

**Model
STANDARD
OPERATING
PROCEDURES for

BLOOD
TRANSFUSION
SERVICE**



World Health Organization
New Delhi



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Foreword

Blood safety has been accorded a high priority by WHO and is an issue of concern to many developed and developing Member Countries. Recognizing the importance of blood safety, the theme of World Health Day 2000 was devoted to this subject with a thought-provoking slogan, “Safe blood starts with me: blood saves life”.

The availability and safety of blood depends on multiple steps in the transfusion chain. This starts with a healthy and motivated population, retention of voluntary non-remunerated donors, processing and testing of all donated blood, availability of blood and blood products, rational use of blood and its components and post-transfusion monitoring of the patient. At every step, any lowering of quality would reflect adversely on the final product. To ensure quality in blood transfusion services, WHO initiated a quality management project in 2001. One of the important areas identified under this project is capacity building in the quality management of blood transfusion services in which emphasis is laid on ensuring consistency in performing various activities so that the safety and quality of blood is guaranteed.

The performance of any procedure will yield desired quality results only if standard operating procedures (SOPs) are followed. Realizing that most blood banks in the countries of the South-East Asia Region may not have the capacity to write their own SOPs, WHO has developed model SOPs for various procedures that are commonly performed in blood transfusion services. Individual blood banks need to adapt these and develop their own blood bank-specific SOPs based on the infrastructure available, test procedures to be followed and availability of reagents.

I am sure the blood banks will find this model SOPs useful to help them in achieving their objective of continuously providing adequate, safe and quality blood.

Dr Uton Muchtar Rafei
Regional Director

Preface

There has been growing awareness about quality in blood transfusion services with the objective of releasing only those blood products and blood which fulfil the desired standards in terms of safety and efficacy. Consistency is the hallmark of quality and can be achieved only through the use of standard operating procedures (SOP) by all staff engaged in blood centres at all times. Use of SOPs has also become essential for licensing and accreditation.

Each blood bank has to develop its own set of SOPs matching their requirement and resources. SOP need to be developed for all critical procedures. There is now an international unanimity on the framework of SOPs. Each SOP must have the following components:

Each SOP must be given a unique identity number along with the revision number, if any. Information about the procedure, location where the SOPs will be used, its function and distribution list; date from which it will be effective and signatures of the author(s) and the person from top management who can authorize the use of SOP from the effective date must precede the technical details.

The technical contents of SOP should include the following:

- Scope and application
- Responsibility
- References for technical content, if any
- Materials required to perform the procedure
- Various steps of procedure
- Interpretation criteria
- Quality assurance
- Documentation

Prior to their use, the SOPs must be validated to demonstrate their utility in the setting of the respective blood bank. Realizing that in the countries of the South-East Asia Region, the capacity to develop their own SOPs is currently limited, we have developed “model” SOPs for some of the important procedures that are followed in blood banks. These are intended to act as a guide and help all blood banks in writing and validating their own SOPs. We are hopeful that these will act not only as models for development of SOPs but shall also stimulate blood transfusion services in using SOPs for various procedures and strengthening their quality systems.

New Delhi

Dr Sudarshan Kumari
Regional Adviser,

Acknowledgements

The first draft of Model Standard Operating Procedures for Blood Transfusion Services was prepared by Dr Zarin S Bharucha, formerly Head of Department of Transfusion Medicine, Tata Memorial Hospital, Mumbai, India. The draft was reviewed by various experts notably Dr Pimol Chiewsilp, National Blood Centre, Thai Red Cross Society, Bangkok and Dr Rama Bhasin, Department of Transfusion Medicine, All India Institute of Medical Sciences, New Delhi, India. We gratefully acknowledge the contributions made by these experts.

Instructions for Use of Model SOP

The standard operating procedures (SOP) are vital documents which are essential components of quality system in any organization. These are used to ensure consistency in performing an activity. Their use is mandatory by all the staff members of the blood bank every time they perform an activity. The accreditation and licensing procedures also demand compulsory use of SOP.

Every SOP has two components: one gives *information about the location, subject, functions, distribution and genesis of SOP* and the other provides *instructions for carrying out the specific activity*. Since equipment, reagents, methodology and kits used may vary in different blood banks, it is important for every blood bank to have its own SOP. To assist blood banks in this endeavour, WHO has developed SOP for most of their activities. These can be used as guide to develop blood bank specific SOP.

The information part of SOP shall have following components:

Name of the blood bank

Subject of SOP

Location of SOP

Function of SOP

Distribution of SOP

Unique Number of SOP

Version and revision

Date from which SOP shall be effective and the period after which it has to be reviewed

Number of pages and No of copies (Quality Manager or designated official shall keep a record of those whom SOP has been distributed)

Name and signature of the author

Name and signature of the person who has been authorized to approve SOP

Name and signature of the person who is to authorize the use of SOP from effective date (He must belong to the top management and is usually the Chief Executive Officer of the blood bank)

Some of the above mentioned details have been left blank in these Model SOP.

Instructions for Use of Model SOP

However, blood bank specific SOP must have these duly filled and signed.

The instructions to perform a test or activity have been described in Model SOP. It is suggested that the same should be rewritten by the blood banks incorporating the material and methodology to be used by them. The format described in the model SOP should be followed. Before use, SOP needs to be validated and periodic review (usually after one year or whenever there is a change in methodology or material) should be undertaken to bring about revisions, if necessary.

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Model SOP on Donor Issues

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 001 | | 3 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|---|--|
| Donor Room | Criteria for Donor Selection |
| FUNCTION | DISTRIBUTION |
| Assessing suitability of donor for blood donation | - Medical Officer in charge of Donor Area - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

The Medical Officer is responsible for determining the suitability of donor for blood donation. He/She should confirm that the criteria are fulfilled after evaluation of health history questionnaire and medical examination including the results of pre donation screening tests.

3. REFERENCES

Technical Manual of American Association of Blood Banks- 13th edition, 1999 pgs 90-97, 103-110.

4. MATERIAL REQUIRED

Donor Questionnaire
Donor Card

5. PROCEDURE

CRITERIA FOR SELECTION OF BLOOD DONORS

A. Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled.

The interval between blood donations should be no less than three months. The donor shall be in good health, mentally alert and physically fit and shall not be a jail inmate or a person having multiple sex partners or a drug-addict. The donors shall fulfill the following requirements, namely:-

1. The donor shall be in the age group of 18 to 60 years
2. The donor shall not be less than 45 kilograms
3. Temperature and pulse of the donor shall be normal
4. The systolic and diastolic blood pressures are within normal limits without medication
5. Haemoglobin shall not be less than 12.5 g/dL
6. The donor shall be free from acute respiratory diseases
7. The donor shall be free from any skin disease at the site of phlebotomy
8. The donor shall be free from any disease transmissible by blood transfusion, in so far as can be determined by history and examination indicated above
9. The arms and forearms of the donor shall be free from skin punctures or scars indicative of professional blood donors or addiction of self-injected narcotics

B. Defer the donor for the period mentioned as indicated in the following table:

| CONDITIONS | PERIOD OF DEFERMENT |
|---|--|
| Abortion | 6 months |
| History of blood transfusion | 6 months |
| Surgery | 12 months |
| Typhoid fever | 12 months after recovery |
| History of Malaria duly treated | 3 months (endemic) 3 years (non endemic area) |
| Tattoo | 6 months |
| Breast feeding | 12 months after delivery |
| Immunization (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin) | 15 days |
| Rabies vaccination | 1 year after vaccination |
| Hepatitis in family or close contact | 12 months |
| Hepatitis Immune globulin | 12 months |

C. Defer the donor permanently if suffering from any of the following diseases:

1. Cancer
2. Heart disease
3. Abnormal bleeding tendencies
4. Unexplained weight loss
5. Diabetes
6. Hepatitis B infection
7. Chronic nephritis

- Signs and symptoms, suggestive of AIDS
- 9. It is important to ask donors if they have been engaged in any risk behaviour. Allow sufficient time for discussion in the private cubicle. Try and identify result-seeking donors and refer them to VCTC (Voluntary Counseling and Testing Center). Reassure the donor that strict confidentiality is maintained.
- 10 Liver disease
- 11 Tuberculosis
- 12 Polycythemia Vera
- 13 Asthma
- 14 Epilepsy
- 15 Leprosy
- 16 Schizophrenia
- 17 Endocrine disorders

D. Private interview:

A detailed sexual history should be taken. Positive history should be recorded on confidential notebook.

E. Informed consent:

Provide information regarding:

1. Need for blood
2. Need for voluntary donation
3. Regarding transfusion transmissible infections
4. Need for questionnaire and honest answers
5. Safety of blood donation
6. How the donated blood is processed and used
7. Tests carried out on donated blood

N.B. This gives the donor an opportunity to give his/her consent if they feel they are safe donors

Request the donors to sign on the donor card indicating that he is donating voluntarily.

6. DOCUMENTATION

Enter all details in the donor questionnaire form/card and computer

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 002 | | 2 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | Biennial | | | |

| LOCATION | SUBJECT |
|-----------------------------------|--|
| Donor Room | Donor Screening |
| FUNCTION | DISTRIBUTION |
| Physical examination of the donor | - Medical Officer-in-Charge of Donor Area - Master File |

1. SCOPE AND APPLICATION

To perform a physical examination on the donor for confirming fulfilment of the criteria which ensure safety of the donor as well as the recipient.

2. RESPONSIBILITY

It is the responsibility of the Medical Officer to perform the physical examination on the donor.

