer.
2. Click the date & time Icon.
3. Go for clock setting and select analog clock with minutes & seconds.
4. Set time zone to indian standard time.



5. Note the time of the system and Start the timer.
6. Note time at 1, 2, 10, 15, 20, 30, 40 & 50 minutes time.
4. The data is recorded in the in-house calibration sheet (Gen-FR-02).
5. Calculate the variation observed for time .

Acceptable uncertainity : ± 0.1 min

Standard Operating Procedure for Centrifugation

Purpose To define the procedure for centrifugation of blood samples to separate serum or plasma for Biochemical analysis.

Scope Covers centrifuging of specimen for all tests done in the lab.

Responsibility Sr. Technicians and Technicians

Procedure

- Place the newly drawn tube in a test tube rack.
- Wait for 20 - 30 minutes after draw time for blood in the tube to clot. Clotting time will depend on patient's condition and medications such as Heparin, aspirin therapy, etc. which prolong clotting.
- Once the blood has clotted, select the tubes of same size and sample quantity.
- Open the lid of the centrifuge
- Balance each tube to be spun with the same sized tube that contains an equal volume of fluid. The balance tube may contain water. This is important for centrifuge to operate properly.
- The same sized tubes should be placed exactly opposite (diagonally) each other in the centrifuge.
- Close centrifuge lid and ensure that it is locked.
- Centrifuge for 10 minutes at 2500 RPM within 1 hour of collection for routine test.
- Centrifuge for 10 minutes at 3000 RPM within 1 hour of collection for coagulation test.
- In case of any abnormal sound coming from centrifuge, stop it immediately
- Once the centrifuge stop, remove the tubes and place them in tube rack.
- Check that the tube has clear liquid on top, if so, the centrifuging process is over.
- In case there is some turbidity, clean the tube inner walls with disposable plastic stick and re-centrifuge it.
- The clear serum is now ready for testing.

Standard Operating Procedure for Equipment Management

Purpose	To define the system of selection, approval, evaluation and method for equipment management used for testing in laboratory.
Scope	It covers all equipments used in the medical laboratory for sample analysis.
Responsibility	Director Lab & Quality Manager

The detailed procedure for management of equipment and supplies is documented covering the selection, purchase, evaluation, Installation, operation and performance of equipments relevant for the testing of specimens. Director-Lab & Quality Manager takes the decision as when to replace equipment to ensure the quality of examination results.

Management of equipment: -

No laboratory equipment is transported outside the premises to any other location for doing testing on specimens / sample. Nor the equipments are transported outside for repair till date.

All equipments / instruments in the lab are kept in air-conditioned environment thus maintaining the temperature and humidity as specified in their respective operating manuals.

All equipment / instruments are either covered under AMC/CMC or have service contract. This ensures that all equipments / instruments are well maintained and regular service is done as per the manufacturers guidelines.

The schedule for their preventive maintenance and calibration is maintained and followed and the records kept in respective equipment file.

All technicians are provided training on the handling of equipments so that they handle the equipment carefully and use it in most optimal manner thus ensuring accuracy of the results obtained.

Criterion for the equipment acceptance testing.

Equipment supplier is asked to give a detailed report of Equipment commissionig.

A. Installation Qualification.

The Application & Service Expert of the equipment gives detailed report of installation of equipment, which defines the documentation of its used to evaluate the instrument Installation in accordance with the manufacturer's specifications and intended use.

Installation checks are performed to verify that the instrument has been installed with proper connections and utilities. The report includes :

a. Environmental conditions as required are recorded. (Free from dust, electrical and magnetic interference)
b. Temperature.
c. Humidity.
d. Adequate space for installation.
e. Electrical Outlets are grounded & Connected through UPS.
f. Manufacturer's specification are included & Accessories/Consumables are listed.
g. Installation of Hardware and software are followed the instructions mentioned in the Installation guide.
H. Installation of Printer are followed the instructions mentioned in the Installation guide.

Standard Operating Procedure for Equipment Management

B. Operational Qualification

The Application & Service Expert of the equipment gives detailed report of evaluation that the instrument have operational features available for the successful operation of instrument in accordance with the manufacturer's specifications.

Following features/ functions are verified in the instrument as per manufacturer's specification e.g. self-test, washer assays, quality control, test assay, maintenance checks, aspiration, Dispensing, water blanking & photometer check.

Detailed calibration certificate with raw data is provided by equipment service provider.

C. Performance Qualification :

Performance qualification validates the test procedure performed on the new instrument.
Performance qualification not only validates instrument performance but also test procedure.
Following are the steps required to validate instrument and method.

a. Run all levels of QC sample and verify the values with acceptable range given in the insert of quality control samples.

b. Run anyone sample for at least 2-3 parameters five times and check for the precision.

c. Check linearity.

d. Run one sample for all parameter on new instrument and cross verify the rests with NABL acreditated other reference laboratory.

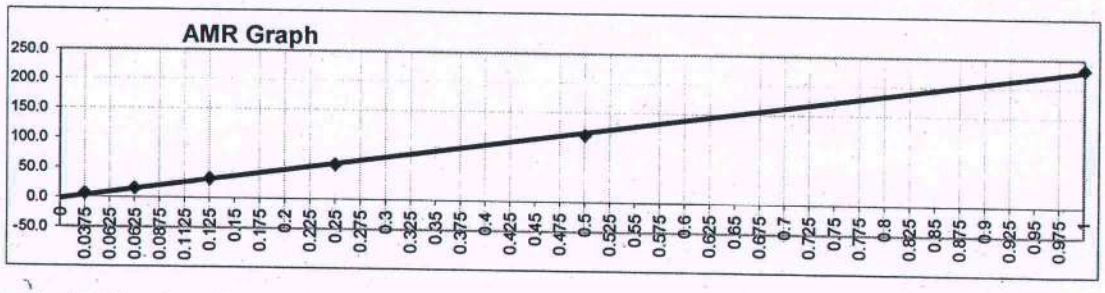
A. Precision

Samples are run 5 times and Calculated CV%. (SD/meanx100=CV%)
CV% shall be less than the CV% defined in the Scope of Accreditation as per NABL.
Frequency of Precision Verification is once in six months.

B. Linearity

Choose a High value parameter sample.
Label five tubes as 1:2, 1:4, 1:8, 1:16 and 1:32.
Dispence 500µL normal saline in all tubes.
Dispence 500µL sample in tube labelled as 1:2 and mix it thoroughly.
Now take 500µL sample from the tube labelled as 1:2 and dispence in tube labelled as 1:4 and mix it thoroughly.
Now take 500µL sample from the tube labelled as 1:4 and dispence in tube labelled as 1:8 and mix it thoroughly.
Now take 500µL sample from the tube labelled as 1:8 and dispence in tube labelled as 1:16 and mix it thoroughly.
Now take 500µL sample from the tube labelled as 1:16 and dispence in tube labelled as 1:32 and mix it thoroughly.

Run all 5 diluted sample tube as sample.
Plot the Analytical Measurement Range Curve



The straight line from '0' to the maximum value shall be more or less touching all points obtained by dilution of the specimen, which will verify that the linear range as specified by the manufacturer is OK and acceptable.

Frequency of linearity Verification is once in a year.

C. Carry Over Verification

Take one high and one Low value parameter sample.

Run sequence of specimen high (a) and low (b) concentrations. High a1 - High a2 , Low a1- Low b2 & High a3 - Low b3.

Calculate the Carry over effect using the equation:

$$q = \frac{b1 - b3}{a2 - b3} \times 100$$

where q may be called the carry over ratio and is expressed as % value (Q = 100 q). It implies that the influence carry over effcts on the analytical results is inversely proportional to the concentration difference of the component to be detected by the analytical procedure in the two specimens.

Frequency of Carryover Verification is once in six months.

Referance: R. Haeckel, Recommendations for defination and determination of carry over effects, Journal of atomic chemistry Vol.10 No:04 (oct-Dec 1988, pp 181-183).

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SOP / 35 / R 00 / Dt.: 01.07.2018

Standard Operating Procedure for Verification of Received Material

Purpose : To define the criteria for verification of received material

Scope : All raw material and consumables received

Responsibility : Deputy Quality Manager and Sr. Technician

Procedure:All material i.e. consumables, reagents, controls, etc. needs to be checked on receipt for the following as applicable and received and put to use only if the said applicable criteria is complied with. The parameter and the acceptable criteria is as follows and shall be applied as applicable.

S. No.	PARAMETER	Criteria for acceptance
1	Make and pack size	Should be as per order
2	Quantity	As per order
3	Physical damage	No physical damage to the packing
4	Cold chain	Items to be kept < 8° C should be brought in ice pack containers so that the temperature of the items is below 8°C.
5	Expiry date	Minimum of one month. Expiry date should be sufficient so that the product is consumed before expiry.

A stamp is put on the challan / invoice [covering above points] which comes with the material and signed by the technician as evidence that he/she has checked the material.
In case the material does not meet the above criteria it is returned to the supplier and not accepted at all.

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Standard Operating Procedure for URGENT Sample Processing

Purpose To define the condition of handling and processing of the urgent samples.

Scope Define how to handle urgent specimen

Responsibility Reception, Technicians and Doctors

Procedure

1. Urgent samples are mainly ordered by the clinician either verbally or in writing. In some cases the customer can also request for urgent reporting.
2. "URGENT" is written on the requisition / registration slip.
3. On receipt of specimen at the lab sample receipt counter, the RED sticker is put on the requisition slip and sample passed to the concerned section.
4. The technician on receipt of such specimen process them on priority.
5. The results of test are informed to the consultant for validation.
6. The validated report is printed and dispatched to the concerned requesting consultant or the customer or to the reception for delivery.
7. Depending upon the request on the mode of informing Urgent Report, the reports can be communicated over phone, faxed or emailed.

Standard Operating Procedure for Confidentiality

Purpose	To define the confidentiality agreement procedure for all employees
Scope	Define when and how to get the agreement signed
Responsibility	Dir-Lab and Administration

Procedure

1. Whenever any new employee joins the organisation, he / she need to sign an confidentiality agreement
2. These agreement after signing has to be kept in respective employees' personal file
3. The confidentiality agreement is as follows:

CONFIDENTIALITY CERTIFICATE

I ..... hereby promise not to use the information gained during my professional / technical work at Laboratory , for any unethical / illegal use, so as to put integrity of the laboratory at jeopardy or stake. I am also aware that sanctity of identity of persons reporting to this laboratory for testing as well as sanctity of test conducted and report is to be maintained at all cost & this information is not to be divulged to any unauthorized person.

Signature: .....
Name: .....
Designation: .....
Date: .....

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Standard Operating Procedure for Disposal of Liquid Waste of Machines

Purpose To define the disposal system for liquid waste generated from the analysers

Scope Covers all analysers generating liquid waste

Procedure:

a. All liquid waste generated from the machine should be collected in the plastic containers and not to be disposed directly in the drain

b. Pour approximately 25% of container volume, 1% hypochlorite solution in the container. (ex. 250 mL in 1000 mL waste.)

c. In evening or earlier when analyser indicate that the waste container is full, remove the container from respective machines.

d. There after pour this waste in the sink with the running water atleast ten minutes.

e. Clean and disinfect the plastic container

f. Pour again approximately 25% of container volume, 1% hypochlorite solution in the container. (ex. 250 mL in 1000 mL waste.) & place the container back in the equipment / analyser.

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Standard Operating Procedure for Risk Assessment

Purpose

To define the procedure for review of Risk during Pre Analytical, Analytical and Post Analytical phase by the laboratory

Scope

It covers

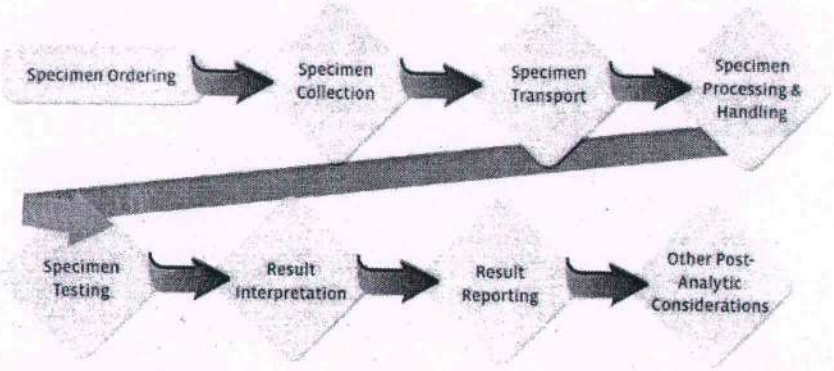
- Review of Sample Volume
- Equipments and Reagents
- Human Resources
- LIS and Reporting

Risk identification is the first and perhaps the most important step in the risk management process. Correctly identifying potential sources of error for a particular test reveals valuable information for developing an individualized quality control plan. Identifying the potential risks embedded in laboratory testing processes allows for the implementation of an overarching quality control plan that effectively mitigates errors not addressed by the test system's internal checks and external quality control.

Responsibility

Authorised Signatories/Quality Manager

Procedure



Risk identification : A risk identification is done listing all the errors identified in the different testing phases for a specific test (see Above).
Regardless of the tool selected, it is important to consider all phases of sample testing: the preanalytic, analytic, and postanalytic phases. The key objectives in implementing an effective risk management process are identifying the potential errors in all phases of testing, and ensuring optimal mitigation by putting in place effective and documented processes.

Risk management process : It is important to consider the following key areas within the five components of the diagnostic process that affect the quality patient test results: environment, testing personnel, specimen, testing process, and reagents.

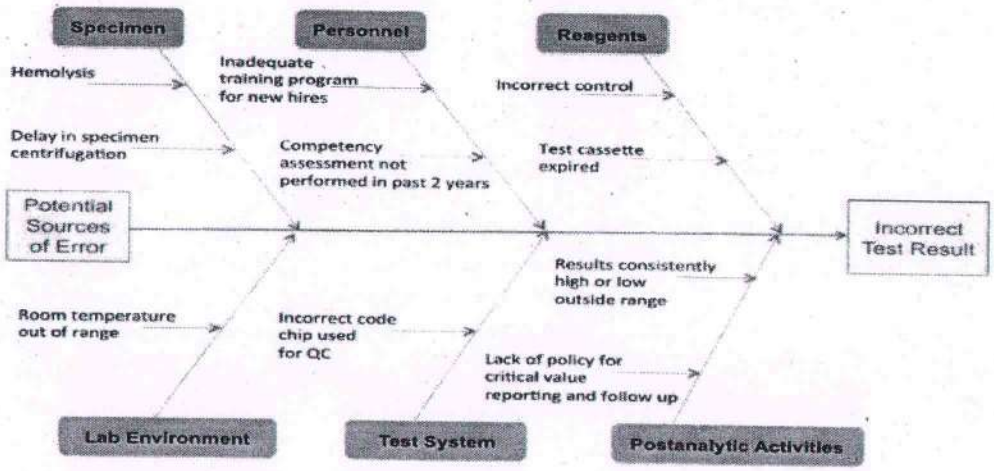
Environment : Areas of importance which require focus include the following:

- Where is testing performed, and what other activities occur nearby? There shall be no Cross Conatamination Activity.
- Are room temperature and humidity is acceptable/ambient ?
- Testing areas level are vibration-free ?
- Adequate lighting, electricity, water quality, and other utilities are as per requirement

Specimen : Ensuring the collection of the right specimen from the right patient is essential.

- Review is done for specimen collection, handling, and storage procedures.
- Review of Primary Sample Volume for test being conducted.
- Underfilled and Overfilled samples are rejected and verified for CAPA.
- Review of all instructions that are provided to patients regarding preparation for the self-collection of specimens is done

It is important to ensure that all specimens are handled and stored appropriately, and are suitable for testing



Reagents : Review of Test reagents are done to verify that reagents can be compromised during shipment, handling, storage, and processing. In addition, consideration is given to the quality and stability of reagents used directly as part of the QC process:

- Calibrators &
- Controls are verifired for their stability as per defined technical Inserts.

All the new reagents technical inserts are verified prior to using for Stability, Limit Of Ditection, Linearity, Precision, Carryover, Biological Reference Intervals and Methodology.

Testing Personnel : Individuals performing testing are evaluated to ensure for their training and competency assessment which validate the potency of testing personnel to accurately perform testing. Key questions are addressed in this area include the following:

- Do testing personnel have laboratory education and experience ?
- Testing personnel is adequately trained to perform the test ?
- Competency assessments been performed on testing personnel ?

Although testing personnel may have been trained to perform specific types of testing, it cannot be assumed that all testing personnel maintain the superior level of performance they initially demonstrated. It is therefore essential that competency assessments be performed on a continuing basis.

Lab Information System and Report Generation :

LIS generally continues to feature patient management, including Date of Testing , reffering Clinician/physician, specimen type, etc. customer data tracking, comparisons of lab orders with their respective Unique ID, quality assurance of ordered tests, workload and report authentication.

Prescription and registration demographic entry is verified by Quality manager
Sample and/or result batching and Task and event scheduling is verified by Quality manager
Results transferred to the LIS through interfacing or manual transcription are accurate
Report is printed and verified by Quality manager by equipment printout and final report

LIS verification data is maintained like customer's prescription, Screenshot of registration/customer service agreement, worksheet generated from LIS, Equipment prinout,Screenshot and final authenticated report.

Risk Assessment is done Half Yearly.

Standard Operating Procedure for Contract Review

Purpose	To define the systems for review of contracts undertaken by the laboratory
Scope	It covers • Contract for work with corporate / hospitals / other organizations • Annual maintenance contract (AMC) for equipments • Waste disposal
Responsibility	Authorised Signatories

Procedure

a. For corporate, hospitals or any other organization requiring laboratory services, a written contract / MOU done and renewed after mutual consent. This is initiated by the marketing and finalised in association with Director, marketing and laboratory.

b. AMC: The laboratory testing is done with reagents and equipments. However for the maintenance of equipments / machines we enter into the annual maintenance contracts and service contracts with the supplier on the standard format provided by them and sign the agreement. After the expiry of the previous agreement new agreement is signed for the same. Care is taken that there is no gap between the expiry and renewal of the AMC contracts.

c. For waste disposal we enter into contract with the concerned authorities (approved by government for bio-medical waste disposal) and is renewed at regular yearly and records are maintained for the same.

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Standard Operating Procedure for Turn Around Time

Purpose	To provide the reports of client's within the specified time
Scope	This procedure is applicable to all tests performed in the all the departments in the laboratory.
Responsibility	Reception, technicians and authorised signatories

Procedure

- Reports of routine tests will be available on the same day at the lab for sample collected till 06 PM. Sample collected after 8 PM will be reported next Day 09 AM. In case of urgent or customer request provisional reports are given.
- Reports of all other tests will be available according to the time required for completion of the tests.
- Investigation results for urgent tests will be given within 2 hours depending upon the type of tests.
- Critical values will be informed to the clinician immediately after the result is obtained and validated by the pathologist which in general is within 30 min.
- Results of outsource test will be as per the MOU with the concerned lab.
- TAT is monitored randomly One sample weekly and recorded in Turn Around Monitoring Record appropriate action are taken for compliance to the TAT and its improvement.
- In LIS the TAT is not calculated, we record the TAT manually of one random sample weekly basis.
- However, when signing the report the pathologist do see the time of registration and reporting thus in case of any un-due delay the matter is investigated and records maintained.

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Standard Operating Procedure for Induction of New QC Lot

Purpose	To define the system of induction of new QC lot
Scope	Covers all biochemistry QC lots
Responsibility	Dir-Lab, Quality Manager & Deputy Quality Manager.
Policy	When new QC lot is inducted we need to ensure that the QC lot is OK and subsequently we should set lab mean for plotting LJ Chart and check compliance to Westgard rules.

Procedure:

1. Check the expiry date of the lot, check its insert and see the variation in target values over the last QC lot.

2. Reconstitute one vial and make aliquotes of 350 uL each and store them in freezer. Vial should befreezes only once.

3. When the control has run for 20 days or more till end of the month, during this period work with floating mean and ensure compliance to westgard rules when plotting LJ chart. Subsequently at the end of the month, calculate the lab mean & SD

   Calculation :
   For Mean : Add all the values and divide by number of values
   For SD : CV divided by mean x 100
   For CV% (MU±) : Divide SD by mean and multiply by 100
   SD is calculated automatically in LJs software.

4. Set the calculated lab mean and SD in the LJ chart and subsequently enter the data in this and ensure compliance to westgard rules.

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Standard Operating Procedure for EQAS Warning Limits

Purpose To define the warning limits of EQAS the lab is participating.

Scope Covers CMC Vellore EQAS for Biochemistry and AIIMS for Haematology

Responsibility Dir-Lab / Quality Manager

Policy To monitor the parameter which comes in the warning limits and take appropriate preventive actions so that it does not fall in outlier range.

Procedure:

The warning limits of EQAS are as follows:

Biorad - for Biochemistry & Haematology EQAS

The parameter used for evaluating the EQAS result is Z score

a) If Z Score $\geq$ 3.0 means that the analyte is out and appropriate action should be taken.

b) If Z Score between 2.0 and 3.0 indicates warning limits and this parameter should be monitored.

c) If Z Score $\leq$ 2.0 indicates that this paratemer is OK for accuracy

If Z score is more than acceptable limits all possible random & Systemic errors are looked into:

Random Error (Recent Event & Changes)

a. New reagent kit or lot (New reagent verification done ?)
b. New control vial (Check Internal Quality control)
c. Instrument component replacement (Calibration of Equipment done ?)
d. Instrument maintenance (Calibration of Equipment done ?)
e. Instrument move (Validation done ?)

Random Error

b. Misplacement of control sample within the run
c. Incorrect reconstitution of the control
d. Inappropriate storage of control in frost free Freezers (Verify temperature status)
e. Operator technique

Systemic Error

a. Improper alignment of sample or reagent pipetts
b. Drift or shift in incubator chamber temperature in equipment
c. Inappropriate temperature/humidity levels in the testing area.
d. Deterioration of reagent while in use, storage.
e. Deterioration of calibrator or control while in use, storage.
f. Failing light source

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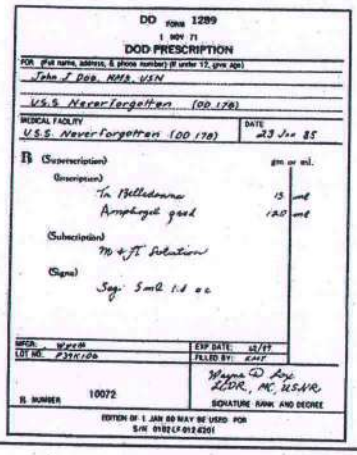
SOP / 46 / R 00 / Dt.: 01.07.2018

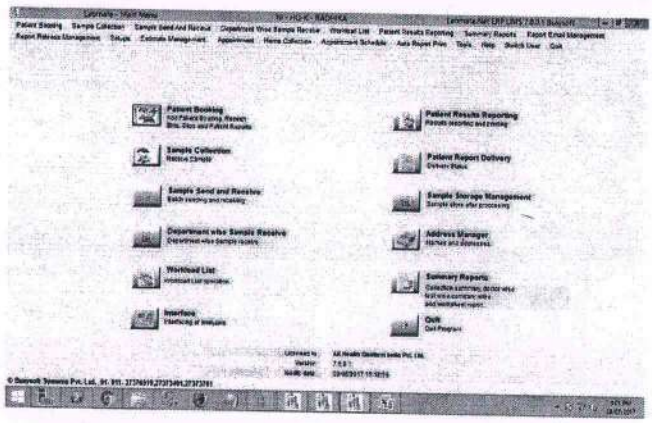
Procedures for Lab Information System Validation & Verification.

Purpose To define Lab Information System Validation & Verification Six monthly.

LIS generally continues to feature the following :
patient management, including Date of Testing , reffering Clinician/physician, specimen type, etc.
customer data tracking, comparisons of lab orders with their respective bar codes
quality assurance of ordered tests, workload and management reporting
LIS features described below come from an analysis of vendor validation checklist.

Customer registration


DD FORM 1289
DOD PRESCRIPTION
John J. Doe, MMA, USN
U.S.S. Neverforgotten (DD 178)
MEDICAL FACILITY: U.S.S. Neverforgotten (DD 178)
DATE: 23 Jun 85
℞ (Superscription)
(Inscription)
Tr. Belladonna 15 ml
Amphogel qsad 120 ml
(Subscription)
M. & ft. Solution
(Signs)
Sig: 5ml 1:d oc
MFGR. Wyeth
LOT NO. F3H/10a
EXP DATE: 12/87
FILLED BY: EMT
R. NUMBER 10072
Wayne D. Doe
LCDR, MC, USNR
SIGNATURE, RANK AND DEGREE



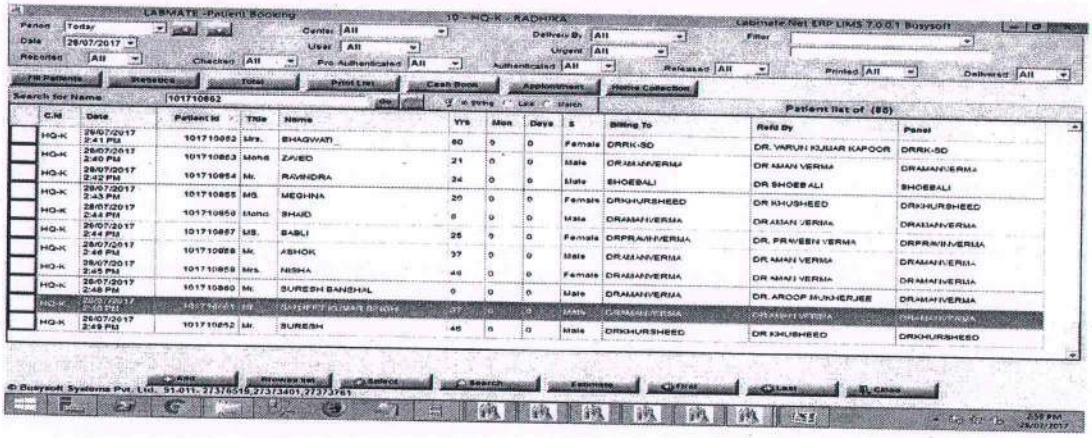
Prescription and registration demographic entry is verified by Quality manager

↓

Sample login, Sample tracking and management

↓

Sample and/or result batching and Task and event scheduling is verified by Quality manager



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Results transferred to the LIS through interfacing of equipment are accurate

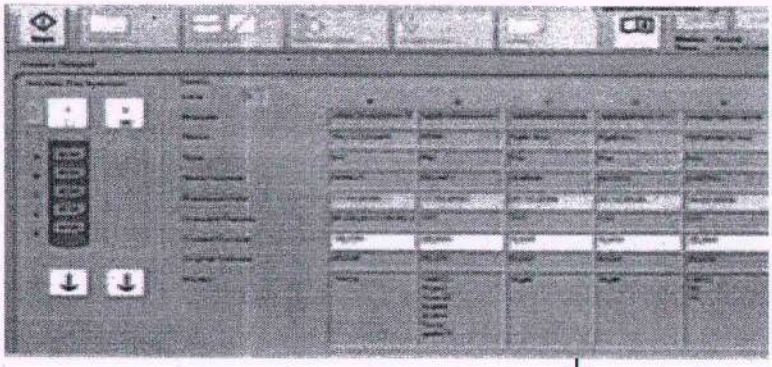
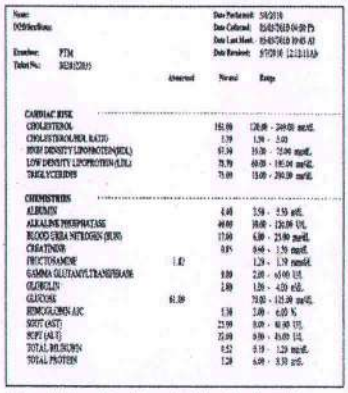
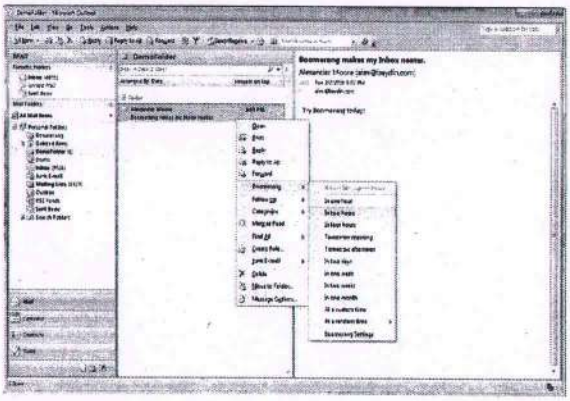


Figure 1-2-19: Example of Analysis Result Printing

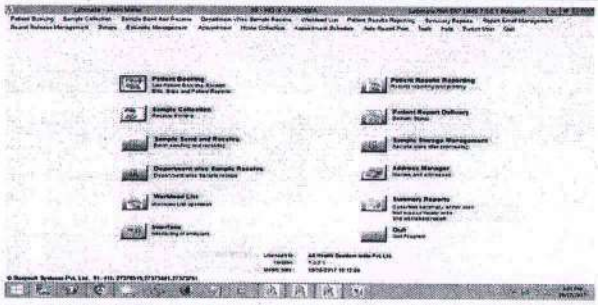
Report is printed and verified by Quality manager by equipment printout and final report



1. This sample lab report shows both normal and abnormal results, as well as acceptable reference ranges for each testing category.



Export to PDF and Email integration is verified by Quality manager on Excel Outlook.



LIS verification data is maintained like customer's prescription, Screenshot of registration/customer service agreement, worksheet generated from LIS, Equipment prinout,Screenshot and final authenticated report.

If any disparity in LIS verification observed the printig of report is stopped and the LIS service provider is called for rectification for the same.

After proper rectification of the same printing of reoprts resumed.

Standard Operating Procedure for Human Resource Management

Purpose	To define HR management systems in the laboratory.
Scope	This applies to all members working in laboratory
Responsibility	Director-Lab.
Policy	The organisation is committed to meet all relevant regulatory and statutory requirements as prevalent on the day and modified from time to time. It also takes care of the employee satisfaction and safety at the work place.

Procedure:

The laboratory is committed to follow the HR's policies which are applicable across the organisation. Incase of any vacancy it is communicated among staff/ news paper.

A **The basic activities covered in HR by Laboratory are**

1 Laboratory maintains the employee records of their qualifications, experiences and any special training attended by them in their respective files

2 The newly joined staff is explained about the organogram and his job responsibility by director laboratory & introduces the department or area in which the person will work, the terms and conditions of employment, staff facilities and occupational health services.

3 Training is given by Quality Manager, Consultants and Sr. Technicians on:
a) The quality management system;
b) Operation of machines and its features.
c) Daily maintainence of equipments
d) Assigned work processes and procedures;
e) The applicable laboratory information system;
f) Health and safety, including the prevention or containment of the effects of adverse incidents;
g) Ethics;
h) Confidentiality of patient information.

4 Laboratory provides controlled copies of all QMS documents to read and understand like:
- Sample Collection Manual.
- General Standard Operating Procedure.
- Working instruction.
- Tecnical Sops of Haematology, Clinical Biochemistry & Clinical Pathology.
- Policies.
- On & Off procedure.

5 The new joinee staff is explained about the Daily recording of various Recods of QMS like :
- Corrective & preventive action record
- Incident / Accident Record
- Critical Value Information Record
- Customer Complaint Record
- Inter-Technician Comparison Record
- New Reagent Verification

Standard Operating Procedure for Human Resource Management

- Primary sample rejection Record
- Primary sample rejection Record
- Retained Sample verification Record
- Inter Lab Comparison Record
- Review of Examination Provided
- System Monitoring
- Hazmat Material & safety Data Sheet
- Sample Discard Record
- Transcription Errror
- TAT
- Safety Chart
- Urgent Sample Report Info Record
- Inter Pathologist Comparison
- Quality Objectives & Improvement
- Stain verification Record

6 Personnel that are undergon training work under supervision and only after judging by By interviewing, Assessing their performance.that they are competent to perform the task independently, independent charge is given for performing the job.

A comprehensive job description for the position is drafted.
Minimum qualifications for various areas of activity have been laid down and resumes for any induction are invited as per these defined criteria. These criteria are briefly listed below:

a. Quality Manager : MSc/ BSc/ DMLT with atleast 03 years of relevant work experience and trained in ISO:15189, 2012.
b. Senior lab technician : MSc/ BSc/ DMLT with at least 3 years of relevant work experience.
c. Lab Technician : MSc/ BSc/ DMLT with at least 1 year of relevant work experience.

d. Phlebotomist : DMLT or 12th pass with minimum 2 years experience in phlebotomy and requisite knowledge of sample type and storage conditions.

e. Medical transcriptionist : Minimum 12th pass with good communication skills and basic knowledge of computers.