3. REFERENCES

- Introduction to Transfusion Medicine, Zarin Bharucha & Chauhan DM 1st edition 1990, Pg. 97-98
- Technical Manual of American Association of Blood Banks, 13th edition 1999, Pg. 93-95

4. MATERIALS REQUIRED

Weighing scale
Sphygmomanometer
Clinical thermometer
CuSO₄ in Coplin's jar
Capillaries
Lancet
Donor card

5. PROCEDURE

Medical Examination:

- General Appearance: Defer a donor who appears ill, under the influence of drugs/alcohol or do not appear to be providing reliable answers to medical history.
- Check and enter donor's weight. The weight should be >50 kg to collect 450 ml and between 45 and 50 kg to collect 350ml blood.
- Check if the blood pressure, pulse and temperature of the donor are within the acceptable limits:
 - Systolic blood pressure not > 160 mm of Hg.
 - Diastolic pressure not > 100 mm of Hg;
 - Pulse regular, between 60 and 100 beats / minute.
 - Oral temperature 37.5 C +/- 0.2C (98.6F +/- 0.5F).
- HAEMOGLOBIN ESTIMATION: Blood donation can be accepted only if the haemoglobin is > 12.5 g/dl. Test for haemoglobin by CuSO₄ specific gravity method (Refer SOP 003).

6. DOCUMENTATION

Enter details in the donor card/computer

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 003 | | 2 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|---|--|
| Donor Room | Qualifying Test for Blood Donation |
| FUNCTION | DISTRIBUTION |
| Method of estimation of donor's haemoglobin by copper sulphate method | - Medical Officer-in-Charge of Donor Area for use by all technicians in the area - Master File |

1. SCOPE AND APPLICATION

To find a fit and healthy donor, assuring his or her safety. This also helps in assuring the quality of the product.

2. RESPONSIBILITY

It is the responsibility of the technician working in the donor area.

3. REFERENCE

Technical Manual of American Association of Blood Banks, 13th edition, 1999 Pg. 711-712

4. MATERIALS REQUIRED

1. Copper sulphate working solution with a specific gravity 1.053.
2. Sterile gauze/cotton, spirit and sterile disposable lancets.
3. Heparinized capillaries (dimensions: 75mmx1mm)
4. Containers with 1% sodium hypochlorite solution for disposing sharp lancets, capillaries and bio hazardous materials.
5. Coplin jar with lid.

For preparation of copper sulphate working solution refer SOP: SP 004.

5. PROCEDURE

Principle:

This is a qualitative test based on specific gravity. The drop of donor's blood dropped

into copper sulphate solution becomes encased in a sac of copper proteinate, which prevents any change in the specific gravity for about 15 seconds. If the haemoglobin is equal to or more than 12.5 gm/dL the drop will sink within 15 seconds and the donor is accepted.

N.B:

- Do not depend on colour of tongue or conjunctiva.
- Accept a donor only if haemoglobin is >12.5g/dL.

Method:

1. 30 ml copper sulphate working solution (Sp.gr.1.053) in a clean, dry coplin jar is used for determining hemoglobin. The jar is kept covered with a lid when not in use. The working solution is changed after every 25 tests.
2. The fingertip is cleaned thoroughly with a spirit swab and allowed to dry.
3. The finger is punctured firmly near the tip with a sterile disposable lancet. A good free flow of blood is ensured. The finger is not to be squeezed repeatedly since it may dilute the drop of blood with excess tissue fluid and give false low results.
4. The first drop of blood is wiped and $\frac{3}{4}$ of the micro capillary is allowed to fill with blood sample by capillary force, without any air bubbles.
5. Allow one drop of blood to fall gently from the capillary from a height of about 1 cm above the surface of the copper sulphate solution, into the coplin jar.
6. The drop of blood is observed for 15 seconds.
7. The lancet and capillaries are disposed off in a container with 1% sodium hypochlorite solution.

Interpretation:

1. If the drop of blood sinks within 15 seconds (i.e. donor's haemoglobin is more than 12.5gm/dL), the donor is accepted for blood donation.
2. However, if the blood drop sinks midway (i.e. haemoglobin level is less than 12.5gms/dL), and then comes up, the donation or donor is deferred.
3. If the drop sinks slowly, hesitates and then goes to the bottom of the jar, confirm the haemoglobin of this donor.
4. If the donor fails the CuSO₄ test, repeat haemoglobin by Sahli's /Drabkin's / Automated Cell Counter.
5. In case if the haemoglobin is lower than 12.5g/dL, prescribe haematinics and ask the donor to come for a recheck after one month.

6. DOCUMENTATION

Enter the result on donor card

N.B.: WHO has developed a simple device for estimating haemoglobin (Haemoglobin Colour Scale)

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 004 | | 1 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | Biennial | | | |

| LOCATION | SUBJECT |
|---|---|
| Donor Room | Haemoglobin Estimation |
| FUNCTION | DISTRIBUTION |
| Preparation of CuSO_4 solution | <ul style="list-style-type: none">- Donor Area- Medical Officer in Charge of Donor Area- Masterfile |

1. SCOPE AND APPLICATION

The specific gravity of 1.053 is equivalent to 12.5 g/dl haemoglobin. Hence CuSO_4 solution of specific gravity 1.053 is used for predonation haemoglobin test.

2. RESPONSIBILITY

The technician/laboratory assistant in the donor area.

3. REFERENCE

Introduction to Transfusion Medicine: Z.S. Bharucha, D.M. Chouhan, 1st Edition, 1990, page 99.

4. PROCEDURE

Stock solution is made as follows and kept in a jar or bottle.

1. Dissolve 170 gm crystalline $\text{CuSO}_4 \cdot 5\text{H}_2\text{O}$ in 1000 ml distilled water (Working solution)
2. Every morning prepare fresh solution.
3. Add 51 ml stock solution to 49 ml distilled water.
4. Check Specific Gravity which should be 1.053. if not, adjust it using either stock solution or distilled water.

5. DOCUMENTATION

Record the volume of stock and working solution prepared on the register (Table 1 of SOP 005)

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(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 005 | | 4 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|----------------------------|---|
| Quality Control Laboratory | Copper Sulphate Solution |
| FUNCTION | DISTRIBUTION |
| Quality control | <ul style="list-style-type: none">- Quality Control Laboratory Supervisor- Quality Manager- Master File |

1. SCOPE AND APPLICATION

Copper sulphate solution is used for screening blood donors by testing the haemoglobin concentration before blood donation.

Copper sulphate solution is checked to ensure that a drop of blood sample of predetermined haemoglobin value reacts as expected (sinks/floats).

2. RESPONSIBILITY

It is the responsibility of the Quality Control personnel to ensure testing of the reagent before use.

3. REFERENCES

Technical Manual[†] of American Association of Blood Banks, 13th Edition, 1999, pg 56

4. MATERIALS REQUIRED

Equipment:

Urinometer

Reagents:

Copper sulphate working solution

Distilled water

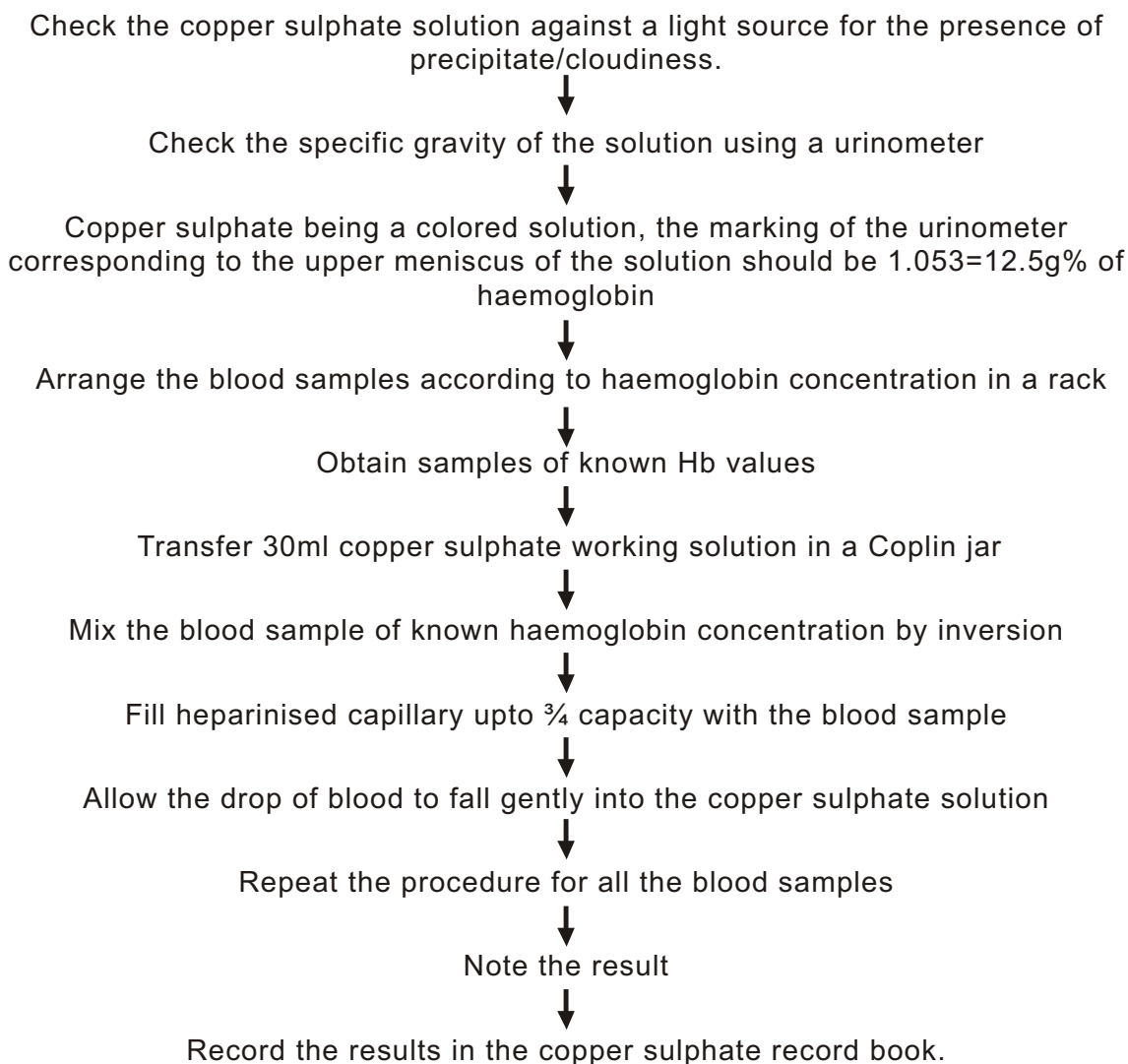
EDTA blood samples of known haemoglobin concentration

Glassware:

Coplin jar
Heparinised capillaries

Miscellaneous:

Tissue paper
Copper sulphate record book
Tube racks

5. PROCEDURE**6. RESULTS**

If the solution appears cloudy or precipitate is present, the solution is discarded.