A three day orientation program is in place for every new joinee. This includes the following:
1) Day 1
- Lab tour with a formal introduction with all employees
- Introduction to the lab process flow

2) Day 2
- Thorough reading of our quality manual and quality policy
- Assigning a username and password wherever relevant
- Creation of an employee personnel file.

Standard Operating Procedure for Human Resource Management

3) Day 3 :

- Every new inductee shall be made to read and understand our Quality manual.
- Specific job related SOPs have to be read and completely understood
- The laboratory staff will also completely understand the QC management protocols pertaining to their section.
- Waste management protocols and lab safety guidelines must be read and understood.
- A written evaluation of all the above activities is conducted by the quality manager and documents are filed in the employee's personnel file. In case an employee is unable to pass the evaluation process, a retraining in the aspects where the employee is found wanted is conducted till the performance level has reached satisfactory levels.

- Training on the Laboratory information system (LIS) is given for relevant modules. This is followed by an evaluation. A retraining is given as long as is necessary.
- For Phlebotomists, specific training of phlebotomy etiquette and sample collection methodologies is given
- All these employees will also be expected to familiarize themselves with the laboratory price list

On the Job training:

1) Regular on-the-job training : This includes continuous reading of SOPs of the assigned department, employee safety programs, waste disposal guidelines are given. The schedule for these trainings is incorporated in the training record by the quality manager and an evaluation process follows each such training.
2) Training on the ISO 15189 standard
3) Continuous trainings on QC management
4) Skill Development: All employees are trained on specific testing procedures and instrument handling and maintenance protocols relevant to their department. Regular evaluations are made for all such trainings. The quality manager documents all such activities in the training record.

5) Inter-departmental training: All employees are mandated to get trained on at least one secondary department, in addition to their primary assigned department. The training and evaluation process for this remains the same as above.
6) Whenever possible, employees are encouraged to participate in internal or external training programs/ CMEs pertaining to their area of activity (primary and secondary)

Appraisal Policy

- Appraisals are done annually in the month of March/April
- Job specific appraisal formats have been designed for the same

Performance is evaluated and scored out of 100 on the basis of the objective criteria laid down.

- Scores > 90 are considered outstanding
- Scores between 80 – 90 are considered good
- Scored between 70-80 are considered average
- Scores between 60-70 are considered below average and need improvement

Standard Operating Procedure for Human Resource Management

- Scores between 50 – 60 are considered unsatisfactory and require to show improvement in the next appraisal cycle
- Scores below 50 are considered extremely unsatisfactory and are liable for punitive action including termination
- The appraisal results are conveyed to all the employees personally by the management.

Dr. Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab. LIC.No. NKD/44 SBTC No. 0270

SOP No.	Page No. 01 No. of Copies 2	Date of review 01.01.2020 Effective Date Two Years	Written By Mr. Rajendra Suryanarayan	Checked By Dr. V. V. Ghule	Approved By Dr. S.H. Khaparde
Function : Donor Selection criteria		Section : Medical Examination Room	Distribution : Social worker/ M.O.		

Donor Selection criteria

Scope: Recruitment of Safe Donor

Materials Required: Donor consent form, Donor weighing scale, stethoscope, BP Apparatus, Clinical thermometer, Asepticsolution, Spirit swab. Lancet, sahali's method/ copper sulphate solution.

Precaution to be taken:

Take proper history of donor. - Symptoms of AIDS related complex, Respiratory infection, Surgical procedure,
Cardio-vasculardiseases, Seizures, viral hepatitis, jaundice, malarial parasite, Syphilis, tuberculosis, fever,

Sr. No.	Activities	Responsibility
1.	State whether the donor is vol. / replacement donor / regular	Social worker
2.	If the donor is replacement donor write the name of patient and C/o Doctor.	Social worker
3.	Ask the donor to fill the consent form, donor should write name, date of birth and detailed address, occupation, telephone number and sign on the consent form.	Social worker
4.	Check if all the points of the consent form are in position, by interviewing the donor make sure that donor has no adverse medical history.	Medical officer
5.	Donor should be between the age of 18-55 yrs.	Medical officer
6.	Donor weighing 50 kgs. or more may ordinarily donate 525 (450 + or – 45 ml blood as well as 350 ml for processing tube), for donors less than 50 kgs, as little as 300 ml may be drawn without reducing the amount of anticoagulant in the primary bag.	Medical officer
7.	Measure the Haemoglobin of donor by sahali's method or by copper sulphate with specific gravity of 1.053.	Technician
8.	Haemoglobin should be more than 12.5 gm%.	Technician
9.	Blood pressure should be less than 150 mm. hg systolic and 100mm.hg.diastolic.	Medical officer
10.	Pulse should be between 60 – 90 beats/min.	Medical officer
11.	Medical exam of cardiovascular system to ensure normal heart beat.	Medical officer
12.	Donors last meals, donor's should have 2 glass of water before donating blood.	Technician
13.	Donor's body temperature should be 37.5^0c.	Medical officer
14.	Label the blood bag and pilot tube by donor's full name donor's number.	Technician

pancreas, Liver kidney diseases, Digestive system, Vaccination and inoculation, Pregnancy and abortion.

Procedure:

Documentation: Consent form, Donor Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

SOP No.	Page No.	Date of review	Written By	Checked By	Approved By
02	02 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Donors HB Estimation by Sahali's Method		**Section :** Medical Examination Room	**Distribution :** Technician		

Donors HB Estimation by Sahali's Method

Scope: To Estimate HB by sahali's Method.

Materials Required: Haemocytometer, N/ 10 Hcl, HB Pipette, Distilled water, Lancet,.

Principle:

This is based on the conversion of hemoglobin to acid. Haematin when blood is mixed with acid.

Precaution to be taken:

- Blood should not be clotted ,
- Reagent should be discarded ,it becomes turbid
- The mixture of blood and reagent should be clear turbidity is done to contamation and give false results.

Pipette should be accurate to take 20ul blood

Procedure:

Sr. No.	Activities	Responsibility
1.	Clean the fingertip with an antiseptic solution and puncture the skin with a sterile disposable lancet.	Technician
2.	Add 20 ul of blood from the finger prick in a calibrated tube containing N/10 Hcl to the 20 mark.	-
3.	Let stand at room temperature for 10 minutes. During this time hemoglobin is converted to acid haematin.	-
4.	Dilute the solution with distilled water till the color matches with that of the permanent comparator.	-
5.	Read the hemoglobin concentration directly.	-

Documentation: Consent form, Donor Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

Dr. V Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab. LIC.No. NKD/44 SBTC No. 0270

SOP No.	Page No.	Date of review	Written By	Checked By	Approved By
03	03 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Donors HB Estimation by CuSo4 Method		**Section :** Medical Examination Room	**Distribution :** Technician		

Donors HB Estimation by CuSo4 Method

Scope: Screening of quantity estimation of donors Heamoglobuline.

Materials Required: Copper Solution, (Specific gravity 1.053) aseptic solution, Disposal needles, lancet Capillary tube, pippette, beaker.

Precaution to be taken:

- Taking first drop of blood from finger prick first drop of blood avoided.
- Squeezing the finger because the blood not flows freely.
- Dirty pippet (pippet not flushed not properly every time.)
- The solution has to be changed after every 25 tests.

Procedure:

Sr. No.	Activities	Responsibility
1.	Take about 50 ml $cuso_4$ with specific gravity of 1.053(>12.5 gm%.) In a beaker.	Technician
2.	Clean the donor's finger tip with aseptic solution and allowed to dry.	-
3.	Disposal needle or lancet used for finger pricks and there be free flow of blood.	-
4.	The drop of blood is colleted either in capillary tube or pipette and allowed to fall gently	-
5.	Allow the drop to fall into the beaker 1 inch above the surface of solution	-

1. INTERPRETATION:

	RESULT	HB CONCENTRATION	INTERPRETATION
A	BLOOD DROP FLOATS BLOOD DROP SINKS & RISES	HB<12.5G/DL	FAIL (F)
B	BLOOD DROP SINKS	HB>12.5G/DL	PASS (P/A)
C	BLOOD DROP SINKS SLOWLY	HB=12.5G/DL	PASS SLOWLY (AS)
S	BLOOD DROP HESITATES MIDWAY & SINKS SLOWLY	HB=12.5G/DL	PASS FAIL RN\(P/F)

Documentation: Consent form, Donor Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

SOP No. 04	Page No. 04 **No. of** Copies 2	Date of review 01.01.2020 **Effective Date** Two Years	Written By Mr. Rajendra Suryanarayan	Checked By Dr. V. V. Ghule	Approved By Dr. S.H. Khaparde
Function : Permanent Deferral		**Section :** Medical Examination Room	**Distribution :** Social worker/ M.O.		

Permanent Deferral

Scope : To Defer Donor Permanently

Principle: The aim of Blood Transfusion service should be to provide effective blood and blood products which are as safe as possible.

Precaution to be taken:
The first approach to the prevention of transmission by transfusion is the selection of donors who are at low risk for transfusion-transmissible infections.
Identifying low-risk donor groups.
Avoiding unsuitable blood donors.
A brief medical history, including possible signs and symptoms related to transfusion-transmissible infection

PROCEDURE:

Sr. No.	Activities	Responsibility
1.	Abnormal bleeding tendencies.	M / O
2.	Aids positive.	-
3.	Allergic disorders	-
4.	Autoimmune disorders.	-
5.	Cardiovascular disorders.	-
6.	Cerebrovascular disorders.	-
7.	Chronic renal disease.	-
8.	Diabetes mellitus.	-
9.	Epilepsly.	-
10.	Hepatitis B & C Carriers.	-
11.	Liver Disease.	-
12.	Malignant Disorders	-
13.	Cancer.	-

Documentation: Consent form, Donor Rejection Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

SOP No. 05	**Page No.** 05 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Mr. Rajendra Suryanarayan	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : Temporary Deferral		**Section :** Medical Examination Room	**Distribution :** M.O.		

Temporary Deferral

Principle: The aim of blood transfusion services should be to provide effective blood and blood Products, which are as safe as possible.

Scope: Requirement of Safe Donor'

Precaution to be taken:
The first approach to the prevention of transmission by transfusion is the selection of donors who are at low risk for transfusion-transmissible infections.
Identifying low-risk donor groups.
Avoiding unsuitable blood donors.
A brief medical history, including possible signs and symptoms related to transfusion-transmissible infection. A basic health check including a brief examination of the arm for needle mark.

PROCEDURE:

Sr. No.	Activities	Responsibility
1.	Abortion deferred for 6 month.	M.O.
2.	Accident deferred for 6 month.	-
3.	Operation deferred for 12 months.	-
4.	Acupuncture treatment should be debarred from blood donation for 6 month	-
5.	Alcoholism deferred for 24 hours.	-
6.	Anemia till proper treatment is done.	-
7.	Blood donation within 3 months.	-
8.	Blood transfusion within 6 months.	-
9.	Common cold deferred for 1 week after stopping medication.	-
10.	Drugs treatments deferred for 1 week after last dose	-
11.	Immunization and vaccination for 2 weeks	-
12.	Skin disease till treatment.	-
13.	Hepatitis within 12 months.	-
14.	Malarial parasite for 3 months	-
15.	Surgical procedures deferred for 6 months after major surgery, 3 months after minor surgery.	-
16.	Pregnancy, till 12 months after delivery.	-

Documentation: Consent form, Donor Rejection Register.
End of document.
Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition

SOP No. 06	**Page No.** 06 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Miss. Savita Barat	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : Bleed the Donor		**Section :** Donor Room	**Distribution :** M.O./ Technician		

Bleed The Donor

Scope: Collection of Blood with aseptic precautions.

Materials Required: Blood Bag Containers, BP Apparatus, Donor weighing scale, stethoscope, Sterile Cotton swab, Poviodine Iodine Solution I.P. & Denatured sprit 70% ethyl alcohol, Bandage, Emergency drug.

Precaution to be taken:

- Inspect the bag for leakage or any other defect
- Anticoagulation solution must be clear
- Check the donor name donation number as the form and the bag. Donation number on the bag and form should be same.
- Blood bag weigh scale should be set zero
- Importance to clear the site of venepuncture very carefully and all aseptic precaution should be taken.

PROCEDURE:

Sr. no.	Activities	**Respon-sibility**
1.	Take the medical history of donor in detail.	M.O.
2.	Fill the donor form.	-
3.	Take consent of donor.	-
4.	Take pulse, hemoglobin, temperature and blood pressure.	-
5.	Donor should be in prone position without pillow.	-
6.	Tie the cuff of B. P. and raise the pressure up to 40 – 50 mm of hg.	-
7.	Examine the anticubital fossa.	
8.	Clean the site of venepuncture with poviodine iodine solution i.p. & denatured sprit 70% ethyl alcohol, allow the spirit to dry.	M.O.
9.	To dry do not touch the area prepared for inserting the needle. Contamination can occur at the time of phlebotomy and it is therefore important to clean the site of venepuncture very carefully and all aseptic precaution should be taken.	
10.	Give hand load or rubber ball to the donor.	-
11.	Ask donor to open and close palm and squeeze cotton bag or rubber ball.	-
12.	Select single, double or triple blood bag as per requirement.	-
13.	Write the name and date of collection, blood group & MBB Sr. No. On the blood bag.	-
14.	Prick the appropriate vein with the bevel of the needle pointing upwards and see that the flow of blood is adequate, the collection should be completed in 3-5 minutes.	-
15.	Gently shake the blood bag to mix anticoagulant.	Technician
16.	Release pressure, Gently remove the needle.	M.O.
17.	Place the sterile swab at the venepuncture site apply light pressure. the donor should remain on the bleeding couch for 5 to 8 min under the observation of MO then the donor is allowed to sit up and go for refreshment check the arm and apply band-aid after bleeding stop.	-
18.	Collect blood from the tube into plain bulb/ pilot tube.	-
19.	Make the smear for malarial parasite.	Technician
20.	Write the name and date of collection, blood group & MBB sr. no. on the bulb/pilot tube.	
21.	Milk the blood in the tube properly and seal it with the tube Sealer.	-
22.	Place the bag in non-tested storage unit.	Technician

Documentation: Consent form, Donor Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

Dr. V Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab.

LIC.No. NKD/44 SBTC No. 0270

SOP No. 07	**Page No.** 07 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Mr. Rajendra Suryanarayan	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : Record of Donor Reaction		**Section :** Donor Room	**Distribution :** Staff Nurse / M.O.		

Record Donor Reaction

date : bb no.

Name: ABO:

Address: Rh.(d):

TYPE OF REACTION: _____

_____

_____

_____

_____

MANAGEMENT: _____

_____

REACTION CONTROLLED

WITHIN _____ TIME: _____

RECOVERY _____

DONOR VITALS	INITIALLY	AFTER REACTION CONTROLLED
1) Blood Pressure (mmHg) 2) Pulse (beats/Min) 3) Temperature C 4) Respiratory Rate		

SIGN OF MEDICAL OFFICER

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08	08 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Emergency Drugs	**Section :** Donor Room	**Distribution :** M. O.			

Emergency Drugs

Precaution: Check the Drugs Expiry date.

CHECKLIST

FIRST AID
A) TETANUS TOXOID
B) SPIRIT AMMOINIA AROMATIC
C) BETADICE
D) BANDAGE
E)GLUCON-D(POWDER)
F) BAND-AID

INJECTION
a) PERINORM
b) BETNESOL
c) DERIPHYLLIA
d) ATROPINE SUPHATE
e) AVIL
f) CALCIUM (SANDOZ)
g) ADRENALINE
h) 5% GLUCOSE
i) NORMAL SALINE
j) DEXAMETHASONE
k) DISTILLED WATER

MISCELLANEOUS
A) OXYGEN CYLINDER WITH MASK
B) TONGUE DEPRESSOR
C) I.V. SET
D) I.V. CANNULA OR SEALP VEIN
E) I.V.STAND
F) 2 ML & ML SYRINGES WITH NEEDLES
G) TOWEL

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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09	09 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Provide Oxygen to the donor		**Section :** Donor Room	**Distribution :** Nurse / M.O.		

Provide Oxygen to the donor

Scope : To provide oxygen to the donor who is having dyspnea.
Material : Oxygen Cylinder with oxygen, Face Mask, Spanner.

Precaution to be taken :

Infection
The use of contaminated equipment can spread infection in the planer.
The causative organisms may be present in such plates as humidifying water & mask. So proper cleaning of face mask and humidifying water is necessary.
Change of humidifying water can prevent infection.
Combustion (fire)
Oxygen itself does not burn, but it supports combustion. Hence fire is a potential hazard when oxygen is administered.
So do not start fire near oxygen cylinder.
Drying of the mucus membrane of the respiratory track when oxygen is administered
Wastage of oxygen:
Knob should be closed tightly if it is not in use to prevent leakage of oxygen.

Procedure

Sr. no.	Activities	Responsibility
1.	Provide comfortable position to the donor.	Nurse
2.	Give propped up position at 45^{o}	-
3.	Arrange the oxygen cylinder near bedside.	-
4.	Clean the facemask with normal saline.	-
5.	Apply facemask on donor face.	-
6.	Start the knob of oxygen cylinder.	-
7.	Check the bubbles in wolf bottle.	-
8.	Adjust the flow of oxygen as per required by the donor in liter.	-

Documentation: Consent form, Donor Reaction form.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

SOP No.	Page No.	Date of review	Written By	Checked By	Approved By
10	10 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : A,B,O Rh Blood Grouping		**Section :** Serology Laboratory	**Distribution :** Technical / M.O.		

A,B,O Rh Blood Grouping

Principle: Human red blood cells possessing A & B antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with anti A anti B anti AB reagents is a positive test result and indicate the presence of the corresponding antigen. Absence of agglutination of red cell with anti A anti B anti AB reagents is a negative test results and indicates the absence of corresponding antigen

Human red blood cells possessing the D (Rh) antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with anti-D (Rh) (IgM) reagent is a positive test result and indicates the presence of D (Rh) antigen. No agglutination with the reagent is a negative test result and indicates the absence of D (Rh) antigen.

Precaution to be taken:

Check the patients name and identification ID No. of the blood specimen and requisition

ABO grouping should done at room temperature

Tube / slide should be labeled properly

Haemolyesd sample are not suitable for testing the blood sample may be centrifuge at 1000 to 3000 rpm for 3 minutes. For adequate serum separation.

Result should be recorded immediately after observation.

Procedure:

Sr. No.	Activities	Responsibility	document Record
1.	Place of one drop of anti-A, anti-B, anti D (Rh).	Technician	Blood Group Register
2.	Reagent separately on a label slide.	-	-
3.	Add one drop of red cells to each drop of typing antisera.	-	-
4.	Mix the cells and reagent using a clean stick spread each mixer.	-	-
5.	Tilt the slid and each slid and lives for two minutes at room temperature.	-	-
6.	Look for agglutination.	-	-
7.	Record the result.	-	-

Documentation: Blood Group Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

Dr. V Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab.

LIC.No. NKD/44 SBTC No. 0270

SOP No. 11	**Page No.** 11 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Mr. Rajendra Suryanarayan	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : A,B,O Typing Done by Tube Technique		**Section :** Serology Lab	**Distribution :** Technician / M.O.		

A,B,O Typing Done by Tube Technique

Scope: The Tube Technique is easy to perform Tube can be centrifuge which enhance antigen and antibody reaction
Materials required: Test tube with rack, ABO Sera, 5% red cells suspension, Microscope.

Principle: human red blood cells possessing A& B antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with anti A anti B anti AB reagents is a positive test result and indicate the presence of the corresponding antigen. Absence of agglutination of red cell with anti A anti B anti AB reagents is a negative test results and indicates the absence of corresponding antigen
Human red blood cells possessing the D(Rh.) antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with anti-D(Rh)(IgM) reagent is a positive test result and indicates the presence of D(Rh) antigen. No agglutination with the reagent is a negative test result and indicates the absence of D(Rh) antigen.

Precaution to be taken:

Check the patients name and identification ID No. of the blood specimen and requisition
ABO grouping should done at room temperature.
Tube should labeled properly
Haemolyesd samples are not suitable for testing the blood sample may be centrifuged at 1000 to 3000 rpm for 3 minutes for adequate serum separation.
Result should be recorded immediately after observation. All negative result must be examine under microscopy

Procedure:

Sr. No.	Activities	Responsibility
1.	Set up three tubes carefully label with donor name and patients name.	Technician
2.	Label anti a, anti b, anti D (Rh).	-
3.	Add one drop anti A, B, D.	-
4.	Add one drop of 5% red cell in three tubes A, B, D.	-
5.	Mix the contained of each tube gentle shaking and leave at room temperature 30 to 45 minute.	-
6.	Mix all the three-tube centrifuge at 1000 rpm for one minutes.	-
7.	Resuspend cell button by gently shaking the tube and reed against well lit.	-
8.	Record result of agglutination.	

Documentation: Blood Group Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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12	12 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Serum Grouping	**Section :** Serology Lab.	**Distribution :** Technician / M.O.			

Serum grouping

Scope: Reverse (serum) Group method to confirm ABO Blood Grouping

Materials required: 5% Red cells, Test tube with rack, Pipette, Table Centrifuge.

Precaution to be taken:

Failure to add proper reagent cell or serum.
Incorrect cell serum ratio.
Over centrifugation can give false positive.

Principle:

The reverse grouping method to confirm ABO Blood grouping is based on the presence or absence of the antibodies, anti-A and anti-B in serum. If these antibodies are present in serum, there should be agglutination when the serum is combined with known red cells.

Procedure:

Sr. No.	Activities	Responsibility
1.	Spin test sample to separate serum.	Technician
2.	Prepare once washed 2.5% suspension of the known cells.	-
3.	Add one drop of 2.5% test cell suspension in the three tubes. A, B & O.	-
4.	Add 2 drop of the test serum in the tubes.	-
5.	Mix the tubes and centrifuge at 1000 rpm. For 1 min.	-
6.	Resuspend cell button by gently shaking the tubes & read against well-lighted background.	-

Cell grouping			Serum grouping			
Anti-A	Anti-B	Anti-AB	Ac	Bc	Oc	Result
+	-	+	-	+	-	A
-	+	+	+	-	-	B
-	-	-	+	+	-	O
+	+	+	-	-	-	AB
-	-	-	+	+	+	Oh or any other irregular Antibody

Documentation: Blood Grouping Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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13	13 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Preparation of Know Pooled cells for reverse grouping	**Section : Serology Section**	**Distribution :** Technician / M.O.			

Sop Of Preparation Of Know Pooled Cells For Reverse Grouping

Scope: The reverse (serum) group method to confirm ABO blood grouping

Principal :- The reverse grouping method to confirm ABO blood grouping is based on the presence or absence of the antibodies, anti-A and anti-B in serum. If these antibodies are present in serum, there should be agglutination when the serum is combined with known red cells.

Safety guidelines:- Pooled cells are preferably prepared fresh Everyday

Procedure:

Sr. No.	Activities	Responsibility
1.	Prepare packed cells from whole blood (A,B,&O) by centrifugation in 3 different tubes from 3 different samples each of A,B,& O.	Technician / M.O.
2.	Centrifuge each pooled samples in a separate tube.	-
3.	Discard the supernatant serum (plasma)	-
4.	Wash red cells sediment with normal saline 3 to 4 times.	-
5.	Centrifuge and remove the supernatant twice repeat the washing with adequate normal saline remove supernatant from each wash.	-
6.	Dilute red cells suspension with normal saline to get A 5 % tomato red suspension.	-
7.	Pooled A cells, B cells & O cells are used for serum (reverse) grouping.	-

Documentation: Blood Grouping Register

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

SOP No. 14	**Page No.** 14 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Mr. Rajendra Suryanarayan	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : Screening Test for the MP		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

Screening Test for the MP

Precaution : Prevent Spoilage of the stain, see at least 100 fields on oil immersion.

Material Required : Fields stain A, stain B, Cedorwood, Microscope, glass slide, Methanol.

Scope : Test for malaria depends on screening for malarial parasite in the RBC.

Procedure:

Sr. No.	Activities	Responsibility
1.	Prepare a thick smear at the time of blood collection while doing blood grouping	Technician
2.	Dry it and label it properly with donor's serial number if collected in camp or with MBB no.	-
3.	If collected in blood bank. stain the slide by field stain in TTD lab.	-
4.	See under microscope and observe for malarial parasite	M. O.
5.	Observe under oil immersion objective.	-
6.	See at least 100 oil immersion fields before giving negative report.	-
7.	If the bag is positive for malarial parasite add hypochlorite solution and shift the bag to discard unit.	-

Documentation: MP Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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15	15 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HIV Elisa Testing	**Section :** TTD Laboratory	**Distribution :** Technician / M.O.			

HIV ELISA Testing

Scope: Microwell ELISA Test for the Detection of HIV I and II (Human Serum/Plasma)
Materials Required: HIV ELISA Test Kit, Micropipettes and microtips, ELISA reader, Distilled or deionized water, Graduated Cylinders for reagent dilution sodium hypochlorite solution, Paper towels or absorbent tissue, Timer Elisa Washer, Incubator 37^{O} C, Vials to store the diluted reagent, Disposable Gloves, Glassware.

Precaution to be taken:

- Do not use kit components beyond the expiration date which is printed on the kit.
- Bring all the reagent &samples to room temp before used.
- Used freshly collected clean serum samples for assay, try to avoid turbid, lipemic and Heamolysed serum or plasma samples.
- All pipetting steps should be performed with utmost care and accuracy.
- Correct volumes of the test samples, conjugate and substrate are added.
- Run negative and positive controls in each assay to evaluate validity of the kit.
- Avoid strong light exposures during the assay.
- Instruction given by the manufactures of kits should be strictly followed.

PRINCIPLE:

- Microlisa HIV (Ag & Ab) test is an enzyme immunoassay based on "Sandwich ELISA".

Recombinant proteins gp41, terminus of gp 120, and gp 36 for HIV-1 and HIV-2 representing immunodominant epitopes and P24 antibodies are coated onto microtiter wells. Specimens and controls are added to the microtiter well followed by addition of enzyme conjugate (HIV-1 & 2 antigen and HIV-1 P24 antibodies linked with HRPO) A sandwich complex is formed in the well where in HIV-1 or HIV-2 antibodies or P24 antigen (from serum sample) is sandwiched between the antigens & antigen HRPO and antibody & antibody HRPO conjugate. The plate is then washed to remove unbound material. Finally substrate solution containing Chromogen and hydrogen peroxide is added to the wells and incubated. A blue colour will develop in proportion to the amount of HIV-1 and / or HIV-2 antibodies and / or HIV-1 antigen present in the specimen. The colour reaction is stopped by a stop solution. The enzyme substrate reaction is read by EIA reader for absorbance at a wavelength of 50 nm. If the sample does not contain HIV-1 or HIV-2 antibodies or HIV-1 p24 antigen, then enzyme conjugate will not bind and the solution in the wells will be either colorless or only a faint background colour develops.

procedure:

Sr.No.	Activities	Responsibility
1.	After completing procedure take reading on an Elisa reader take printout. Confirm validity of test as per manufacturer's instructions.	Tech./ MO
2.	Take the printout & keep in the file.	-
3.	If test is valid, show to medical officer & take signature.	-
4.	Remove HIV positive blood bags/component with pilot sample from quarantine fridge and keep in discard Box.	-
5.	Send HIV positive blood bags to Bio Medical Waste for discard. Within 48 hours	-

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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15	16 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HIV Elisa Testing		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

HIV ELISA Testing

caculation of results (JML kit.)
Test validity: Blank must be <0.100
Negative control acceptance Criteria Nc must be ≦ 0.150
Positive control acceptance Criteria PC 1 must ≥0.50
PC-2 must be ≥0.400
Determine the mean (PC-1x) value.
Cut off value = NCx+0.20
Absorbance

NC - 0.042	B1 well	PC – 1.412	D1 well
- 0.040	C1 well	- 1.392	E1 well
Total: 0.082	**2 well**	- 1.407	F1 well
	Total :	**4.211**	**3 wells**

Inerpretation of results
Test specimens with absorbance value less than the cut off value are non- reactive and may be considered as negative for anti-HIV and HIV-1 P24 antigen.
Test specimens with absorbance value greater than or equal to the cut off value are reactive for anti-HIV and /or HIV-1 antigen by Microlisa HIV (Ag & Ab).

Documentation: HIV Register, Master Register, HIV Discard Register (ZBTC).
Note: Test specimens with absorbance value within 10% below the cut off should be considered suspect for the presence of antibodies and/or antigen, should be retested in duplicate.
Specimens with absorbance value equal to or greater than the cut of value are considered initially reactive by the critera of Microlisa HIV (Ag & Ab). Original specimen should be retested in duplicate. If both duplicate retest sample absorbance value is less than cut off value, the specimen is considered non reactive.
If any one of the duplicates retest sample absorbance value is equal to or greater than the cut off or both duplicate retest value are equal to or greater than the cut off, the specimen is considered reactive by the criteria of Microlisa HIV (Ag& Ab) Further confirmation by other EIA assays or confirmation assays including Westem Blot or PXR is recommended.

Documentation: HIV Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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16	17 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HCV Elisa Testing	**Section :** TTD Laboratory	**Distribution :** Technician / M.O.			

HCV Elisa Testing

Scope: Microwell Elisa Test for Detection of Antibodies to Hepatitis C Virus in Human Serum/ Plasma.

Materials Required: HCV ELISA Test Kit, Micropipettes and microtips, ELISA reader, Distilled or deionized water, Graduated Cylinders for reagent dilution sodium hypochlorite solution, Paper towels or absorbent tissue, Timer Elisa Washer, Incubator 37^{O} C, Vials to store the diluted reagent, Disposable Gloves, Glassware.

Precaution to be taken:

- Do not use kit components beyond the expiration date which is printed on the kit.
- Bring all the reagent &samples to room temp before used.
- Use freshly collected clean serum samples for assay; try to avoid turbid, lipemic serum or plasma samples.
- All pipetting steps should be performed with utmost care and accuracy.
- Correct volumes of the test samples, conjugate and substrate are added.
- Run negative and positive controls in each assay to evaluate validity of the kit.
- Avoid strong light exposures during the assay.
- Instruction given by the manufactures of kits should be strictly followed.

Principal:

ELISA microplates well are coated with HCV antigen, on adding serum the antibodies present in the serum binds the immobilized HCV antigen. Add enzyme conjugate antihuman IgG conjugated with horseradish peroxide (HRPO). This helps to detect the bound antigen – antibodies HCV enzyme conjugate complex. A substrate chromogen is added which imparts blue colour, which is stopped by adding stop solution a yellow colour appears which is finally read at 450 nm spectrophotometrically.

PROCEDURE:

Sr. no.	Activities	Responsibility
1.	Leave A-1 well as blank.	Tech./M.O.
2.	Add 50 ul Negative Control in each well no. B-1 and C-1 respectively.	-
3.	Add 50 ul Positive Control -1(PC-1) in D-1, E-1 & F-1 wells.	-
4.	Add 50 ul Positive Control-2 (PC-2) in G-1 wells.	-
5.	Add 50 ul of sample in each-well, starting from HJ-1 well.	-
6.	Add 100 ul of working Enzyme conjugate to each well except A1. Gently shake the plate for 2-3 seconds to mix the sample & conjugate.	-
7.	Cover the plate and incubate in an incubator at 37ºC+ 1 ºC for 60 minutes.	-
8.	Dilute the wash buffer concentrate with distilled water to 1:25 dilution.	-
9.	At the end of incubation period, take out the plate from incubator and wash with working wash buffer.	-

Calculation of Results:

Abbreviation

HC - Absorbance of the negative control

NCx – Mean absorbance of negative control

PC - Absorbance of the positive control

PCx – Mean absorbance of positive control

Test Validity :

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16	18 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HCV Elisa Testing	**Section :** TTD Laboratory	**Distribution :** Technician / M.O.			

HCV Elisa Testing

Blank acceptance criteria (JML kit.)
Blank mus be<0.100 in case of differential filter being used. In case differential filter is not available in the reader the blank values may go higher.
Positive control acceptance Criteria:
PC or PCx must be > 0.5 if it is not so, the run is invalid and must be repeated.

	-1.297	D1 Well
PC	-10255	E1 Well
	-1.258	F1 Well
Tatal	**3.810**	

PCx = 3.810/3 = 0.27

Negative Control Acceptance Criteria :
NC must be -0.005< NC < 0.150

NC	0.042	B1 Well
	0.036	C1 Well
Total :	**0.078**	

Ncx = 0.078/2 = 0.039

Cut off Value is calculated as below :
Cut off value = 0.1 X 1.27 + 0.1 = 0.227

Interpretation of results:

- Test specimens with absorbance value less than the cut-off value are non-reactive for Anti HCV.
- Test speciments with absorbance value greater than or equal to the ct-off value are reactive for Anti-HCV.
- Test specimens with absorbance value within 10% below the cutoff should be considered suspect for the presence of antibodies and should be retested in duplicate.
- Specimens with absorbance value equal to or greater than the cut-off value are considered initially reactive. Original specimen should be retested in duplicate.
- If both duplicate retest sample absorbance value is less than cutoff value, the specimen is considered nonreactive.
- If any one of the duplicate retest sample absorbance value is equal to or greater than the cutoff or both duplicate retest value are equal to or greater than the cutoff, the specimen is considered reactive by the criteria of HCV Microlisa. Further confirmation by other EIA assays or confirmation assays including RIBA is recommended.
- Specimens which are not repeatedly reactive, may have shown colour due to:
- Carry over of a highly reactive sample due to contamination of pipette tips.
- Substrate contamination
- Inadequate wash or aspiration during wash procedure.
- The O.D. for Crystal clear negative samples can be in minus and the value could be in the range of (-) 0.00 to (-) 0.10. However, the minus (-) 0.D. does not in any way affect the result interpretation. Itrather gives better specificity.