The result of testing the solution is interpreted as follows:

| | RESULT | Hb CONCENTRATION | INTERPRETATION |
|-----|---|------------------|-----------------------------|
| (a) | Blood drops floats | Hb<12.5g% | Fail (F) |
| (b) | Blood drops sinks | Hb<12.5g% | Pass (P) |
| (c) | Blood drops sinks slowly or Blood drop hesitates midway and sinks slowly | Hb<12.5g% | Pass fail reaction (P/F) |

7. DOCUMENTATION

The result are noted in the copper sulphate record book as given in Table on next page.

TABLE-1[illegible]

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 006 | | 2 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|--|--|
| Donor Room | Blood Collection |
| FUNCTION | DISTRIBUTION |
| Solutions and method for preparing phlebotomy site | - Medical Officer in Charge of Donor Room for all phlebotomists - Master File |

1. SCOPE AND APPLICATION

Cases of transmission of bacterial infection in blood are fortunately rare, but when they do occur can be fatal. Thus careful preparation of the skin at the phlebotomy site before venepuncture is very important.

2. RESPONSIBILITY

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

3. REFERENCE

Technical Manual of American Association of Blood Banks, 13th edition, 1999 Pg. 713

4. MATERIALS REQUIRED

- Sterilising tray
- Demethylated spirit
- Povidone Iodine
- Cotton/gauze/swabs
- Artery forceps
- Tourniquet

5. PROCEDURE

After selection of the vein for venepuncture, apply spirit, povidone-iodine (Ioprep) and finally spirit swab, in this order, to the skin at the phlebotomy site. Start disinfection of the skin of about an area of 5 cm diameter from the centre outwards in a circular

motion. Scrub the providone-iodine vigorously for at least 30 seconds or till froth forms. Do not touch the site prepared for venupuncture. Should it be necessary, touch the skin away from the point of needle insertion. If the puncture site is touched, repeat skin preparation procedure as detailed earlier.

Discreetly check the used swab. If it is physically soiled/contaminated, take a new swab and repeat skin preparation procedure as detailed earlier.

Dispose off used swab(s) into a waste bin meant for bio-hazardous materials. Allow the skin to air dry. Do not wipe the area with cotton wool, fan or blow on it.



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(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 007 | | 2 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|---|---|
| Donor Room | Selection of Bags |
| FUNCTION | DISTRIBUTION |
| Choice of bag depending on component to be prepared | - Medical Officer-in-Charge of Donor Area for use of all technicians & phlebotomists - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCE

Introduction to Transfusion Medicine, Zarin Bharucha & D M Chouhan, 1st edition 1990, Pgs 116, 124

4. MATERIALS REQUIRED

Different types of blood bags in use

5. PROCEDURE

Select the bag as per the following chart:

| DONOR | | COMPONENTS | BAGS | |
|----------|---------------|-------------------------------------|---------------------|--------------------|
| Weight | Asprin intake | Required | Type | Qty. (ml) of Blood |
| >55 Kg | No | PC+FFP+PLT | Triple or Quadruple | 450ml |
| >55 Kg | Yes | PC+FFP PC+FVIID+CRYO | Double | 350/450ml |
| 45-55 Kg | No | PC+FFP PC+FVIID+CRYO PC-PLT | Double | 350ml |
| 45-55 Kg | Yes | PC+FFP PC+FVIID PC+FVIID+CRYO | Double | 350ml |

PC : Packed Cells FFP : Fresh Frozen Plasma PLT : Platelets FVIID : Factor VIII Deficient Plasma Cryo : Cryoprecipitate

- Check the bag visually
- In case of puncture or discolouration, do not use
- Check the expiry date of the bag
- Use single bag when;
 1. Components are not to be separated from that unit.
 2. When autologous blood is collected for patients e.g. elective surgery.
 3. Therapeutic phlebotomy is being performed on a patient.

6. DOCUMENTATION

Enter the following details on donor card and register:

- Type of bag
- Manufacturer's name
- Batch No.
- Expiry date

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 008 | | 3 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|---|--|
| Donor Room | Blood Collection |
| FUNCTION | DISTRIBUTION |
| Assessing suitability of donor for blood donation | - Medical Officer-in-Charge of Donor Area - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

The phlebotomist or doctor is responsible for blood collection from the donor after verifying the donor screening details, checking the unit number labels and preparing the phlebotomy site.

3. REFERENCES

Technical Manual of American Association of Blood Banks, 13th edition 1999
Pgs 98, 713-716

Introduction to Transfusion Medicine, Zarin Bharucha & D M Chouhan 1st edition 1990 Pg 99 - 100

4. MATERIALS REQUIRED

- Cotton/Gauze swabs
- Artery forceps
- 2% Xylocaine
- Disposable plastic syringes (2ml)
- Disposable needles (26 gauge)
- Pilot tubes: Plain and CPD

- Tourniquet
- Oxygen cylinder with accessories
- Rubber gloves
- First aid tray
- Tubing stripper
- Electronic tube sealer
- Needle destroyer
- Blood collecting bags
- Discard jar with 10% sodium hypochlorite
- Scissors
- Hi Tech (adhesive) tapes
- Blood bag mixer (Bio mixer)
- Comfortable donor couch or chair

5. PROCEDURE

- (a) Make the donor lie down with a pillow under the head or recline in a comfortable donor chair. Loosen tight garments.
- (b) Identify the donor by name. Enter the bag and segment numbers on the donor card/form.
- (c) Ask the donor if he/she is in a comfortable position. Give the donor a hand roller / squeezer to hold.
- (d) Select a bag for blood collection (SP 007)
- (e) Clean the venepuncture site (SP 006)
- (f) Set the biomixer for the required volume of blood (350/450ml) to be collected and place the bag on it.
- (g) Apply the tourniquet on donor arm.
- (h) Clamp the bleed line of the blood bag using plastic forceps to ensure that no air enters the tubing or bag once the needle cover is removed.
- (i) Keep the level of the needle facing upward and the shaft at an angle of 15° to the arm.
- (j) Once the needle is beneath the skin, release the clamp.
- (k) Insert the blood bag needle into the vein for about 1 to 1.5cms by a bold single prick to ensure smooth flow of blood and secure on the arm with adhesive strips.
- (l) Advise the donor to gently squeeze the hand roller to improve blood flow.
- (m) If the venepuncture is unsuccessful do not make further attempt in the same arm. Take the donor's permission for a second attempt. Use a new bag.
- (n) Once blood enters the bag tubing, press the bio mixer 'start' switch to allow the blood to flow into the bag. After the programmed volume of blood is collected, the bio mixer automatically clamps the tubing.
- (o) Clamp the bloodline at 2 sites and cut in the middle. Collect blood in the pilot tubes from the tubing so that blood flows directly into the tubes from the donor arm.

- (p) Release the tourniquet and remove the needle gently from the donor's vein pressing the phlebotomy site. Fasten a Velcro cuff around the donor's arm in a flexed position.
- (q) Seal the blood bag tubing with the tube sealer.
- (r) Burn the needle of the bag in the needle incinerator. Discard the tubing with the burnt needle in a container of sodium hypochlorite solution.

6. DOCUMENTATION

Make entries in the donor register/ computer.

Make an entry of the failed venepuncture, as double prick.

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 009 | | 2 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
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| LOCATION | SUBJECT |
|--------------------|--|
| Donor Room | Blood Collection |
| FUNCTION | DISTRIBUTION |
| Post donation care | - Medical Office- in-Charge of Donor Area - Master File |

1. SCOPE AND APPLICATION

The donor needs to be observed after blood collection, in order to attend to any adverse reactions in the immediate post-donation period.

2. RESPONSIBILITY

The medical officer in attendance attends to the donor.

3. REFERENCE

- Technical Manual of American Association of Blood Banks, 13th edition 1999 Pgs. 98-99
- Introduction to Transfusion Medicine - Zarin Bharucha & D.M. Chouhan 1st edition 1990 Pgs. 100-101

4. MATERIAL REQUIRED

- Sterile swabs
- Adhesive tape
- Thrombophob ointment
- Leaflet for post donation instructions

5. PROCEDURE

- To prevent adverse reactions like giddiness ask the donor not to get up from the chair/cot for 5 minutes even if he feels perfectly all right.
- Observe for another 10 minutes in the refreshment area whilst having coffee.
- Inspect the venepuncture site before the donor leaves the donor room. Apply an adhesive tape only after oozing stops. If there is persistent oozing at the

site of venepuncture, apply pressure with a dry, sterile cotton swab. If there is haematoma apply Thrombophob ointment gently over the area after 5 minutes. Inform the donor about the expected change in skin colour. If the pain persists, ask him/her to apply ice.

- d. Instruct the donor to drink adequate fluid in the day and avoid strenuous activities.

6. DOCUMENTATION

Give a leaflet of post donation instructions to the donor.

Record any adverse reaction on the donor card.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
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| SP 010 | | 3 | | |
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| LOCATION | SUBJECT |
|--|--|
| Donor Room | Blood Collection |
| FUNCTION | DISTRIBUTION |
| Management of adverse reactions in a donor | - Medical Officer-in-Charge of Donor Area - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

The medical officer in attendance is responsible for managing the adverse reaction in the donor.