Documentation: HCV Register, Master Register, HCV Discard Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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17	19 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Veneral Disease Research Laboratory (RPR Test)		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

Veneral Disease Research Laboratory (RPR Test)

Scope: Test for syphilis in prevention of post Transfusion syphilis.

Materials Required: VDRL Rotator, Stop watch, Serum, Cards, Reagent, Mixing stick, Microscopic.

KIT/REAGENT : RPR TEST (RAPID PLASMA REAGIN) TEST
LOT NUMBER : MFD: EXP:

Precaution to be taken:

- Allow the entire reagent to come to room temperature before use.
- Two negative controls & two positive controls must be included with each run.
- Improper mixing of the sample with reagent may lead to error result.
- RPR test result should be recorded immediately after rotation of the card under high intensity lamp or strong day light.

PRINCIPAL: FLOCCULATION
When serum is mixed with carbogen reagent ,the antilipodial antibodies (if present) will react with the carbogen reagent forming visible black floccules

Procedure:

Sr. No.	Activities	Responsibility
1.	Prepare a chart of serum numbers to be tested.	Technician
2.	Follow manufacturer's instruction.	-
3.	Place 1 drop of the serum of test sample on the card.	-
4.	Add one drop each of carbogen reagent to the test sample ,	-
5.	Add one drop of corbogen to Positive control and negative control by using the needle dropper provided with the kit.	-
6.	Mix uniformly with a mixing stick	-
7.	Start VDRL rotator, slide gently and continuously	-
8.	After 4 min look for flocculation macroscopically	M.O.
9.	Remove VDRL positive blood bags/component from quarantine fridge and keep in discard Box.	Technician
10.	Record in discard register VDRL/ master register with red ink.	M.O.
11.	Enter results & take sign of M.O.	-

Observation of results:-

- Large and medium black floccules : Reactive
- Small black floccules : Weakly reactive
- No floccules : Non reactive
- Report results as reactive or non-reactive for VDRL antibodies.
- Record the type of Kit, Lot No., Expiry Date on the VDRL data sheets.

Documentation: VDRL Register, Master Register, VDRL Discard Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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18	20 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HBsAg Elisa Testing		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

HBsAg Elisa Testing

Scope: Microwell Elisa Test for Detection of Hepatitis B surface antigen HBsAg in Human Serum/Plasma.

Materials Required: HBsAg ELISA Test Kit, Micropipettes and microtips, ELISA reader, Distilled or deionized water, Graduated Cylinders for reagent dilution sodium hypochlorite solution, Paper towels or absorbent tissue, Timer Elisa Washer, Incubator 37^{O} C, Vials to store the diluted reagent, Disposable Gloves, Glassware. :

Precaution to be taken:

- Do not ~~use kit compo~~nents beyond the expiration date which is printed on the kit.
- Bring all the reagent &samples to room temp before used.
- Use freshly collected clean serum samples for assay, try to avoid turbid, lipemic serum or plasma samples.
- All pipetting steps should be performed with utmost care and accuracy.
- Correct volumes of the test samples, conjugate and substrate are added.
- Run negative and positive controls in each assay to evaluate validity of the kit.
- Avoid strong light exposures during the assay.
- Instruction given by the manufactures of kits should be strictly followed.

Principal:

ELISA micro wells are coated with monoclonal antibodies with high reactivity for HBsAg. Add samples in to the wells followed by addition of enzyme conjugate (polyclonal antibodies linked to horse radish peroxides. A sandwich complex is formed in the well wherein HBsAg from sample is trapped between the antibody and antibody (HRPO) conjugate. On addition of substrate buffer and chromogen a blue colour develops which is stopped by adding stop solution a yellow colour appears which is finally read at 450 nm spectrophotometrically.

Procedure:

Sr. no.	Activities	Responsibility
1.	After completing procedures, take reading on an ELISA reader & take print out. Confirm validity of test as per manufactures instructions.	Tech./M.O.
2.	Take Xerox copy of printout & keep in the file	-
3.	If test is valid show to medical officer & sign on report.	-
4.	Remove HBsAg positive blood bags/ component with pilot sample from quarantine fridge and keep in discard Box.	-

Test Validity: Blank acceptance criteria: (JML kit.)
Blank must be <0.100 in case of differential filter being used. Incase differential filter is not available in the reader; the blank value may go higher.
Positive control Acceptance criteria:
PC or PCX must be >0.5 if it is not so, the run is invalid and must be repeated.

	1.430	D1 well
PC	1.500	E1 well
	1.478	F1 well
Total	----------	
	4.408	

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18	21 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : HBsAg Elisa Testing		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

HBsAg Elisa Testing

Mean absorbance PCX=4.408/3 1.469 (JML kits)
Negative Control Acceptance Criteria :

NC must be < 0.150
NC 0.012 B1 Well
0.010 C1 Well
Total : 0.022

Mean absorbance NCx = 0.022/2 = 0.011
Cut-off value
Cut off Value can be determined by using the following formula:
Cut off value = NCx + 0.1
Where NCx is mean absorbance (0.D) if Negative control.
e.g.0.011+0.1=0.111

Interpretation of results:

The absorbance of the unknown sample is compared with the calculate cut-off value.

- Test specimens with absorbance (0.D)value less than cut-off value are non reactive and may be considered as negative for HBsAg.
- Test specimens with absorbance (0.D.) value greater than or equal to cut-off value are reactive for HBsAg by HEPALISA.
- Test specimens with absorbance value within 10% below the cut-off should be considered suspect for the presence of HBsAg and should be retested in duplicate.
- Specimens with absorbance value equal to or greater than the cut off value are considered initially reactive by the criteria or Hepalisa. Original specimen should be retested in duplicate.
- If both duplicate retest sample absorbance value is less than cutoff vale, the specimens is considered non-reactive.
- If any one of the duplicates retest sample absorbance value is equal to or greater than the cutoff or both duplicate retest value are equal to or greater than the cutoff, the specimen is considered reactive by the criteria of HEPALISA. Further confirmation by other EIA assays or confirmatory assays are recommended.
- The 0.D, for Crystal clear negative sample can be in minus. However the minus (-) I.D /dose not in any way affect the result interpretation. It rather gives better specificity.

Documentation: HBsAg Register, Master Register, HBsAg Discard Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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19	22 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Use ELISA Reader	**Section :** TTD Laboratory	**Distribution :** Technician / M.O.			

ELISA Reader

Scope: The optical densities (OD values) of the solution are read by the Elisa reader after calculating cut off value and the results are recorded.

Precaution to be taken :

I

PROCEDURE:

Sr. no.	Activities	Responsibility
1.	Let the machine warm up.	Technician
2.	Select the test you want to perform.	-
3.	Press the I. D. no. Of test.	-
4.	Select the no. Of wells in the strip with negative and positive control.	-
5.	Insert well plate.	-
6.	Press start button to take the reading.	-
7.	Print the result.	-
8.	Switch off the machine after taking the result.	-

Documentation: Elisa File, Master Register, Discard Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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20	23 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Use Elisa Washer		**Section :** TTD Laboratory	**Distribution :** Technician / M.O.		

Elisa Washer

Scope: wells are washed to remove excess sera
Material: Elisa washer / wash bottle /wastebottle /rinsebottle

.

Precaution to be taken:

Ensure that the main power switch is in off position before connecting
Prime the mainfold before and after use.
Always prime immediately after switching ON the instrument
Always rinse before switching off
Keep wash, waste and rinse bottle clean.
The tubing should be checked for leaks/crumpling
Disconnect the tubing before opening wash, waste and rinse bottles caps.

PROCEDURE:

Sr. no.	Activities	Responsibility
1.	Before starting the machine take care that all the tubes are connected properly and also the sensor is plugged properly.	Technician
2.	On the machine.	-
3.	The instrument will display wash well.	-
4.	The instrument carries out power on self test to check all the internal parameters.	-
5.	It displays robonik and the time indicating that initialization is complete.	-
6.	The instrument is now ready to use.	-
7.	Prime the machine immediately after starting the machine.	-
8.	Press s (slow) wash key.	-
9.	Enter the soak time in seconds i.e. 30 seconds and press enter.	-
10.	Enter number of wash cycles required i.e. 5 washes.	-
11.	Select the required volume of wash buffer.	-
12.	Select the type of well to be washed i.e. flat well.	-
13.	Enter number of strips to be washed.	-
14.	Load strips/plates in micro plate carriage and press enter.	-
15.	Prime and rinse the machine before shutting down the machine.	-

Documentation: A.M.C.
End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Preparation of 5% Red Cells Suspension		**Section :** Serology Laboratory	**Distribution :** Technician / M.O.		

Preparation of 5% Red Cells Suspension

Scope: 5% red cells suspension is required Blood Banking procedure.

Materials Required: A, B, or O Anticoagulant blood, Test tube with rack, Normal saline, Table top Centrifuge.

Principal: - Dilute red cells concentrate with normal saline to get approximately 5% red cells suspension

Precaution to be taken: - Stability of Suspension is 24 hours. A Suspension is approx 5% suspension and adequate for day to day. No hemolysis or turbidity in supernatant by visual inspection.

Procedure

Sr. No.	Activities	Responsibility
1.	5% Red cell suspension is required for most blood banking procedures	Technician
2.	Place 1 to 2 ml of anticoagulant blood in a test tube	-
3.	Centrifuge the blood sample	-
4.	Separate the cells from (plasma)	-
5.	Fill the tube with saline and centrifuge the tube	-
6.	Aspirate the supernatant saline	-
7.	Repeat the procedures 3 to 4times	-
8.	Repeat washing until the supernatant is clear.	-
9.	Pipette 9.5 ml of normal saline into a clean test tube	-
10.	Add 0,5 ml of the packed cell button (or take 1 drop washed packed cells and add 19 drop saline)	-
11.	Mix properly , immediately before use, invert the tube several times until the cells are in suspension	-

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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22	25 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Saline Cross Match (Major)		**Section :** Serology Lab	**Distribution :** Technician / M.O.		

Saline Cross Match (Major)

Scope : Saline technique is inadequate as a complete compatibility test because it is indadequate to detect clinically significant IgG antibodies. In emergency saline technique is acceptable.

Principle: saline technique is designed to detect compatibility of IgM antibody (ies) in patient's serum against antigens on donor's red cells.

Precaution to be taken: Room temperature should be at 20 º to 24 º hot environment weakness the reaction Over centrifugation, Dirty glassware saline stored in plastic container for long period may change pH.

Material required:
Test tube with rack, 5% donor's red cells suspension, Patient's serum, Normal saline 0.9%, Microscope.

Procedure :

Sr. No.	Activities	Responsibility
1.	Label 1 tube for MBB. No. and patient's name	Technician
2.	Add 2 drops of patient's serum.	-
3.	Add 1 drop of 5% saline washed suspension of donor's	-
4.	Red cells.	-
5.	Incubate at room temperature at 20 to 24 ^{0}c for 15 minutes.	-
6.	Spin at 1000 rpm for 1 minute and look for agglutination & heamolysis	-
7.	No agglutination should occur if the donor and recipients blood are compatible.	-

Documentation: Master Register, Cross Match Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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23	26 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Antiglobulin Test (Indirect Coomb's test)		**Section :** Serology Section	**Distribution :** M.O. / Technician		

Direct Coomb's Antiglobulin Test

Scope: screening and detection of unexpected antibodies.

Materials Required: Test Tube with rack, 5% Patient's red Cells Suspension, AHG Reagent, Coomb's Control cells, Normal saline, Bovine Albumin (Optional).

Precaution to be taken:

Inadequate or improper washing of cells.
Contamination of AHG reagent by extraneous Protein.
Do not use finger or hand to cover tube.
Contaminated dropper or wrong reagent dropper can spoil entire vial of AHG reagent.

Principle: AHG will react with human globulin anti bodies either bound to RBC or free in serum.

Procedure:

Sr. No.	Activities	Responsibility
1.	Place 1 drop of 2-5 % suspension of patient red cells in a clean labeled test tube	Technician
2.	Wash the cells 3-4 times with saline and decant the final wash completely	-
3.	Add 1-2 drops of AHG reagent	-
4.	Mix and centrifuge at 1000 RPM for 1 minute	-
5.	Shake the tube gently to dislodge the cell button and read the results	-
6.	If result is negative ,incubate the test for further 5 minutes at room temperature ,centrifuge and look for agglutination	-
7.	Add 1 drop of 5 % IgG sensitized red cells to the negative test Look for agglutination if a negative result is obtained the test result is invalid and test should be repeated.	-
8.	Appropriate controls are put with the test	-

Interpretation : Agglutination of red cells indicate a positive AT Control tubes should be read before final interpretation.

Documentation: Cross Match Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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24	27 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : O Positive Sensitized Cells		**Section :** Serology Section	**Distribution :** M.O. / Technician		

O Positive Sensitized Cells

Objective: To prepare O + Positive sanitized cells.

Scope: Prepare O + positive sanitized cells for DU testing of negative Blood groups.

Material required:- Positive red cell suspension, IgG – anti – D.

Precaution to be taken:

Make dilution properly.
Proper incubation.

Procedure:

Sr. No.	Activities	Responsibility
1.	Take 0.5 ml of 5 – 6 times saline washed O + positive red cells.	Technician
2.	Dilute IgG – anti – D1: 50.	-
3.	Add 2 – 3 drops of diluted IgG – anti – D.	-
4.	Mix and incubate for 37^{o}c for 30 minutes.	-
5.	No agglutination should be seen.	-
6.	If agglutination occurs, increase the dilution of IgG – anti – D.	-

Documentation: Cross Match Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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25	28 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Weak (D) Typing (DU)	**Section :** Serology Section	**Distribution :** M.O. / Technician			

SOP Of Weak (D) Typing (D^u)

Principle:
Human red blood cells processing the D (Rho) antigen will agglutinate in presence of antibody directed towards the antigen. Agglutination of red blood cells with anti-D(Rho) IGM) reagent is a positive test result and indicates the presence of D(Rho) antigen. No agglutination with the regent is a negative test result and indicates the absence of D(Rho) antigen. All negative test results should be further tested for D^u (presence of weak /partial D's) by performing the D^u test procedure using an incomplete Anti-(Rho) of IgG class, as described later.

Guideline : Du positive persons are regarded as Rh negative if blood has to be transfused to them.
Du positive person are considered Rh positive for blood donation.
Material, accessories equipment: Anti D, Normal saline, Test tubes with rack, Pasteur pipette, Table lamp, Centrifuge.

Procedure:

Sr. No.	Activities	Responsibility
1.	Prepare 5% suspension of the red cells to be tested in Isotonic saline.	Technician
2.	Place one drop of ani incomplete anti D (Rho) (IgG class) Reagent such as ERYCLONE Anti-D(Rho)(IgG) into a labeled test tube.	-
3.	Add to the test tube one drop of the 5% cell suspension and mix well. Incubate at 37°C for 15 minutes.	-
4.	Wash the contents of the tube thoroughly, atleast three times, with isotonic saline and decant completely after the last wash.	-
5.	Add two drops of ERYCLONE Anti Human globulin reagent and mix well.	-
6.	Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).	-
7.	Very gently, resuspend the cell button and obseve for agglutination macroscopically.	

Interpretation of Results :-
Agglutination indicates the presence of D^U Antigen (Presence of weak / partial D's) No agglutination indicates the absence of D^U Antigen (Absence of weak / partial D's). (B) Mixed field agglutination in the D^U test on red cells from a recently delivered woman may indicate a mixture of maternal Rho (D) negative and fetal Rho(D) positive blood. (c) Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for D^U antigen (Presence of weak / partial D's).
Documentation: Cross Match Register, Master Register,

End of document.

Reference: Kohler C.& Milstein C., Lee H.H., Rouger P. , Germain C., Human Blood Groups by Geoff Daniels., HMSO, Data on file: Tulip Diagnostics.