3. REFERENCE

- Technical Manual of American Association of Blood Banks 13th edition 1999 Pgs. 99-100
- Introduction to Transfusion Medicine Z.S. Bharucha & D.M. Chouhan 1st edition 1990, Pgs. 101-102

4. MATERIALS REQUIRED

Following materials are required to attend to any emergency arising in the post donation period.

i. Oral medication

- Analgesic Tablets
- Calcium and Vitamin C Tablets
- Electrolyte replacement fluid

ii. Injection

- Epinephrine (Adrenaline)

- Atropine sulphate
- Pheniramine maleate
- Diazepam
- Glucocorticosteroid
- Glucose (Dextrose 25%)
- Furosemide
- Metoclopramide
- Prochlorperazine maleate
- Sodium bicarbonate
- Glucose saline (Sodium chloride and Dextrose 500 ml.)

iii. Antiseptics

- Savlon
- Mercurochrome
- Tincture benzoine
- Hydrogen peroxide

iv. Miscellaneous

- Bandages/Dressings
- Band-aids
- Anti-histaminic cream
- Heparin and Benzyl Nicotinate ointment.
- Smelling salt-Spirit of Ammonia
- Analgesic balm
- Tongue depressor
- Disposable syringes and needles 22 g
- Clinical Thermometer
- Oxygen cylinder
- Infusion set
- Paper bag

5. MANAGEMENT OF ADVERSE REACTIONS

1. Giddiness/Syncope (vasovagal syndrome):

Raise feet and lower head end.

Loosen tight clothing (belt, tie etc.)

Ensure adequate airway.

Check pulse and blood pressure.

Apply cold compresses to forehead and back.

Administer inhalation of spirit of ammonia if needed. The donor should respond by coughing which will elevate the blood pressure.

If there is bradycardia and hypotension-

- Administer inj. Atropine 1 ml IM, if bradycardia continues for more than 20 minutes.
- Administer IV normal saline or dextrose saline infusions if hypotension is prolonged.

2. Convulsions: Keep the head tilted to the side; prevent the tongue bite; keep the airway patent by inserting a tongue blade or gauze between the teeth.

3. **Vomiting:** Usually this provides relief. If the donor feels nauseous or if vomiting is severe, inject Stemetil. Usually subsides on its own.
4. **Tetany/muscularspasm/twitching:** These are usually due to hyperventilation in an apprehensive donor. Ask the donor to breath in a paper bag, which provides prompt relief. Do not give oxygen.
5. **Haematoma:** Release the tourniquet/pressure cuff immediately. Apply pressure on the venepuncture site and withdraw the needle from the vein. Raise the arm above the head for a few minutes. Apply Thrombophob ointment gently around the phlebotomy site after about 5 minutes. Advise the donor to apply ice if there is pain and inform about the expected change in skin colour.
6. **Eczematous reactions of the skin around venepuncture site:** Apply steroid ointment.
7. **Delayed syncope:** These may occur as late as 30 minutes to 1 hour after donation, usually after the donor has left the blood bank. Permanently defer any donor who gives history of such attacks more than twice.

6. DOCUMENTATION

- Enter details of adverse reactions and the management in the donor card/form or register.
- Keep a record of stocks of materials required, especially the expiry date of medicines.

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 011 | | 2 | | |
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| LOCATION | SUBJECT |
|--|--|
| Donor Room | Traceability of Blood Bags |
| FUNCTION | DISTRIBUTION |
| Method of accurately relating product to donor | - Medical Officer-in-Charge of Donor Area for all phlebotomists - Document Control Officer - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

It is the responsibility of the phlebotomist collecting the blood units to ensure proper labelling and recording of the requisite details, even if the donor area attendant affixes the labels.

3. MATERIAL REQUIRED

Sticker labels with pre printed serial number (10 Labels/Unit Number).

4. PROCEDURE

- Give each donor a unique number and once his blood is collected, identify by that number only.
- Do not write donor's name on his/her blood bag or sample tube. This maintains the donor's confidentiality.
- Affix pre printed number labels on the primary bag on both sides, on all the satellite bags in case of multiple bags and the three pilot tubes (2 plain and one with CPD anticoagulant).
- Verify the donor's identity by tallying with the name on the master registration card. Affix the unit number label, which is loosely attached to the bag now to the card.

- Cross check the numbers on the bag, pilot tubes and master registration card to ensure identity. Record the entry in the donor register using the same number.
- Transcribe this number on all records hence forth for storage, testing and distribution.
- Whilst issuing the unit, use the same number on issue record.

5. DOCUMENTATION

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

Model SOP on Component Separbation

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 012 | | 5 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
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| LOCATION | SUBJECT |
|---|---|
| Component Laboratory | Blood Component Separation |
| FUNCTION | DISTRIBUTION |
| Method for separation of blood components | - Supervisor-in-Charge of Component Laboratory - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. EQUIPMENT AND MATERIALS REQUIRED

1. Tube sealer
2. Laminar flow
3. Refrigerated centrifuge
4. Plasma expresser
5. Electronic weighing scale
6. Double pan weighing balance
7. Cryoprecipitate thawing bath
8. Double bags (350ml) or triple bags with SAGM solution (450ml)
9. Manuals of all equipment for reference regarding use and maintenance of each equipment

4. REFERENCE

- i. Technical Manual of American Association of Blood Banks 13th edition 1999
Pgs 26, 168-170, 172-173, 177, 716-717, 723-726
- ii. Introduction to Transfusion Medicine - Zarin Bharucha & D.M. Chouhan 1st edition 1990 Pg 124-125

5. PROCEDURE

Preparation of packed cells and FFP or FVIII deficient plasma using double bags:

1. Keep the units vertical on the laminar flow table for 30 to 45 minutes (Process all units within 6 hours of blood collection).
2. Keep the bags in the buckets and balance them. Keep the equally balanced buckets with bags diagonally opposite in the refrigerated centrifuge ensuring that the position of the bags in buckets is parallel to the direction of the spin.
3. After centrifugation, gently remove the bags from the bucket and place them on the expresser stand under the laminar flow. Break the integral seal of the tube connecting it to the satellite bag/s manually and express the supernatant plasma into the satellite bag. In case of double bag, leave 50-60ml of plasma back along with the red cells in the primary bag and this component is Packed Red Cells (PC).
4. Label the plasma in the satellite bag, as Fresh Frozen Plasma (FFP) if separated within 6 hours of collection and stored immediately below 30°C.
5. If plasma is separated after 6 hours of collection label as Factor VIII deficient plasma (FVIID).
6. Cut the segment of FFP and FVIID bags short.

Preparation of packed cells, platelet concentrates and FFP using triple bags with or without additive solution:

1. Process the blood collected within 6 hours.
2. Keep the bags erect on the laminar flow for 30-45 minutes.
3. Note the weight of the primary bag and record in the register.
4. Balance the bags in the buckets using dry rubber or unused bags.
5. Keep equally balanced buckets diagonally opposite each other in the refrigerated centrifuge.
6. Position the bags in buckets parallel to the direction of the spin. Centrifuge the bags at 3500 rpm* for 10 minutes at 4°C.
7. Keep the bag on the separator on the laminar flow. Break the seal of the tubing connecting to the satellite bag. And express the plasma into the satellite bag leaving 50-60 ml plasma along with the red cells. If the bag

- with additive solution is used, remove all plasma in satellite bag before clamping. Remove the clamp of the bag containing additive solution and let the additive solution slowly pass into the primary bag containing red cells.
8. Mix the contents thoroughly and seal the tubing and detach the bags.
 9. Keep the primary bag containing packed cells with additive solution in quarantine storage in the blood bank refrigerator kept in the component room.
 10. Label the bag and take it on the inventory after the testing is over.
 11. Spin the satellite bag containing platelet rich plasma (PRP) and connecting bag from which additive solution was emptied, at 22° C in refrigerated centrifuge at 500 rpm* for 10 minutes after balancing the buckets.
 12. Place the bag containing PRP on the expresser stand.
 13. Express the plasma into the empty bag leaving 50-60 ml plasma along with the platelets.
 14. Seal the tubing and cut the tubing of the plasma bag short (1") to avoid breakage during frozen storage.
 15. A small segment of tube containing platelets (about 8 cms long) is prepared after mixing of the bag contents as and when requested by quality control laboratory.
 16. Leave the platelet concentrates on the laminar flow for 30 minutes, keeping the label side down. Mix the contents of the bag manually before transferring the units to quarantine storage in the incubator at 22° C on the lower shelf.
 17. After the required test results are available place the platelet concentrates on the agitator in the upper shelf for use.
 18. Keep the plasma bag in the quarantine storage in the deep freezer kept in the component room and transfer to deep freezer in issue area when the tests are completed after labelling and entering in the inventory.

* Standardise the speed of the centrifuge as it depends on the type of bag, the amount of blood collected and centrifuge in use.

Preparation of Cryoprecipitate:

1. The basic material is platelet poor fresh frozen plasma. The plasma should be free of red cell. Use the plasma frozen at 80° C preferably within a day or two of freezing.
2. Keep the segment of the bags for potential cryo-preparation longer.
3. Fill the cryobath with double distilled water.
4. Maintain the temperature of water in continuous circular motion at 9° C.
5. Keep the frozen plasma bags in this cryobath. When the plasma is thawed, place the bags in centrifuge buckets and balance the buckets on weighing scale.
6. Keep the position of the bags in buckets parallel
7. Spin the buckets at 5000rpm for 15 minutes at 4° C .

8. Under laminar flow, connect empty transfer bag to the bag containing plasma and cryoprecipitate using sterile connecting device.
9. Place the plasma bag on expresser and separate plasma into the transfer bag leaving approximately 15-25 ml as cryoprecipitate suspension in the original bag.
10. Seal the tubing and separate the cryoprecipitate and the cryopoor plasma bags.
11. Weigh the cryo and plasma bags and record.
12. The plasma separated is F-VIII deficient plasma. Both the bags are kept in quarantine till the tests are completed.
13. Label, enter the inventory and place them in deep freezer in issue area after test results are available.

Washed Packed Red Cell

1. Undertake the washing procedure only after the compatibility test is over.
2. If a single bag is used for blood collection attach a transfer bag using sterile connecting device.
3. Balance the blood bag in the centrifuge bucket with another empty bucket.
4. Spin the bag at 3500 rpm for 10 minutes at 4° C.
5. Remove the supernatant plasma completely in a transfer bag using expresser under laminar flow.

Before washing the unit, red cell serology laboratory should perform the compatibility tests. The washing procedure is undertaken only after the proposed unit is found to be compatible with recipient.

6. The proposed blood unit is balanced in the centrifuge bucket with another empty bucket. The buckets are centrifuged as per programme.
7. The bag is removed and supernatant plasma is completely removed in a transfer bag using an expresser under laminar flow.
8. Connect the bag with a sterile 0.9% saline bag using a transfer set.
9. Record batch number and expiry dates of saline in use.
10. Introduce approximately 200 ml of saline into the packed cell bag and mix thoroughly and centrifuge again.
11. Transfer the supernatant saline with some plasma into a transfer bag using the expresser under laminar flow.
12. Disconnect the transfer bag, seal and discard.
13. Repeat the washing with saline twice more (total three times) exactly in the same manner as described above. In the end keep 25-30ml saline with the red cells in the bag.
14. Seal the final thrice washed red cell unit.
15. Weigh the bag and record details in the register.
16. Store the washed packed red cell unit at 1-6° C and use within 24 hours of washing.
17. Use this blood only for the patient for which requested. If not used discard after 24 hours with standard disposal protocol, after subjecting small sample for bacteriological examination.

6. DOCUMENTATION

- a. Enter following details in the Component Register
 - Date and time of separation.
 - Unit number.
 - Type of bag used, with batch number and manufacturer's name.
 - Weights of whole blood and different components.
 - Date of expiry of different components.
 - Type of centrifuge and speed used.
 - Blood group and serology code.
- b. Enter in stock register of red cells, FFP and platelets after the testing is completed and the units are labelled.
- c. Incident reporting: If there are any problems encountered during the component processing enter the incident report form and inform the supervisor / medical officer in charge.

Model SOP on Immunohaematology

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 013 | | 4 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
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| LOCATION | SUBJECT |
|---------------------------------------|---|
| Red Cell Serology Laboratory | ABO Blood Group |
| FUNCTION | DISTRIBUTION |
| Cell and serum testing by tube method | - Red Cell Serology Laboratory - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks, 13th Edition, 1999, pages 150-151, 270, 277-280, 378-379, 285-286, 650-651.
2. Introduction to Transfusion Medicine, Zarin Bharucha and D.M. Chouhanst, 1st edition, 1990. Pages 43-47.
3. Procedures in Blood Banking and Immunohaematology - H.M. Bhatia, 1977. Pages 13-15.

4. MATERIAL REQUIRED

Equipment:

- Refrigerator to store samples and reagents at 2-6°C.
- Table top centrifuge.
- Microscope.

Specimen:

- Clotted and anticoagulated blood samples of donors.
- Clotted blood sample of patients.
- Test red cells suspended in native serum/plasma or saline.

Reagents:

- Anti A, Anti-B, Anti-AB antisera.
- Group A, B and O pooled cells.
- 0.9% saline.
- Distilled water.

Glassware:

- Serum tubes.
- Micro tubes.
- Pasteur pipettes.
- Glass slides.

Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Wooden blocks to hold micro tubes.
- Aluminium racks to hold sample tubes.

5. PROCEDURE

Principle:

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

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

RBC Testing

1. Label tubes with donor/patient and test identification.
2. Prepare cell suspension for cells being tested (Refer SP 015)
3. Place two drops of anti-A, anti-B and anti-AB reagent in the appropriately labelled tubes.
4. Add to each tube one drop of a 2 - 5% cell suspension (in normal saline, serum or plasma) of the red cells to be tested.
5. Mix the contents of the tubes gently and incubate at room temperature for 15 minutes.
6. Centrifuge at 1000 rpm for 1 minute.

(Note: Always follow manufacturer's instructions from package insert)

Serum Testing

- Label tubes with donor-patient and test identification.
- Add 2 drops of test serum in all tubes in the corresponding column.
- Prepare cells for testing of A, B and O groups by pooling 3 samples of each group. (Refer SP 015)
- Add 1 drop of 2% pooled A red cell suspension in tube labelled A_c.
- Add 1 drop of 2% pooled B red cell suspension in tube labelled B_c.
- Add 1 drop of 2% pooled O red cell suspension in tube labelled O_c.
- Mix the contents of the tubes gently and incubate the test for minimum 15 minutes at room temperature.
- Centrifuge all tubes at 1000 rpm for 1 minute.
- Gently resuspend the red cell button & examine for agglutination.

RESULTS

- Depending on presence (+) or absence (-) of agglutination, the position of the tubes is changed or remains unaltered as shown below:
- Confirm the cell grouping results with those obtained in serum grouping and vice versa.

| TEST | INITIAL POSITION | TUBE POSITION AFTER RESULT | |
|----------------|------------------|----------------------------|-----------------|
| | | Agglutination + | Agglutination - |
| Anti - A | Row 1 | Row 3 | Row -1 |
| Anti - B | Row 2 | Row 4 | Row 2 |
| Anti - AB | Row 3 | Row 5 | Row 3 |
| A _C | Row 1 | Row 3 | Row 1 |
| B _C | Row 2 | Row 4 | Row 2 |
| O _C | Row 3 | Row 5 | Row 3 |

INTERPRETATION

1. Agglutination in any tube of RBC tests and agglutination or haemolysis in serum test constitutes a positive test result. The expected agglutination reaction for positive tests are 3⁺ to 4⁺.
2. A smooth suspension of RBCs after resuspension of RBC button is a negative test result. All negative results must be verified under microscope. Cells should be separate without any clumping.
3. The interpretation of ABO group is as follows:

| CELL TYPING | | | SERUM TYPING | | | INTERPRETATION OF ABO GROUP |
|-------------------|--------|---------|--------------|-----|----|-----------------------------|
| Anti-A | Anti-B | Anti-AB | AC | BC | OS | |
| C | - | C | - | C/L | - | AB |
| - | C | C | C/L | - | - | B |
| C | C | C | - | - | - | AB |
| - | - | - | + | + | - | O |
| C=Clumps, L=Lysis | | | | | | |

4. Resolve any discrepancies between cell and serum typing tests before the patient's or donor's ABO group is interpreted.

6. DOCUMENTATION

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

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 014 | | 3 | | |
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| LOCATION | SUBJECT |
|------------------------------|--|
| Red Cell Serology Laboratory | Rh D Typing |
| FUNCTION | DISTRIBUTION |
| Tube test for Rh testing | - Supervisor-in-Charge of Red Cell Serology Laboratory - Masterfile |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th Edition, 1999. Pages 150-151, 307-312, 657-658.
2. Introduction to Transfusion Medicine; Zarin Bharucha & D.M. Chouhan, 1st edition, 1990. Pages 47-48.
3. Procedures in Blood banking and Immunohaematology; H.M. Bhatia, 1977, Page 37.

4. MATERIAL REQUIRED

Equipment:

- Refrigerator to store samples and reagents at 2-6°C

- Table top centrifuge
- Microscope
- Incubator/dri bath

Specimen:

- Clotted or anti-coagulated blood samples of donors
- Clotted blood sample of patients
- Test red cells suspended in native serum/plasma or saline

Reagents:

- Anti D bicalonal
- Anti D monoclonal (IgM/IgG blend)
- 0.9% saline
- Distilled water

Glassware:

- Serum tubes
- Micro tubes
- Pasteur pipettes
- Glass slides

Miscellaneous:

- Rubber teats
- Disposal box
- 2 plastic beakers
- Wooden block to hold micro tubes
- Aluminium racks to hold serum tubes

5. PROCEDURE

Principle:

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

D Typing:

1. Label tubes with patient/unit and test identification.
2. Prepare cells for testing in accordance with the Preparation of Cell Suspension (SOP 015)
3. Add one drop of reagent anti-D to the test tube.
4. Using a pipette, add one drop of the cell suspension to each test tube.
5. Mix well (incubation temperature and time depends on manufacturer's instructions).

RESULTS:

1. Centrifuge all tubes at 1000 rpm for 1 minute (or as specified by manufacturer).
2. Gently resuspend the red cell button and examine for agglutination.
3. Grade and record test results.

Interpretation:

1. Agglutination of the red blood cells in the presence of reagent is a positive test result and indicates the presence of the D antigen.
2. A smooth suspension of RBCs after resuspension of RBC button is a negative test result. All negative results must be verified under microscope. Cells should appear separate without any agglutination.
3. The interpretation of Rh D type is as follows:

| CELL TYPING ANTI-D BICLONAL | CELL TYPING ANTI-D MONOCLONAL | INTERPRETATION OF Rh D TYPE |
|--------------------------------|----------------------------------|--------------------------------|
| V | V | Positive* |
| - | - | Negative* |
| V | - | ?* |
| - | V | ?* |
| V= Visible Clumps | | |

4. Proceed with weak D (Du) TYPING using indirect anti-globulin technique in case of **blood donor sample**.

* Hand over sample to Advanced Red Cell Serology Laboratory for further work-up.