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26	29 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Indirect Antiglobulin test (Coomb's test)		**Section :** Serology Section	**Distribution :** M.O. / Technician		

Indirect Antiglobulin test (Coomb's test)

Scope: Hemolytic disease of new born. Auto immune Hemolytic anemia, Drug Induced Hemolytic Anemia, Hemolytic transfusion reaction, Detection of atypical antibodies on donor or patient red cells.
Materials Required: Test Tube with rack, 5% donor's red Cells Suspension, Patient's serum, Control IgG coated RBC (O+), Normal saline.

Precaution to be taken:
Blood sample should be fresh as possible not more than 24 hours.
Inadequate or improper washing of cells.
AHG serum should be stored properly. Do not used finger and Hand to cover tube

Principle: Indirect antiglobulin test is use to detect in vivo sensitization (coating) of red cell with immuno antibodies (IgG) of the compliment component of the red cell.

Procedure:

Sr. No.	Activities	Responsibility
1.	Label 1 tube for MBB. No. And patient's name	Technician
2.	Add 2 drops of patient's serum	-
3.	Add1 drop of 5% saline washed suspension of donor's red cell.	-
4.	Incubate at 37 ^{o}c for 45 minutes.	-
5.	Spin at 1000 rpm for 1 minute and look for agglutination	-
6.	Discarded supernant	-
7.	Wash cells with large volume of normal saline 3 times and prepare a 5% cells suspension.	-
8.	Mix one drop each of 5% cell suspension and (AHG) coombs	-
9.	Incubate at room temperature for 5 min	-
10.	Centrifuge at 1000-rpm 1minute.	-
11.	Gently shake the tube to dislodge the button and examine for agglutination.	-
12.	Microscopic absence of agglutinating denotes compatibility.	Medical officer

Documentation: Cross Match Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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27	30 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Laminar Air Flow Safe Manipulation of Infected Material		**Section :** Componant Preparation Room	**Distribution :** Technical supervisor		

Laminar Air Flow

Scope: To reduce Risk to personal, & laboratory environment to prevent Air Bone Infection in test Material

Precaution :

Every morning the table top should be cleaned with sodium hypochloride
Clean pre-filter by removing four knobs every once in a month
Pressure indicator should display pressure between 5 to 9 mm of water. if any change is observes in the pressure level, informed supervisor.
Manometer reading drops 5 mm and above and if it reaches 20mm please inform the manufacturer.
Once a year validation of laminar airflow is necessary. Which its performance.\ Insure
Before making any maintenance make sure the power supply is cut off.
Never see with your nacked eye towards U.V. light.
U.V. light Replacement after 500 hours is necessary.
The environment of laminar should be kept highly clean.
Maintain house keeping and make practice to wear cap, mask, hand gloves, and apron and shoe cover

Principle:

The effectiveness of the biological safety cabinet is function of directional airflow inward and downward thru a high efficiency filter.

Procedure:

Sr. No.	Activities	Responsibility
1.	Laminar airflow (biological safety cabinet)	Technician supervisor
2.	Biological safety cabinet devices that facilitate safe manipulation of and infectious material and reduce risk to personal and laboratory environment	-
3.	Start U.V. light half hour before the work.	-
4.	Extreme right buffer of blower.	-
5.	Before starting the blower put off the U.V. light.	-
6.	The effectiveness of the biological safety cabinet is a function of directional airflow (in ward & downward) through a high efficiency filter.	-

Documentation: (AMC)

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

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28	31 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Preparation of FFP		**Section :** Componant Preparation section	**Distribution :** Technical supervisor / M.O.		

Preparation of FFP

Scope: To prepare Fresh Frozen Plasma.

Materials Required: Double / Triple blood Bag container, Laminar air flow, electronic weighing scale, Refrigerated Centrifuge, Plasma Expressers, Aluminum clip, Rubber disc.

Precaution to taken:

- Blood should be colleted by a clear single veinpunture, flow of blood should be rapid and constant, total time taken to colleted 350/450ml of blood should not be more than 5 to 8 min.
- Balance the blood bag properly and handle the refrigerated centrifuge carefully & process all blood bags within 6 hours of blood collection.

PROCEDURE

fresh frozen plasma

Sr. No.	Activities	Responsibility
1.	Select freshly collected blood in CPDA /ADSOL/ SAGM Double / Triple or Quadraple blood bag as per the requirement.	Technical Supervisor
2.	Keep the blood bag vertical on the laminar air flow 45 to 60 minutes.	-
3.	Ensure balance of weighing machine reads zero without blood bags.	-
4.	All blood bags should be accurately balanced on electronic weighing machine.	-
5.	Set the temperature of refrigerated centrifuge at 4^{o} - 6^{o}c.	-
6.	Place the blood bags in the refrigerated centrifuge with its flat side facing the center of the centrifuge.	-
7.	Close the lid of the centrifuge properly.	-
8.	Centrifuge the blood bags at 3000-3500 rpm for 5 minutes.	-
9.	After centrifugation gently remove the blood bag from buckets and place them on the plasma expressor stand in the laminar air flow break the integral seal of tube	-
10.	Express approximately 75% of plasma into satellite bag (Transfer bag) if CPDA / Double bags are used. In case special blood bags with additive solution are used than maximum amount of plasma can be separated into the satellite bag, and transfer the red cell additive solution into the red cells countained in the primary bag.	-
11.	Seal the transfer bag and disconnect from primary bag.	-
12.	The bag containing the red blood cells is labelled as packed red Blood cells and the transfer bag which contains fresh plasma as labeled as FFP.	-
13.	Label all the Blood bags with their number and blood group, component number (product number).	-
14.	Keep packed red blood cells at 2^{o}-6^{o}c in refrigerator and plasma at –30^{o}c or lower within 6 hrs of collection.	-
15.	Record in the component preparation register.	-

Note

- Fresh frozen plasma from a standard donation of whole blood (450 ml) usually measures 175 to 250 ml, containing 70-80 units /dl of factor viii, factor ix, vwe and other plasma clotting factors.
- One unit of factor activity is defined as the amount present in 1 ml of fresh frozen plasma, average normal plasma anticoagulated with one tenth part of citrate.

Documentation: FFP Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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29	32 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Preparation of Platelet Concentrate		**Section :** Componant Preparation section	**Distribution :** Technical supervisor / M.O.		

Preparation of Platelet Concentrate

Scope: Prepare Platelet Concentrate.

Materials Required: Double / Triple blood Bag container, Laminar air flow, electronic weighing scale, Refrigerated Centrifuge, Plasma Expressers, Aluminum clip, Rubber disc.

Precaution: (Aspirin take in last three days not excepted Blood be used for preparing platelets) Blood bags should be stored at 20 to 24 °C before separation in air conditioner room. To prevent partial activation of coagulation system blood must be collected rapidly with single vein puncture. The flow of blood should be rapid and constant the blood bag should filled 5 to 7 minutes & 450 ml in 10 minute. The vein puncture must be done without giving pressure of B.P. cuff. Balance the Blood bag properly and handle the Refrigerated centrifuge carefully. Platelet should be separated within 4 - 6 hours from blood donation. Preferably immediately.

Basic requirement: using CPDA/ADSOL/SAGM Double or Triple Blood bags and refrigerated centrifuge can prepare platelet concentrate.

Procedure

Sr. No	Activities	Responsibility
1.	Collect the blood in double or triple ADSOL/SAGM Triple Blood collection bags	Technical Supervisor
2.	Keep the blood at room temperature or BOD incubator and temperature 20 to 24°c and till it is processed do not refrigerate, the separation is done within four to six hours of blood collection	-
3.	Set the temperature of centrifuge at 20-24°c	-
4.	Ensure balance of weighing machine reads zero without blood bags.	-
5.	All the blood bags should be accurately balanced on electronic weighing machine	-
6.	Place the blood bags in the refrigerated centrifuge with its flat side facing the centre of the centrifuge	-
7.	Start the centrifuge and set the speed at 2000 rpm for three minutes at 20-24°c.	-
8.	After completion of first spin gently remove the blood bag from buckets and place them on the plasma. Expresser stand in the laminar air flow break the integral seal of tube	-
9.	Express plasma into the first satellite bag (in case ADSOL / SAGM Triple bags are used then transfer the red cell additive solution into the red cells contained in the primary bag)	-
10.	In case of triple blood bags seal the tubing between the primary bag and satellite bags and separate the primary bag using a die electric sealer.	-
11.	If double bag was used place a temporary seal between primary and satellite bag.	-
12.	Balance the separated platelet rich plasma and then centrifuge at 3000-3500 rpm (heavy spin) for 6 minutes 20-24°c	-
13.	Express supernatant platelet poor plasma into second satellite bag if triple bag is used or back in to the original bag if double bag is used leave 50ml of plasma with the rich platelet concentration.	-
14.	Seal the tubing and separate the bags.	-
15.	Leave the platelet concentrate on the laminar air flow for 1 hour for disaggregation	-
16.	Leave the platelet concentrate undisturbed for an hour at 20-24°c.	-
17.	Label all the blood bags with their number and blood group, component number (product number).	-
18.	At the end of one hour re-suspend the platelets by gently agitating the bag and keep it in their platelet agitator which maintains 20-24°c.	-
19.	Record in the component preparation register.	-

Documentation: Platelet Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

PMID: 561028 [PubMed - indexed for MEDLINE]

Dr. V Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab.

LIC.No. NKD/44 SBTC No. 0270

SOP No. 30	**Page No.** 33 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Miss. Savita Barat	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khaparde
Function : Quality Control of Whole Human Blood		**Section : QC** room	**Distribution :** Medical Officer		

Qulaity control of Whole Human Blood

$$\text{Vol (ml)} = \frac{\text{weight of blood (gm) weight of empty bag (gm)}}{1.05}$$

Parameter	Quality requirement	Frequency of control
Volume	350 ml +_ 10 %	1% of all units.
Haematocrit	30 -40 %	4 UNITS MONTH
HBsAg	Negative by Elisa	All units
HIV		
HCV		
VDRL	Negative by screening test	
Sterility	bag culture	1%

Documentation: Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

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31	34 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Discard unit-expired bag		**Section :** Serology Section/ Washing room	**Distribution :** Technician / M.O.		

Discard Unit – Expired Bag

Scope: To discard blood bags/Component bag that have expired/haemolysed/ leakage..
Precaution to be taken:
Bags should kept separately with proper labeling.
Maintain the records of discarded bags properly.

Procedure:

Sr. No.	Activities	Responsibility
1.	If the bag is not used within 35 days recover the plain plasma centrifusing the bag.	Technician
2.	Before discarding the bag sent it for the microbiologic contamination test.	-
3.	Add hypochlorite to blood bag/Component bag keep the blood bag/Componant bag.	-
4.	Autoclave the blood bag/Component bag for 15 pounds pressure for 15 minutes.	-
5.	Send the bag for biomedical waste disposal.	-
6.	Record the blood bag/Component bag number, name of the donor, date of collection, blood group of the blood bag/Component bag.	-
7.	In discard register along with receiver's signature and date.	

Note: Before 5 days of expiry plain plasma can be separated from the blood bag.

Documentation: Expiry Discard Register, Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by (WHO)

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32	35 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : To Discard HBsAg Positive Blood Bags/Componant		**Section :** Serology Section/Washing room	**Distribution :** Technician / M.O.		

To Discard HBsAg Positive Blood Bag / Component

Scope: Discard HBsAg positive blood bag & component

Precaution to be taken:
Bags should kept separately with proper labeling.
Maintain the records of discarded bags properly.

Procedure:

Sr. No.	Activities	Responsibility
1.	Immediately after Elisa testing is done. Label the HBsAg positive bag with red ink.	Technician
2.	Take 10 ml 4 to 6% hypochlorite in a syringe and inject it in reactive blood bags & component.	-
3.	Seal the tube & mix well.	-
4.	Put the bag in dark room for 12 hours.	-
5.	Autoclave the blood bag & Componant bag at for 15 pounds pressure for 15 minutes.	-
6.	Transfer the HBsAg positive blood bag / component along with its pilot sample into the discard box.	-
7.	Send for biomedical waste disposal.	-
8.	Record in discard register along with receiver's signature along with date.	-

Documentation: HBsAg Discard Register, Master Register.

End of document.

Dr. V Vikhe Patil Memorial Hospital & medical College's Blood Bank & Blood Component Lab.

LIC.No. NKD/44 SBTC No. 0270

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Function : To Discard TTD Positive Blood Bags		**Section :** TTD, lab. ZBTC	**Distribution :** Technician / M.O.		

To Discard HIV Positive blood bag/component

Scope: To Discard HIV Positive Blood Bags & Component Bags.

Precaution to be taken:
Bags should kept separately with proper labeling.
Maintain the records of discarded bags properly.

Procedure:

Sr. No.	**Activities**	**Responsibility**
1.	Immediately after Elisa testing is done, label the HIV positive blood bag & component bag with red in ink.	Technician
2.	Take 10 ml 4 to 6 % hypochlorite in a syringe and inject it in reactive blood bags & component bag.	-
3.	Seal the tube & mix well	-
4.	Keep blood & component bag in dark room for 12 hours	-
5.	Autoclave the blood bag & component bag at for 15 pounds pressure for 15 minutes.	-
6.	Type a letter to ZBTC for discard of HIV blood bag/Componant bag.	-
7.	Send the HIV blood bag & component bag with pilot sample and letter to ZBTC.	-
8.	Endorse the receiver's signature and date in HIV discard register.	-

:

Documentation: HIV Discard Register, Master Register.

End of document.

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34	37 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : To Discard HCV Positive Blood Bags		**Section :** Serology Section/Washing room	**Distribution :** Technician / M.O.		

To Discard HCV Positive Blood Bag / Component

Scope: To discard HCV positive blood bag & component.

Precaution to be taken:
Bags should be kept separately with proper labeling.
Maintain the records of discarded bags properly.

Procedure:

Sr. No.	Activities	Responsibility
1.	Immediately after Elisa testing is done. Label the HCV positive bag with red ink.	Technician
2.	Take 10 ml 1 % hypochlorite in a syringe and inject it in reactive blood bags & component.	-
3.	Seal the tube & mix well.	-
4.	Put the bag in dark room for 12 hours.	-
5.	Autoclave the blood bag & Component bag at for 15 pounds pressure for 15 minutes.	-
6.	Transfer the HCV positive blood bag / component along with its pilot sample into the discard box.	-
7.	Send for biomedical waste disposal.	-
8.	Record in discard register along with receiver's signature along with date.	-

Documentation: HCV Discard Register, Master Register.

End of document.

Reference: Transfusion medicine technical manual.

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Function : Autoclave		**Section :** Washing room	**Distribution :** Technician Attendants		

Autoclave

Scope : All infected laboratory waste must be autoclave before disposal.

Material required: Autoclave, Basket, Water,

Principle: the principle is that water boils when its vapor pressure is equal to the pressure of the surrounding atmosphere. If the pressure is raised inside a closed vessel the temperature at which water boils will raise above 100^{o} c. At 15 lbs. Pressure water boils at 120^{o} c.

Precaution to be taken: The steam must be saturated. There must be complete discharge of air from the sterilizing chamber. The autoclave must be loaded in such a way that all the materials to be sterilized can be adequately penetrated by steam. The duration of autoclaving would depend on the pressure inside and hence on the steam temperature efficiency of autoclave should be checked using spore of B. THERMOPHILUS.

Procedure:

Sr. No.	Activities	Responsibility
1.	Fill boiler with water to a point just below the basket bottom.	Technician Attendants
2.	Place article within basket.	-
3.	Close the lid and tighten the screws.	-
4.	Open out let valve and adjust safety valve to the require pressure.	-
5.	Tune on the heat source and when steam flows smoothly.	-
6.	Close the ventcock and the eternal pressure rice.	
7.	See that all air has been expelled from the cylinder.	
8.	Let pressure rise to the required level and maintain at that level for the required period of time.	
9.	Switch off the heat source and let the pressure meter register zero	
10.	Open the ventcock and the lid slowly.	

Note : 15 lbs. Pressure for 20 minutes-infected material.
All infected laboratory waste must be autoclave before disposal.
Incineration is the ideal method of final disposal waste

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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Function : Platelet Incubator With Agitator		**Section :** Component Storage Room	**Distribution :** Technical supervisor		

Platelet Incubator With Agitator

Scope: Platelet stored at 22 to 24 (controlled temperature) with continuous gentle agitation in platelet incubator and agitator with maintained pH.