N.B.:

- Invalid test results may be obtained with this reagent if the blood tested is from a person with autoantibodies or abnormal serum proteins. Concurrent testing for the ABO blood group serves as a routine simultaneous control. The simultaneous use of an Rh control is required only when the cells under test are found to be reactive with anti-A, anti-B and anti-D. If the use of an additional control is necessary, isotonic saline or 6% to 8% albumin in isotonic saline or a patient auto control may be used. If the control gives a positive result, a valid interpretation cannot be made.
- Cord red blood cells heavily sensitised with anti-D may demonstrate a false negative test result.

6. DOCUMENTATION

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

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| SP 015 | | 3 | | |
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| LOCATION | SUBJECT |
|---|---|
| Red Cell Serology Laboratory | Preparation of Red Cell Suspensions |
| FUNCTION | DISTRIBUTION |
| To prepare RBC suspension of appropriate concentration for a given test | - Superviso- in-Charge Red Cell Serology Laboratory for use by all technicians - Master File |

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCES

1. Technical Manual of American Association of Blood Bank, 13th Edition, 1999, Pages 150, 311
2. Introduction to Transfusion Medicine; Zarin Bharucha & D.M. Chouhan, 1st Edition, 1990. Page 262.

4. MATERIALS

- **Equipment:**

Calibrated centrifuge.

- **Reagents:**

0.9% saline.

- **Specimen:**
 - Clotted or anticoagulated blood specimen of donor.
 - Clotted or anticoagulated blood specimen of patient.
 - Donor unit segment.
- **Glassware:**
 - Pasteur pipettes.
 - Serum tubes.
- **Miscellaneous:**
 - Discard box.
 - 2 plastic beakers.
 - Rack to hold tubes.

5. PROCEDURE

Principle:

The ratio of serum to red cells may dramatically affect the sensitivity of agglutination tests. Consistent preparation of either 2 to 5% red cell suspension is critical to any agglutination test.

Pooled Cell Suspension:

1. Label tubes with A,B, and O groups.
2. Place 1 drop of red cells each from 3 of A group sample tubes or segment into the A labelled tube.
3. Place 1 drop of red cells each from 3 of B group sample tubes or segment into the A labelled tube
4. Place 1 drop of red cells each from 3 of O group sample tubes or segment into the A labelled tube
5. Fill the tube $\frac{3}{4}$ full with 0.9% saline to resuspend the cells.
6. Centrifuge the tubes for at least 2 to 3 minutes on high speed. Decant the supernatant fluid.
7. Remove any debris or fibrin with the pipette. Add enough saline to produce a cherry red colour comparable to that of the reagent red cell suspension.
8. If the colour is too dark, add additional isotonic saline to the tube until the suspension colour is right.
9. If the colour is too light, repeat steps 6 and 7.
10. Test the pooled cells prepared using the antisera (anti-A, B, AB and D) in use.

Donor/Patients' sample

Proceed to use the same procedure to prepare cell suspension of particular donor or patient sample for grouping and crossmatching.

LIMITATIONS:

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

6. DOCUMENTATION

- Enter the donor unit numbers from which pooled cells are prepared in the donor register.
- Record the results of testing with the antisera in use.
- Enter the manufacturer's name and batch number of the antisera.

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
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| SP 016 | | 4 | | |
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| LOCATION | SUBJECT |
|--|---|
| Red Cell Serology Laboratory | Antibody Screen |
| FUNCTION | DISTRIBUTION |
| Detection of Unexpected Blood group Antibodies | - Supervisor in charge of Red Cell Serology Laboratory - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th Edition, 1999. Pages, 256-262, 383-384, 392-393, 379, 668-671, 676.
2. Procedures in Blood Banking & Immunohaematology H.M. Bhatia, 1977, Pages 72-75
3. Introduction to Transfusion Medicine Zarin Bharucha & D.M. Chouhan, 1st Edition 1990. Pages 51, 58-60, 69-71, 85.

4. MATERIAL REQUIRED

4.1 Equipment:

- Refrigerator to store samples & reagents at 2-6°C.
- Deep Freezer to store enzyme papine cystein in frozen state.
- Tabletop centrifuge.
- Automated cell washer (for patient pre-transfusion and prenatal testing).

- Microscope.
- Dri bath/ Incubator

4.2 Specimen:

Clotted blood sample of donors/patients.

4.3 Reagents:

- Group O pooled cells/Antibody-screening reagent red blood cells (two or three cells).
- Papain cystein.
- 22% Bovine albumin.
- Antihuman globulin reagent(anti-IgG+anti-C3d)
- IgG sensitised control cells.
- 0.9% saline
- Distilled water

4.4 Glassware:

- Serum tubes.
- Coombs' tubes(for patient pre-transfusion & prenatal testing).
- Micro tubes.
- Pasteur pipettes.
- Glass slides.

4.5 Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Wooden blocks to hold micro tubes.
- Aluminium racks to hold serum and coombs' tubes.

5. PROCEDURE

5.1 Principle:

The antibody screen test is used in the detection of unexpected blood group antibodies. In this test, pooled O cells or the antibody-screening reagent red blood cells are combined with serum under investigation. The addition of a potentiating medium enzyme / albumin helps to promote the interaction of red cells and antibodies allowing antibody/antigen reactions to occur. Positive reactions (haemolysis or agglutination) in any tests indicate the presence of allo antibody or auto antibody in the serum.

5.2 Antibody Screen:

1. Label tubes with donor/patient and test identification.
2. Add two drops of test serum to each tube.

3. Add 1 drop of papain cystein to all tubes labelled 'enzyme' (if enzyme method is being followed).*
4. To each of the tubes labelled 'saline' or 'enzyme/albumin', add 1 drop of 2% pooled O red cell suspension (or 2% suspension of the antibody-screening reagent red cells).
5. Add 1 drop of 22% abovine albumin to tubes labelled 'albumin' (if albumin method is being followed).*
6. Add 1 drop of 5% pooled O red cell suspension (or 5% suspension of antibody-screening reagent red cells) to tubes labelled 'IAT', followed by 2 drops of 22% bovine albumin.
7. Mix the contents of the tubes gently and incubate for minimum 15 minutes.

| TEST | INCUBATION TEMPERATURE | IDEAL INCUBATION TIME |
|--|------------------------|-----------------------|
| Saline | Room Temperature | 1 hour |
| Enzyme | 37°C | 45 minutes |
| Albumin | 37°C | 45 minutes |
| IAT | 37°C | 1 hour |
| Follow manufacturer's directions when using commercial reagents. | | |

- * Either enzyme or albumin method may be followed for detection of incomplete antibodies.

5.1 Results:

1. Centrifuge saline, enzyme and albumin tests at 1000rpm for 1 minute.
2. Examine for haemolysis.
3. Gently resuspend the red cell button and examine for agglutination.
4. Examine all visually negative tests microscopically.
5. Grade and record test results immediately.
6. Proceed to perform antiglobulin phase of the indirect antiglobulin test on tubes labelled 'IAT'.
7. Wash the cells 3 times with saline. Decant completely after last wash. (washing can be done manually or using automated cell washer).
8. Add 2 drops antihuman globulin reagent to the dry cell button.
9. Mix well and centrifuge at 1000 rpm for 1 minute.
10. Read and record results.
11. Add drop IgG sensitised cells to all negative results. This shows a positive agglutination.

5.2 Interpretation:

1. Hemolysis or agglutination in any test may indicate the presence of an unexpected antibody.
2. The absence of agglutination and hemolysis in all tests is a negative test result.
3. After addition of IgG-sensitized cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.

4. If IgG-sensitised cells added to confirm the activity of the anti-IgG show only weak or no agglutination after centrifugation, the test is invalid and must be repeated.

5.5 Limitations:

If tests with all reagent red cells are reactive, the possibility of spontaneous agglutination should be considered. A control of cells washed three to four times added to two drops of saline must be non-reactive.

6. DOCUMENTATION

Results of donor unit antibody screen are entered in the donor grouping register and computer.

Results of patients antibody screen are entered in the patient grouping register, blood group requisition form, serial case number register and computer.

All records are initialled by the technician who has performed the test and by the technician who has checked the results.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| SP 017 | | 3 | | |
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| LOCATION | SUBJECT |
|------------------------------|---|
| Red Cell Serology Laboratory | Detection of incompatibility between patient and donor |
| FUNCTION | DISTRIBUTION |
| Saline/ Enzyme Cross-match | -Supervisor in charge of Red Cell Serology Laboratory -Master File |

1. SCOPE & APPLICATION

This procedure is applied for compatibility testing of all patients requiring transfusion.

2. RESPONSIBILITY

It is the responsibility of the technician in the red cell serology laboratory to perform cross match and document the results. If any unexpected antibody is detected, the advanced Red Cell Serological should be informed.

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th Edition, 1999. Pages 380-381, 383-384, 256-257, 392-393, 667-668
2. Introduction to Transfusion Medicine Zarin Bharucha & D.M. Chouhan, 1st Edition, 1990. Pages 82-85, 58-59.

4. MATERIAL REQUIRED

4.1 Equipment:

- Refrigerator to store samples & reagents at 2-6°C.
- Deep Freezer to store enzyme papine cystein in frozen state.
- Tabletop centrifuge.
- Automated cell washer (for patient pre-transfusion and prenatal testing).
- Microscope.
- Dri bath.

4.2 Specimen:

Clotted blood sample of donors/patients.

4.3 Reagents:

- Group O pooled cells/Antibody-screening reagent red blood cells (two or three cells).
- Papain cystein.
- 22% Bovine albumin.
- Antihuman globulin reagent(anti-IgG+anti-C3d)
- IgG sensitised control cells.
- 0.9% saline.
- Distilled water

4.4 Glassware:

- Serum tubes.
- Coombs' tubes(for patient pre-transfusion & prenatal testing).
- Micro tubes.
- Pasteur pipettes.
- Glass slides.

4.5 Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Wooden blocks to hold micro tubes.
- Aluminium racks to hold serum and coombs' tubes.

5. PROCEDURE

5.1 Principle:

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

5.2 Cross-match:

1. Label 3 tubes with patient/donor test identification.
2. Add 2 drops of patient's serum to each tube.
3. Prepare 5% cell suspension in 0.9% saline from each donor unit segment. (Sp015).
4. Add 1 drop 5% donor red cell suspension to the tubes containing patient's serum.
5. Add 1 drop pap-cysteine to tubes labelled enzyme.
6. Add 1 drop of 22% albumin to the tubes labelled albumin.
7. Mix the contents of tubes gently and incubate for minimum 15 minutes. (Saline tubes at room temperature and Enzyme / Album at 37°C).
8. Centrifuge the tubes at 1000 rpm for 1 minute.

9. Examine for hemolysis.
10. Gently resuspend red cell button and examine for agglutination.
11. Examine all visually negative reactions under microscope.
12. Grade and record test results immediately.
13. Let a second technician check the results.

5.3 Interpretation:

1. Hemolysis or agglutination in any test indicates incompatibility.
2. Absence of hemolysis / agglutination in all tests indicates compatibility.

5.4 Limitations:

Th saline / enzyme cross match will not:

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

6. DOCUMENTATION

Enter results in cross-match register and compatibility report form.

All records are initialled by technician who performed the test and the technician who has checked the results.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 002 | | 3 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
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| LOCATION | SUBJECT |
|---|---|
| Red Cell Serology Laboratory | Antiglobulin Cross-match |
| FUNCTION | DISTRIBUTION |
| Detection of incompatibilities caused by warm complete antibodies | - Supervisor in charge of Red Cell Serology Laboratory - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

It is the responsibility of the technician in the cross match facility of the red cell serology laboratory to perform the anti-globulin cross match using quality controlled reagents and proper cell concentrations. One technician performs the tests and another checks it. If any unexpected blood group antibody is detected, inform the staff of Advanced Red Cell Serology to carry out further investigations.

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th Edition, 1999. Pages 380-381, 383-384, 258-262, 668-671.
2. Procedures in Blood Banking and Immunohaematology; H.M. Bhatia, 1977. Pages 72-75.
3. Introduction to Transfusion Medicine Zarin Bharucha & D.M. Chouhan, 1st Edition, 1990. Pages 69-71, 74-76, 85.

4. MATERIAL REQUIRED

4.1 Equipment:

- Refrigerator to store samples & reagents at 2- 6°C.
- Table top centrifuge.
- Automated Cell Washer.

- Microscope.
- Dri bath.

4.2 Specimen:

- Clotted blood sample of patient.
- Segment from donor unit.
- Donor red cells suspended in saline.

4.3 Reagents:

- 22% bovine albumin.
- Antihuman globulin reagent(anti-IgG+anti-C3d).
- IgG sensitised control cells.
- 0.9% Saline.
- Distilled water.

4.4 Glassware:

- Serum tubes.
- Coombs' tubes.
- Pasteur pipettes.
- Glass slides.

4.5 Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Aluminium racks to hold serum and coombs' tubes.

5. PROCEDURE

5.1 Principle:

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

5.2 Anti-Globulin Cross-Match:

1. Label tube with patient/unit and test identification.
2. Add two drops of patient serum to each tube.
3. Prepare a 5% cell suspension in saline from each donor unit segment. (Sp015).
4. Add 1 drop of donor's 5% red cell suspension to the tube.
5. Add 2 drops of 22% bovine albumin and mix well.
6. Incubate at 37°C for minimum 15 minutes. (Follow manufacturer's directions when using commercial reagents).
7. Wash the cells a minimum of 3 times with saline. Decant completely after last

wash. (washing can be done manually or in automated cell washer).

8. Add two drops of antihuman globulin reagent to the dry cell button.
9. Mix well and centrifuge at 1000 rpm for 1 minute.
10. Resuspend and read for agglutination. Grade and record test results immediately.
11. To all negative antiglobulin tests add 1 drop of IgG-sensitised control cells. Centrifuge, resuspend and read for agglutination. Grade and record test results. After the addition of IgG-sensitised control cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.

5.3 Interpretation:

1. Hemolysis or agglutination indicates the presence of a serologically incompatible cross-match. This result is interpreted as **Incombatile**.
2. Absence of agglutination and hemolysis is a negative test result and indicates a serologically compatible crossmatch. This result is interpreted as **Combatile**.

If the IgG-sensitised control cells added to confirm the activity of the polyspecific reagent show only weak or no agglutination the test is invalid and must be repeated.

5.4 Limitations:

The anti-globulin cross- match will not:

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

6. DOCUMENTATION

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

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 028 | | 5 | | |
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| LOCATION | SUBJECT |
|---|--|
| Advanced Red Cell Serology | Investigation of Transfusion Reaction |
| FUNCTION | DISTRIBUTION |
| To identify cause of transfusion reaction | <ul style="list-style-type: none">- Supervisor in charge of Advanced Red Cell Serology Laboratory- Supervisor in charge of Red Cell Serology Laboratory- Master File |

1. SCOPE & APPLICATION

This Standard Operating Procedure (SOP provides the protocol to be followed to identify the cause of an adverse transfusion reaction and prevent its reoccurrence).

2. RESPONSIBILITY

It is responsibility of the technician in the Red Cell Serology Laboratory to accept the blood/component implicated in the transfusion reaction which is returned from the ward/OT. It is the duty of the same technician to ensure that there is documented evidence of the nature of reaction either on the transfusion request form or on a separate letter addressed to blood bank, along with the post-transfusion blood sample (both EDTA and clotted) and urine specimen, if necessary. The direct antiglobulin test (DAT) should be performed on the post-transfusion EDTA sample immediately on receipt before refrigeration. The unit and samples should be preserved properly and handed over to the advanced red cell serology technician who is responsible for detail investigation.

3. REFERENCES

1. Introduction to Transfusion Medicine: Zarin Bharucha and D.M. Chouhan 1st Edition, 1990. Pages 216-219.

4. MATERIALS REQUIRED

4.1 Equipment:

- Refrigerator to store samples and reagents at 2- 6°C.

- Deep Freezer to store enzyme papain-cystein in frozen state.
- Table Top Centrifuge.
- Automated Cell washer.
- Microscope.
- Dri bath / Incubator.

4.2 Specimen:

- Blood/component bag returned room ward/OT.
- Patient's pre-transfusion blood sample(clotted).
- Patient's post-transfusion blood sample (EDTA and clotted).
- Patient's post-transfusion urine sample.

4.3 Reagents:

- ANTI-a, Anti-B, Anti-AB Antisera.
- Group A,B &O pooled cells.
- Papain-cystein/22% Bovine albumin.
- Antihuman globulin reagent(anti-IgG anti-C3d).
- IgG Sensitised Control Cells.
- 0.9% Saline.
- Distilled water.
- 30g/l sulfosalicylic acid solution.
- Ammonium Sulphate $\{NH_4(so_4)_2\}$.

4.4Glassware:

- Serum tubes.
- Coombs' tubes(for patient grouping only).
- Micro tubes.
- Pasteur pipettes.
- Glass slides.
- Small funnel.
- 20ml test tubes.
- 5ml pipette.

4.5 Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Wooden block to hold micro tubes.
- Aluminium racks to hold serum and coombs' tubes.
- Whatmen No.1 filter paper.
- 5ml plastic vial with screw cap.

5. PROCEDURE

5.1 Principle:

Red Cell Serological tests are based on the principle of agglutination and help to identify haemolytic transfusion reactions caused either by ABO incompatible transfusion or irregular red cell antibodies in patient's blood.

Leuco-agglutinations, if present are detected by agglutination of random donor leucocytes in cases of febrile transfusion reaction. Serum bilirubin total and indirect are raised in case of haemolysis. The sulfosalicylic acid test helps to differentiate between haemoglobin and non-protein pigment, probably porphyrin in the urine. The ammonium sulphate precipitation test is based on the fact that haemoglobin and myoglobin are precipitated in urine at different degrees of ammonium sulphate saturation.

5.2 Serological Tests

- 5.2.1 Perform a direct antiglobulin test (DAT) on post-transfusion EDTA sample before refrigeration immediately on receipt. If test is positive, perform DAT on pre-transfusion sample to verify whether sensitisation is due to transfusion or it pre-existed.
- 5.2.2 Repeat grouping and antibody screening of patient's pre-transfusion sample.
- 5.2.3 Repeat grouping and antibody screening of patient's post-transfusion sample.
- 5.2.4 Repeat grouping and antibody screening of donor sample.
- 5.2.5 Repeat grouping of unit from bag. In case of packed cell unit, do only cell grouping. In case of FFP, do only serum grouping.
- 5.2.6 Repeat crossmatching of donor with patient's pre and post transfusion samples using saline / enzyme / IAT. Use donor cells from blood bag and not the pilot tube.

5.3 Leucocyte Antibody Test:

In case of febrile transfusion reaction and hypotension, look for leukocyte antibodies.