Precaution to be taken: The **incubator** should be cleaned with sodium hypochlorite
The temperature should be recorded daily. Preventive maintenance is performed twice a year.
Platelet agitator: any spills due to leakage should be immediately cleaned with sodium hypochlorite .the number of strokes should be monitored as well as after repair.

Procedure:

Sr. No.	Activities	Responsibility
1.	The alarm system should be set in such a manner as to make sound when the temp out side the required range 22 to 24.	Technician
2.	Alarm system should be operated and independent of main electric supply	-
3.	Check the temperature of the platelet incubator with thermometer.	-
4.	Agitator (flat bed) with strokes at 50 to 60 cycle per min at 20 to24	-

Documentation: A.M.C.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

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37	40 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Deep Freezer		**Section :** Blood Storage Room	**Distribution :** Technical		

Deep Freezer

Scope: Store the Fresh Frozen Plasma with at -40^{o}C or below

Precaution to be taken:
Periodically check the temperature of digital system by precision thermometer kept inside the cabinet periodically.
Deep Freezer should be defrosted whenever needed.

Procedure

Sr. No.	Activities	Responsibility
1.	Open the deep freezer door only when required	Technician
2.	The component units showed be kept in an upright position.	
3.	component should be arranged group wise for easy access	
4.	Component should be issued to the donor according to serial numbers.	

Documentation: Temperature record file, Data logger.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

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38	41 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Refrigerated Centrifuge		**Section :** Component Separation Room	**Distribution :** Technical Supervisor		

Refrigerated Centrifuge

Principle : The Blood Components are Prepared by centrifuging at different relative centrifugal force in g at different time. Conversion of relative centrifugal force (RCF) to rpm depends upon the radius of centrifuge rotor.
Scope: Component preparation allows transfusing only specific blood component that the patient requires.

Precaution to be taken:
Apposing cups with blood bag and Satellite bags must be equal weight.
The Blood bag should be placed that it board side face out site wall of the cup.
Rubber disc should be used for balance.
Correct speed of centrifugation and time maintained.
Observe for any abnormal Vibration till the required speed is attained if there is any vibration stop the centrifuge and check weight of the cups with the bags.

Procedure:

Sr. No.	Activities	Responsibility
	Set the Temperature as per the requirement of Platelet/FFP.	
1.	Place the blood bag in the refrigerated centrifuge with its flat site passing the center of the refrigerated centrifuge.	Technical Supervisor
2.	Close the lid of refrigerated centrifuge properly.	-
3.	Centrifuge the blood bag as per the requirement speed preparation of platelet / FFP.	-

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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39	42 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Blood Storage Cabinet		**Section :** Blood Storage Room	**Distribution :** Technical Supervisor		

Blood Storage Cabinet 1, 2, 3

Scope: To maintain temperature for proper storage of blood units (2^{O} to 6^{O} C).

Precaution to be taken:
The System should be checked once a week by immersing the sensor in ice water (for low temperature) and in water at $15^{O} – 20^{O}$ C (for higher temperature)
If alarm system is not working properly corrective properly corrective measures should be taken.
Blood refrigerator must be clean and well lit.

Procedure:

Sr. No.	Activities	Responsibility
1.	Open the blood storage cabinet door only when required.	Technician
2.	Blood bag should be arranging group wise for easy access.	
3.	Blood bag should be issue to the Donor according to serial numbers.	
4.	Read recording temp data logger and digital temperature frequently clockwise a day the proper temp range is between 2^{o} to $6^{o.}$	-
5.	Periodically temp inside the cabinet should be counter checked with the help of precision thermometer.	-
6.	Alarm system should be operated and independent of main electric supply.	-
7.	The alarm system should be set in such a manner as to make sound when the temp out side the required range of 2^{o} to 6^{o}.	-

Documentation: Temperature Record file, Data logger.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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40	43 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Centrifuge		**Section :** Component Room	**Distribution :** Technician / M.O.		

Centrifuge

Scope : To Operate Centrifuge.

Material required:

Precaution to be taken:

Place it on a flat surface. Tubes balance properly.
Safety guidelines:- balance the tube properly and
Handle the carefully centrifuge.

Principle:

Procedure:

Sr. No.	Activities	Responsibility
1.	Place the test tubes properly balanced into opposite tubes of centrifuge	Technician
2.	Set the speed regulator as per requirement.	-
3.	Set the timer as per requirement.	
4.	Wait for the centrifuge to stop.	
5.	Remove the tubes from the buckets.	

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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41	44 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Tube Sealer		**Section :** Cross match Room	**Distribution :** Technician / M.O.		

Tube Sealer

Scope : To Seal Blood Bags Tube.

Material required:

Precaution to be taken:
Check for leakage of tubes before and after sealing.

Principle:

Procedure:

Sr. No.	Activities	Responsibility
1.	Tube sealer before the switch in on position.	Technician
2.	Place the blood bag tube in position.	-
3.	Blood bag tube should be appartemaxily 4to 9 inch long	-
4.	Wait for the sealing to take place.	-
5.	Check each tube sealing for likening	-
6.	Tube sealer when not in used switch off.	-

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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42	45 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Patient Registration	**Section :** Administration	**Distribution :** Administration / M.O.			

Patient Registration

Scope: To maintain record of all patients to whom the blood bags / component units are issued.
Materials Required: Issue Register, Blood Transfusion Report.

Precaution to be taken:
Check the identity of paint and all relevent paper to insure that there was no clerical error. Unlabelled or hemolysed sample should never be accepted. In neonate please take baby sample (4 to 6 months) with Mother Sample.

Procedure:

Sr. No.	Activities	Responsibility
1.	Read the requisition form with the name and details of patient and hospital with doctor signature, telephone number.	Administration
2.	Write the details of the patient address in the I.D. register.	-
3.	Accept the patient's sample in plain bulb, which is labelled properly with Reg. No/ Ward no.	-
4.	Write diagnosis & requirement of blood & blood component.	-
5.	Write I.D. number on the requisition form and pilot sample.	-
6.	Before reservation of the blood/component check the patient samples blood group.	-

Documentation: I. D. Register, Requisition form,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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43	46 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Issue of Blood/ Component	**Section :** Administration	**Distribution :** Administration / M.O.			

Issue of Blood Bags & Component Bags

Scope: Issue of Blood Bags / Component Bags.

Materials Required: Issue Register, Blood Transfusion Report.

Precaution to be taken:

Recheck the identification of the patient and donor blood. Inspect the unit to make contain that is does not have abnormal colour a appearance any sign of damage or leakage of the blood/component give the blood bags to patients relative in thermocool box along with ice the blood bag should not be directly in contact with ice. There should be aluminium foil or card board between the bag and ice

Procedure:

Sr. No.	Activities	Responsibility
1.	Confirm the details of the patient from the I.D. register.	Administration
2.	Read the cross match report carefully.	-
3.	Read the label on component/ blood bags carefully, see that there is no transcription error.	-
4.	Read date collection & date of expiry and quantity of bag.	-
5.	Write the issue number.	-
6.	Write date & time of issue	-
7.	Enter the details of the component/ blood bag in the issue register.	-
8.	Enter the patients name & address	-
9.	Name of the doctor/ hospital	-
10.	Indication of transfusion	-
11.	Give the blood bags to patient's relative in thermocool boxes along with ice and cross-match report.	-
12.	The blood bag should not be directly in contact with ice.	-
13.	There should be aluminium foil or card board between the bag and ice	-
14.	Take the signature of person who carries component /blood bag.	-

Documentation: Issue Register, Master Register,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Transportation of Blood Bags/components		**Section :** Administration	**Distribution :** Administration		

Transportation of Blood Bags/Components

Scope: Transportation of Blood Bags/Components

Materials required: Ice Pack, Ice, cool box.

Precaution to be taken:

The blood Bags should be Transported along with Ice or Ice Pack in cool box.. To Maintain cold chain while transporting from camp site to blood Bank, from blood bank to blood Storage center & Hospital's

Principle:

To maintain cold chain while transportation of blood bags.

Procedure:

Sr. No.	Activities	Responsibility
1.	Blood bags should be kept at 2° c to 8 ° C, the bags should be kept in ice-box, but not in direct contact with ice.	Technician
2.	Blood bags are kept with aluminum foil to avoid direct contact with ice, blood bag can be kept for 8 hours.	
3.	Ice should be refilled as soon as it melts.	
4.	FFP should be transported without thawing kept in ice-box with enough quantity of ice.	
5.	Transfer the bags to the (blood storage cabinet) as soon as it reach es blood storage center.	
6.	Platelets are transported to +20° to +24° c if the distance is less than 2 hours it can be transported without ice.	
7.	Confirm the number and name of donor after receiving the bags.	
8.	All blood bags will be visually inspected for haemolysis, leakage, turbidity, clot and weigh the bag.	

Documentation: Procurement file

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Investigation of Transfusion Reaction Record		**Section :** Serology Section	**Distribution :** M.O. / Technician		

Investigating A Transfusion Reaction

Scope: Transfusion Reaction investigation and record

Material required: Plain Bulb, EDTA Bulb, AHG /ALB/ENZ/ reagent, Grouping Sera, Pooled cells, culture plate, Total biochemistry.

Precaution to be taken: Inadequate or incorrect labeling of blood bag , Recipients blood sample, confusion in the identity of the patient at the time of collection of sample or at the time of transfusion, Improper identification of patients blood sample by blood bank technician, Wrong blood issued, Error in blood grouping and cross-matching, Incompatibility not detected in cross-matching due to improper test, Weak antibodies are not detected by tests.

Principle: Transfusion of blood and its product is , ordinarily , safe and effective way of correcting hematological defects but adverse effects do occur during or after transfusion and they are commonly called blood transfusion reaction. Each blood product transfused carries a small risk of an acute or late adverse effect.

Procedure:

Take blood / blood component with transfusion reaction report and samples to blood bank, with post reaction blood samples (EDTA)

Post reaction urine samples (Do not delay investigation while waiting for a urine sample)

Sr. No.	Activities	Responsibility
1.	Check for clerical errors. Identify the patient /donor /sample correctly	M.O/ Tech.
2.	Centrifuge and compare the colour of plasma for evidence of free haemoglobin or bilirubin visually or colorimetrically	-
3.	Perform DAT/IAT on the post transfusion blood sample of patient	-
4.	Dat demonstrates sensitization of patient red cells by immune antibodies (IgG)or by complement (C3d)	-
5.	IAT demonstrates atypical antibodies in patient's serum.	-
6.	Regroup pre-transfusion sample of patient (p)	-
7.	As well as post-transfusion sample of patient (p)	-
8.	Re cross match pre and post transfusion samples of patient (p) with pre transfusion sample of donor (D)	-
9.	Examine the first post transfusion urine sample (after5-6 hours) for evidence of haemoglobin or bilirubin	-
10.	Gram stain contents of blood bag and look for bacteria	-
11.	Culture the contents	-
12.	Look for free haemoglobin in plasma after centrifugation	-
13.	Repeat test after three days to detect delayed haemolytic reaction	-
14.	Report the results to the clinician immediately.	-

Documentation: Investigation of transfusion reaction record Register.

End of document.

Reference: Transfusion Medicine Technical manual by (WHO) second edition 2003 & Technical manual American Association of Blood Banks-13th edition.

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Function : Re-issue of Blood Bags		**Section :** Administration	**Distribution :** Technical Supervisor / M.O.		

Returned Blood Bags

Scope : To determine whether returned blood is suitable for Re-issue

Precaution to be taken:-

Retune of blood bag will be taken only if retune within 1 and 1/2hour and see that cold chain has been maintained .look for the blood bag seal should be intact and no knot is present . both parts are intact.inspect the blood to make certain that is does not have abnormal colour or appearance

.

Procedure:

Sr. No.	Activities	Responsibility
1.	Date of issue of blood bags	Technician
2.	Write the MBB number	
3.	Write the name of patient	
4.	Write the time of issued of blood bag	-
5.	Write the date of issued of blood bag	-
6.	Write time of return of blood bag will be taken only if return within 1 & ½ hour and see that cold chain has been maintained.	-
7.	Write date of return blood bag	-
8.	Write the reason of blood bags return.	-
9.	Look for the blood bag seal should be intact and no knot is present. Both parts are intact.	-
10.	No signs of tampering are there with the blood bag	-
11.	Blood shows no color change of haemolysis after centrifugation	-
12.	For platelet will be accepted back only if returned within 1 & ½ hours of issue	-
13.	FFP/Plasma/Cryoprecipitate will not be accepted back if accepted for discarded.	-
14.	Signature of technician	-
15.	Signature of blood transfusion officer	-

Documentation: Return Blood bag register, Cancellation Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Cancel of Reserved Blood Bags		**Section :** Issue Counter	**Distribution :** Administration / M.O.		

Sop of Cancellation of Reserved Blood Bags

Scope: To cancel the blood bags which are reserved.

Procedure

Sr. No.	Activities	Responsibility
1.	Write the date of reservation of the blood bag.	Technician / M.O.
2.	Write the I.D. number	-
3.	Write the name of patient for whom the blood bag was prepared.	-
4.	Write the name of hospital/doctor incharge.	-
5.	Write the blood bag number.	-
6.	Write the blood group of the blood bag.	-
7.	Write the date of cancellation of blood bag.	-
8.	The name of the hospital & talk to doctor incharge asks the cancellation of blood bank.	-
9.	Write the name of the technician by whom the blood bag is cancelled.	-
10.	Write the name of the technician who had shifted the blood bag to issue section.	-

Note: the blood bags should be cancelled within 3 days of reservation.

Documentation: Cancellation Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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48	51 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Master Register		**Section :** Record kipping	**Distribution :** Technician / M.O.		

Master Register

Scope : To Maintain Records.

Precaution to be taken:
Entries should be done periodically.

PROCEDURE:

Sr. No.	Activities	Responsibility
1.	Enter the details of donor, donor name, address, blood bag number, date of collection, age, sex, weight, blood group, HB, B.P., temperature, pulse, single/double bag, voluntary or replace, details of blood bag, expiry date of blood bag.	Administration M.O.
2.	Enter the results of serology tests-malaria, V.D.R.L., HIV, HBsAg, HCV, date of testing and data sheet number.	-
3.	Positive test report should be entered with red ink in the appropriate column.	-
4.	The positive bag should be discarded and date of discard should be entered.	-
5.	Enter the details of patient to whom the bag has been issued.	-
6.	Name of the patient, name of hospital/ doctor incharge, blood group of the recipient, issue number, date and time of issue, cross match result, whether voluntary, replace or card is given and indication of transfusion	-
7.	Take the signature of the medical officer.	-

Documentation: Master Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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49	52 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Issue of FFP		**Section :** Issue Counter	**Distribution :** Technician / M.O.		

Issue Register Of FFP

Scope : To maintain record in issue register of FFP.

Materials required: FFP Issue register, Blood Transfusion report.

Precaution to be taken:
Recheck the identification of the patient I.D. and blood donor serial number .check the ABO and Rh (D) group, donor and recipient blood. Date of collection date expiry of blood component. Donor- blood non-reactive to HIV -HCV-HBsAg-MP-VDRL
Proper labeling of donor blood before issue
Dry ice should be kept at the bottom and the top
Inside the well insulated container.

Procedure:

Sr. No.	Activities	Responsibility
1.	Write the serial number.	Administration / M.O.
2.	Write Name Date and Time of issue.	-
3.	Write the FFP number.	-
4.	Write the blood group of blood bag.	-
5.	Write the quantity in ml..	-
6.	Write the name of patient with address.	-
7.	Write the name of hospital or doctor incharge.	-
8.	Write the blood group of recipient.	-
9.	Write results of compablity.	-
10.	Write the indication of transfusion.	-
11.	Take the sign of B.T.O.	-
12.	Take the sign of the person carrying bag.	-

Documentation: FFP Issue Register, Requisition form,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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50	53 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Issue Register of Platelet		**Section :** Issue Counter	**Distribution :** Administration / M.O.		

Issue Register of Platelet

Scope: Issue of Platelet.
Materials Required: Platelet Issue Register, Blood Transfusion Report.

Precaution to be taken:
pH should be never fall below 6. monitored Agitation During Storage Helps The Exchange of Gases, maintance of pH and reduce formation of platelets aggregates .Agitator (flat bed) with strokes at 50 to 60 cycles / minute at 20 º to 24º C. note that (Rh positive)platelet should not be issued to(Rh-negative)
group of patient.
Procedure:

Sr. No.	Activities	Responsibility
1.	Write the serial number.	Administration
2.	Write name Date and Time of issue.	-
3.	Write the platelet number.	-
4.	Write the blood group of blood bag.	-
5.	Write the quantity in ml.	-
6.	Write the name of patient with address.	-
7.	Write the name of hospital or doctor incharge.	-
8.	Write the blood group of recipient.	-
9.	Write results of campability.	-
10.	Write the indication of transfusion.	-
11.	Take the sign of B.T.O.	-
12.	Take the sign of the person carrying bag.	-

Documentation: Issue Register, Requisition form,

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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51	54 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Quality Control of PCV		**Section :** QC Room	**Distribution :** Technical Supervisor / M.O.		

Quality Control of PCV (1%)

STORAGE & SHELF LIFE: AT 04^{O}C - 6 ^{O}C FOR 35 DAYS FROM DATE OF COLLECTION (CPDA)

STORAGE & SHELF LIFE: AT 04^{O}C - 6 ^{O}C FOR 40 DAYS FROM DATE OF COLLECTION (SAGM)

- DATE OF QC
- BLOOD BAG MANUFACTURE
- DOUBLE /TRIPLE
- MBB NO.
- DATE AND TIME PREPARATION
- WIGHT OF BLOOD COLLECTED
- ANY VISIBLE SIGN OF HAEMOLYSIS
- HEAMOGLOBIN
- HAEMATOCRIT
- PLASMA AFTER CENTRIFUGATION
- VOLUME
- PCV BAG TO BE GIVEN FOR MICRO BIOLOGICAL STUDIES

PRECAUTION TO BE TAKEN:
Maintained the record as per batch no.

REMARK :

QC

SIGN OF BTO

Documentation: QC of PCV File

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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52	55 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Quality Control of FFP		**Section :** QC Room	**Distribution :** Technical Supervisor / M.O.		

Quality Control Of FFP

STORAGE & SHELF LIFE: AT BELOW-30^{O} FOR ONE YEAR FROM THE DATE OF COLLECTION

- DATE OF QC
- BLOOD BAG MANUFACTURING
- DOUBLE/TRIPLE
- BB NO COMPONENT NO.
- DATE & TIME OF BLEEDING DONOR
- DATE & TIME OF PREPARING
- PTT.
- FACTOR VIII
- SMEAR EXAMINATION FOR BACTERIA / CULTURE STUDIES

PRECAUTION TO BE TAKEN:

Maintained the record as per batch no.

Cold chain should be maintained from the time of collection to the completing procedure

Remark

QC :

SIGN OF BTO

Documentation: QC of FFP File

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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53	56 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Quality Control of Platelet		**Section :** QC Room	**Distribution :** Technical Supervisor / M.O.		

Quality Control of Platelet

(SHELF LIFE & STORAGE 3 DAYS AT 22^{O}C to 24 ^{O}C

- DATE OF QC
- BLOOD BAG MANUFACTURING
- DOUBLE/TRIPLE
- BB NO PLATELET NO.
- DATE & TIME OF BLEEDING DONOR
- DATE & TIME OF PREPARING
- SPEED & DURATION OF FIRST SPIN
- SPEED & DURATION OF SECOND SPIN
- WEIGHT OF EMPTY TRANSFER BAG
- VOLUME OF PLATELET
- VISIBLE EVIDENCE OF RBC SEDIMENT
- VISIBLE EVIDENCE OF PLATELETS AGGREGATES
- PH : (6.4 to 7.4)
- PLATELETS COUNT : (X10^{3} UL x VOLUME)
- SMEAR EXAMINATION FOR BACTERIA / STUDIES FOR CULTURE

PRECAUTION TO BE TAKEN:
Maintained the record as per batch no.

REMARK

QC

Documentation: QC of Platelet File

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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54	57 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Mr. Rajendra Suryanarayan	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : QC of Equipment		**Section** : Q. C. Room	**Distribution :** Technical Supervisor / M.O.		

Guidelines for Quality Control of Equipment in Blood Transfusion Service

- BENCH CENTRIFUGE : CHECK ACCURACY OF SPEED AND TIME WITH PRECISIONS RPM METER (TACHOMETER) & STOP WATCH EVERY THREE MONTHS. CHECK MOTOR BRUSHES AT REGULAR INTERVALS
- WATER BATH :- CHECK TEMPERATURE 2-3 TIMES A DAY CHANGE DISTILLED WATER EVERY WEEK CULTURE THE DISCARDED WATER FOR FUNGAL OR MICROBIAL CONTAMINATION. USE STIRRER FOR UNIFORM MAINTENANCE OF TEMPERATURE. IF NO STIRRER IS ATTACHED CHECK TEMPERATURE AT DIAGONAL ENDS TO ENSURE UNIFORMITY.
- INCUBATOR: - CHECK THE TEMPERATURE 2-3 TIMES IN A DAY.
- PH METER: - TWO POINT CALIBRATION (CHECK CONTROL SOLUTION PH (4-7 TO 7-10) BEFORE EACH TIME OF USE. FULL MAINTENANCE EVERY SIX MONTHS.
- WEIGHING BALANCE: - CHECK THE SENSITIVITY OF ELECTRONIC BALANCES USING KNOWN WEIGHTS ONCE A WEEK. FULL MAINTENANCE EVERY SIX MONTHS.
- ELISA READER: - CHECK REPRODUCIBILITY OF RESULTS EVERY 3 MONTHS. CALIBRATION GRAPH SIX MONTHLY. FULL MAINTENANCE EVERY SIX MONTHS. CHECK THE FILTERS FOR ANY FUNGAL GROWTH EVERY 3 MONTHS KEEP FILTERS IN A DESSICATOR.
- AUTOPIPETTES :- CALIBRATE THE PIPETTES FREQUENTLY USING MERCURY OR WATER.

Documentation: Quality Control Register & Calibration record.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : QC of Blood Storage Cabinet		**Section :** Storage room	**Distribution :** Technical Supervisor / M. O.		

Sop of Qc test for determining the temperature of inside chamber of Refrigerator

- Model: Date of performing the test
- Test conducted by Time of performing the test
- Desirable Temp. Range (+4-^{O}C to +6^{O}C) (Acceptable 2^{O} to 8^{O}C)
- Thermometer used: specify / Range
- Initial temperature before placing

Which thermometer was place	
Time of placing the thermometer	
Time of recording the temperature after placing	

Place thermometer on each side of the inner chamber:

Place thermometer on each side of the inner chamber					
	Left	Centre	Right		No. of units placed
Temperature recorded	1	2	3	4	

Sign of BTO

Documentation:. Temperature File

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : QC of Refrigerated centrifuge		**Section :** Componant room	**Distribution :** Technical Supervisor / M. O.		

QC test for determining the temperature of inside chamber of Refrigerated centrifuge

- Model: Date of performing the test
- Test conducted by Time of performing the test
- Desirable Temp. Range (+4-^{O}C to +6^{O}C) (+20^{O} to 24^{O}C) (Tick appropriate)
- Digital display showing temperature ^{O}C
- Thermometer used: specify / Range
- Initial temperature before placing

Which thermometer was place	
Time of placing the thermometer	
Time of recording the temperature after placing	

Place thermometer on each side of the inner chamber:

Place thermometer on each side of the inner chamber					
	Buckets		Buckets		No. of units placed
Temperature recorded	1	2	3	4	

Sign of BTO

Documentation: QC record, Calibration Register..

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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57	60 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Q.C. of Platelet Incubator with Agitator		**Section :** Storage room	**Distribution :** Technical Supervisor/ M. O.		

Sop of Qc test for determining the temperature of inside chamber of Platelet Incubater With Agitator

- Model: Date of performing the test
- Test conducted by Time of performing the test
- Desirable Temp. Range (+20-^{O}C to +24^{O}C)
- Thermometer used: specify / Range
- Initial temperature before placing
-

Which thermometer was place	
Time of placing the thermometer	
Time of recording the temperature after placing	

Check the stroke of Platelet Agitator	Desirable 50 to 60 /minute.

Sign of BTO

Documentation: .Data logger, QC record, Calibration Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Q.C. of Deep Freezer		**Section :** Storage Room	**Distribution :** Technical / M. O.		

QC test for determining the Temperature of inside Chamber Of Deep Freezer

- Model : Date of performing the test
- Test conducted by Time of performing the test
- Desirable Temp. Range $-30^{O}C$ or below
- Digital display showing temperature ^{O}C
- Thermometer used : specify / Range
- Initial temperature before placing

Which thermometer was place	
Time of placing the thermometer	
Time of recording the temperature after placing	

Place thermometer on each side of the inner chamber:

	Left	Centre		Right			No.of nuits placed
Temperature recorded							

Documentation: Data logger, Calibration, Temperature file.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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59	62 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Quality Control of Antisera		**Section :** QC Room	**Distribution :** Technical Supervisor / M.O.		

Quality control of Antisera

Use of the speed with the antiserum agglutinates the red cells.

Material required:

20% A cells B cells, Rh positive cells
Glass slide
Anti-A serum anti-B serum anti-D serum
Stopwatch

PROCEDURE

Sr. No.	Activities	Responsibility
1.	Label a row of test tubes, according to antisera dilution (1:1through 1:512)	Technician Attendants
2.	Put 1 drop saline into all tubes except the first tube	-
3.	Add 1 drop antisera to tube 1 and 2 (dilution 1:1)	-
4.	Mix the contents of tube 2 with a clear pasteur pipette and then transfer 1drop of the mixture to tube 3	-
5.	Continue the same technique, through all the tubes and remove 1 drop from the dilution tube of 1:512 and discard.	-
6.	Add 1 drop of 5% saline suspension of appropriate red cells to each tube	-
7.	Incubate for 5-10 minute	-
8.	For anti-a and anti-b at room temperature	-
9.	For anti-d at 37 º	-
10.	Centrifuge at 1000 rpm for 1 minute	-
11.	Gently resuspend the red cells and look for agglutination macroscopically	-

Result :

The agglutination titer is recorded as the reciprocal of the highest dilution showing weak agglutination.
Limit
15 seconds,
Appearance should be clear anti-a & anti-b
Limit
60 seconds
Appearance should be clear anti-d

Precaution to be taken:

Make dilution's properly.

Documentation: Antisera QC Register

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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60	63 **No. of** Copies 2	01.01.2020 **Effective Date** Two Years	Miss. Savita Barat	Dr. V. V. Ghule	Dr. S.H. Khaparde
Function : Preparation of Copper solution		**Section :** Quality room	**Distribution :** Technical Supervisor		

Preparation of (CUSO4) Copper Solution

Scope : Preparation of CUSO4 Solution.

Precaution to be taken:
Measurement should be accurate.

Material required: Distrill water, CUSO4 Solution.

Step –1

- Add exact =159.6 gm of cuso4 crystal in 1000 ml distriled water mix well to dissolve
- Filter the stock of cuso4 solution using whatman filter paper to remove undissolved particles
- Store at room temperature

Step 2

- Preparation of working solution.
- Add 52 ml of stock solution in 48 ml distill water ready to used.

Documentation: Preparation copper solution Register.

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : General Laboratory Precautions		**Section :** Laboratory	**Distribution :** Technical Supervisor / M. O.		

SOP GENERAL LABORATORY PRECAUTIONS.

- Lab systems

DO'S	DON'T
MINIMIZE SPLASHING OR THE FORMATION OF DROPLETS OR AEROSOLS IN ALL PROCEDURES AND WHILE HANDLING POTENTIALLY INFECTIOUS	DO NOT EAT, DRINK, SMOKE OR APPLY COSMETICS IN THE PLACE OF WORK.
TAKE EXTRAORDINARY CARE TO AVOID ACCIDENTAL WOUNDS FROM SHARP INSTRUMENTS CONTAMINATED WITH POTENTIALLY INFECTIOUS MATERIALS	DO NOT DO ANY PAPER WORK ON POTENTIALLY CONTAMINATED SURFACES.
DISCARD ALL DISPOSABLE ARTICLES CONTAMINATED WITH BLOOD IN PLASTIC BAGS IN OR IN CONTAINERS WITH SODIUM HYPOCHLORITE SOLUTION WITH CAUTION LABELS.	DO NOT WEAR GLOVES TO EXAMINE A PATIENT WITH INTACT SKIN.
DISCARD NEEDLES AND OTHER SHARP INSTRUMENTS IN PUNCTURE RESISTANT CONTAINERS.	DO NOT TOUCH YOUR EYES, NOSE, MOUTH OR SKIN WITH GLOVED HANDS.
WEAR GLOVES WHEN THERE IS TO BE CONTACT WITH BLOOD, BODY FLUIDS, MUCOUS MEMBRANES NON-INTACT SKIN, ITEMS OR SURFACES CONTAMINATED WITH BODY FLUIDS, AND FOR PERFORMING ALL VASCULAR ACCESS PROCEDURES.	DO NOT WALK AROUND, THE WORKPLACE WEARING GLOVES.
IF YOU HAVE A BREACH IN SKIN OR HANDS, THEN WEAR GLOVES IN ALL SITUATIONS.	DO NOT TRY TO RECAP USED NEEDLES OR TRY TO BEND OR BREAK THEM WITH HANDS.
USE STERILE / DISPOSABLE SYRINGES AND NEEDLES	DO NOT GIVE UNDUE EMPHASIS TO COMMERCIALLY PRODUCED DISPOSABLE NEEDLESS AND SYRINGES. AUTOCLAVING IS AN EFFECTIVE WAY OF ACHIEVING STERILIZATION.
USE GLOVES AND TAKE SPECIAL CARE IF THERE ARE CUTS OR SCRATCHES ON THE HANDS.	AVOID SPILLAGE OF BLOOD.
USE THICK DRESSING PAD OR ABSORBENT COTTON BELOW THE FOREARM WHEN DRAWING BLOOD.	DO NOT REMOVE NEEDLES FROM SYRINGES.
PLACE A COTTON SWAB SOAKED IN SPRIT AND MAINTAIN PRESSURE TILL BLEEDING STOPS.	
LABEL ALL BOTTLES BEFORE COLLECTION OF BLOOD.	

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition.

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Function : Management Adverse Donor Reaction		**Section :** Refreshment room	**Distribution :** Medical Officer		

Management - Adverse Donor Reaction

Management :

Sr. No.	Activities			Responsibility
	Reaction		Management	
1.	**Mild Reaction :-**		**Discontinue the donation**	M.O.
	a) Fainting	–	Rest for 10 to 15 minutes. Raise foot end of bed and lower the head to improve blood supply	
	b) Nausea vomiting	–	Oral stemetil is given.	
	c) Haematoma formation	–	Ice fomentation, thrombophobe ointment is applied.	
	d) Muscular twitching	–	Reassurance	
	e) Inflammation of Venepuncture site	–	Anti - inflammatory drugs.	
2.	Moderate reactions :-			-
	a) Convulsions	–	I. V. Diazepam 5 - 10 mg. 5% DNS, O_2 inhalation Inj. Dexamethasone 10 mg. I.V.	
3.	Severe reaction :-			-
	a) Sudden cardio respiratory arrest.	–	ABC Airway – is cleared	
	Hyper Ventilation	–	Breathing Mouth to mouth ventilation Ambubag 100 % Oxygen inhalation Circulation to be checked- Pulse, BP	
	Cardiac resuscitation	–	I. V. Atropine sulphate I. V. Adrenaline 1: 10000 diluted in 10 ml D.W.	

Documentation:

End of document.

Reference: Transfusion Medicine Technical manual by WHO second edition 2003 & Technical manual American association of Blood Banks-13th edition,

OP No. 62	**Page No.** 65 **No. of** Copies 2	**Date of review** 01.01.2020 **Effective Date** Two Years	**Written By** Mr. Rajendra Suryanarayan	**Checked By** Dr. V. V. Ghule	**Approved By** Dr. S.H. Khapar
ction : Management Adverse Donor Reaction		**Section :** Refreshment room	**Distribution :** Medical Officer		

SOP For Blood Transfusion Officer

1) B.T.O. should check & Sign all the blood groups done for cross matching.
2) B.T.O. should check & Sign all the cross match done for transfusion.
3) B.T.O should work for 8 hrs at a stretch in rotation.
4) B.T.O. should check & Sign all the per transfusion testing for diseases like AIDS, Syphilis, Hepatitis B, Hepatitis C & Malaria.
5) B.T.O. should check pre transfusion & post transfusion samples for the management of adverse reaction.
6) B.T.O. should be approved by F. D. A. Department.
7) B.T.O. should check & Sign all the entries in all register .
8) B.T.O. should approve the donors before blood donation checking all the criteria for ideal donor.
9) B.T.O. should have minimum degree of MBBS with diploma in pathology / transfusion medicine/ MD in pathology / transfusion medicine having adequate knowledge of blood group, methodology & medical principles involved in procurement of blood & its components.