5.4 Biochemical Tests:

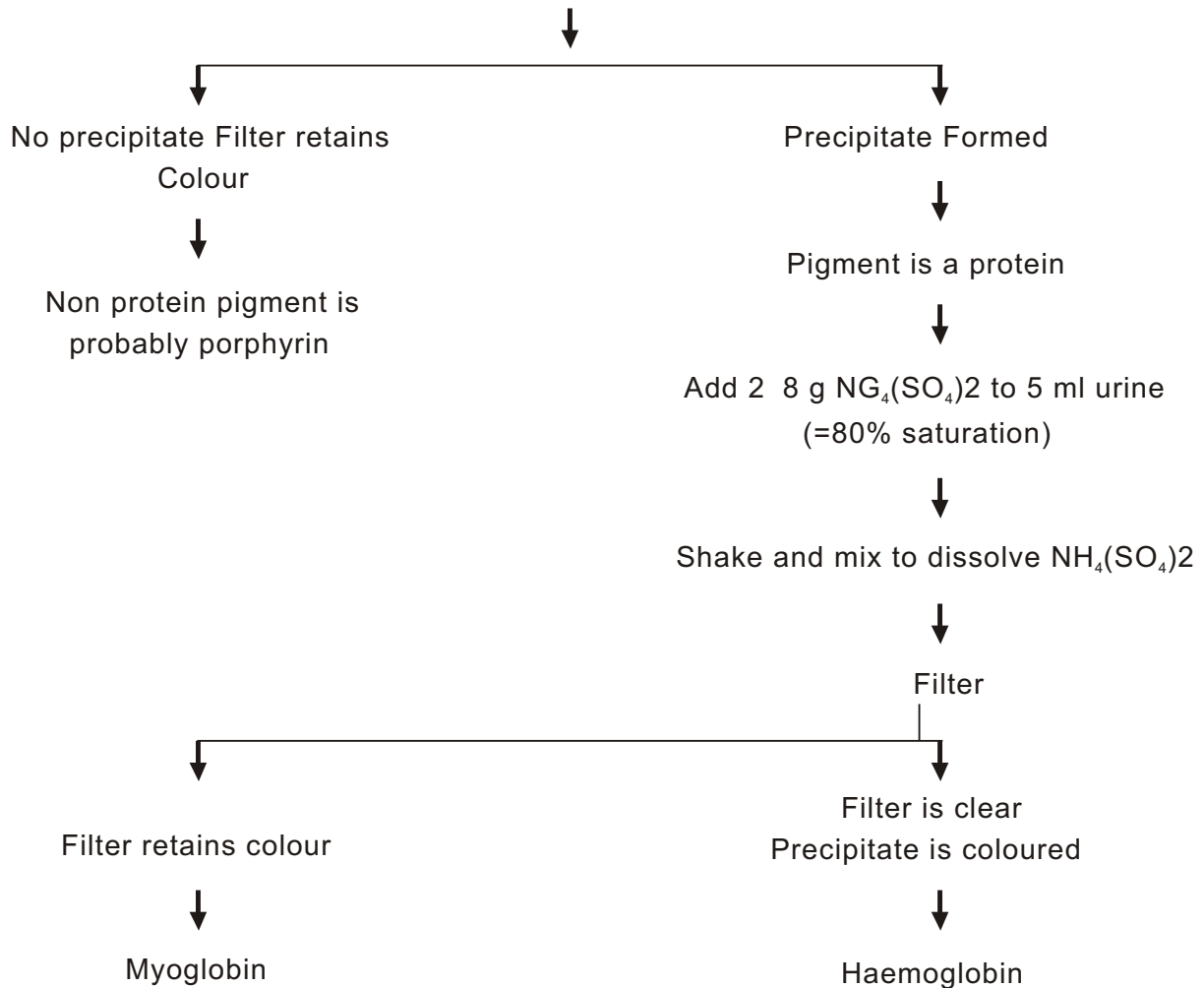
- 5.4.1 Note colour of plasma. Plasma is pink, if haemoglobin is present and icteric if bilirubin is present.
- 5.4.2 Separate the patient's pre and post transfusion serum and send to biochemistry department in a 5 ml screw cap plastic vial bearing the date, patient and test identification for estimation of serum bilirubin total, direct and indirect and estimation of plasma hemoglobin.
- 5.4.3 Send the biochemistry request form with proper entries along with the sample.

5.4.4 Collect the report from biochemistry lab.

5.4.5 Tests on post-transfusion urine sample.

Red colour indicates haematuria or haemaglobinuria.

Add 3ml of 30g/l solution of sulfosalicylic acid to 1 ml urine. Mix well and filter.



5.5 Microbiology:

1. Send the donor unit for smear and culture (at 37°C, room temperature and 4°C) to bacteriology department.
2. Make proper entries in the bacteriology despatch book and bacteriology request form and send along with the unit.
3. Collect the report from bacteriology lab.
4. If donor unit reveals bacteremia, then request the attending doctor to get the patient's blood culture done and report the findings to the blood bank officer.

5.6 Interpretation:

1. Any red cell incompatibility found during the investigation explains a haemolytic transfusion reaction.

2. The DAT will be positive and a mixed field reaction will be seen if in vivo sensitisation of transfused red cell has occurred.
3. The DAT may be negative even in cases of haemolytic transfusion reaction, if the cell destruction is severe.
4. If any antibody is detected in patient's serum, the donor cells should be positive for the corresponding antigen.
5. Detection of leucoagglutination explains a febrile reaction or hypotension.
6. Serum bilirubin total and indirect are raised in case of haemolysis.
7. Haemoglobinemic and haemoglobinuric are highly suggestive of red cell destruction, but are not necessarily caused by antigen-antibody reaction, unless confirmed.

5.7 Limitations:

The non serologic possibilities of haemoglobinemia and haemoglobinuria are:-

1. Hemolysis of blood before transfusion.
2. Poor technique of collecting post transfusion sample.
3. Myoglobinuria following major surgery.
4. Infusion of distilled water during prostatectomy.
5. Hemolysis due to artificial valve.
6. Patient's clinical condition; Autoimmune haemolytic anemia or paroxysmal nocturnal hemoglobinuria.
7. Use of glucose or dextrose through the same line before starting blood.
8. Addition of certain drugs to blood such as ethacrynic acid, hydrocortisone or diphenyl hydantoin.

6. DOCUMENTATION

1. Enter the transfusion reaction in blood issue register, showing date and time of return of the unit and nature of reaction.
2. Enter the DAT/IAT results in the Antiglobulin test book in the red cell serology laboratory.
3. Document the results of the entire investigations in the Transfusion Reaction work up form.
4. Keep record in the Transfusion Reaction Record Register in advanced red cell serology laboratory.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 030 | | 4 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|--|--|
| Red Cell Serology Laboratory | To ensure reliability and reproductivity of blood group results |
| FUNCTION | DISTRIBUTION |
| Daily Quality Control of ABO & Rh Blood Group reagents | - Supervisor in charge Red Cell Serology Laboratory - Master File |

1. SCOPE & APPLICATION

This Standard Operating Procedure (SOP) provides the daily checks on blood group reagents to ensure reliability and reproducibility of blood group results.

2. RESPONSIBILITY

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

Any fault in the reagents should be immediately reported to the Quality Assurance Manager.

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th edition 1999, Page 22.
2. Introduction to Transfusion Medicine Zarin Bharucha and D.M. Chouhan; 1st Edition, 1990. Pages 225-226.

4. MATERIALS REQUIRED

4.1 Equipment:

- Refrigerator to store samples and reagents at 2-6°C.
- Table top Centrifuge.
- Automated Cell Washer.
- Microscope.

4.2 Reagents:

- Anti-A, Anti-B, Anti-AB, Anti D (Monoclonal and Bioclone) Antisera.
- Clotted or anticoagulated blood samples of random blood donors.
- Group A, B and O pooled Cells.
- 0.9% saline.

4.3 Glassware:

- Serum tubes.
- Micro tubes.
- Pasteur pipettes.
- Glass slides.

4.4 Miscellaneous:

- Rubber teats.
- Disposal box.
- 2 plastic beakers.
- Wooden block.
- Aluminium racks.

5. PROCEDURE

5.1 Principle:

Test for reactivity and specificity is based on the principle of agglutination of antigen positive red cells in the presence of antibody directed towards the antigen.

5.2 Quality Control Checks:

5.2.1 Visual Inspection:

Examine each vial carefully for precipitate, gel formation, turbidity or change in colour.

5.2.2 Reactivity and Specificity:

1. Add one drop of 3-5% suspension of the appropriate red cells to the one-drop of antiserum in a microtube.
2. Mix well and incubate (as per manufacturer's instruction).

3. Note the reactions as under:

| | RED CELLS FOR TESTING | |
|-------------------|--|--|
| | POSITIVE REACTORS | NEGATIVE REACTORS |
| Anti-A | Pooled A Cells | Pooled B, Pooled O Cells |
| Anti-B | Pooled B Cells | Pooled A, Pooled O Cells |
| Anti-AB | Pooled A, Pooled B Cells | Pooled O Cells |
| Anti-D Bioclone | RhD- positive cells (any ABO group) | RhD- negative cells (any ABO group) |
| Anti-D Monoclonal | RhD- positive (any ABO group) | RhD- negative (any ABO group) |

5.3 Results:

5.3.1 Visual Inspection:

Record presence or absence of precipitate, gel formation, turbidity or colour change.

5.3.2 Reactivity and Specificity:

- Centrifuge the Tubes (as per manufacturer's instruction).
- Resuspend the red cell button and examine for agglutination / haemolysis.
- Grade and record test results.

5.4 Interpretation:

5.4.1 Visual Inspection:

- The presence of precipitate, gel formation, turbidity, colour change indicates that the reagent is contaminated and should not be used.
- The absence of all the above indicates that the reagent is 'clear' and suitable for use.

5.4.2 Reactivity and Specificity:

- Agglutination of specific red cells is a positive reaction and indicates the reactivity of the corresponding antibody in the reagent. The expected agglutination reaction for positive test is +3 to +4.
- The absence of agglutination / haemolysis is considered to be a negative reaction and indicates the absence of the corresponding antibody specificity in the reagent.
- Clear cut negative reactions with the negative reactors rules out the presence of irregular agglutinins and haemolysis in the reagent.

6. DOCUMENTATION

Enter the results in the Blood Group Register in the Red Cell Serology Laboratory. Enter identification number of the individual donor cells used for pooling and the reaction strengths. Sign the results as the individual preparing the pooled cells and testing the reagent.

7. END OF DOCUMENT

***Model SOPs on
Transfusion
Transmissible
Infections***

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 019 | | 3 | | |
| Version | Review Period | No. of Copies | Approved by | Date |
| 1 | Biennial | | | |

| LOCATION | SUBJECT |
|-------------|---|
| TTI Testing | Transfusion Transmitted Infections |
| FUNCTION | DISTRIBUTION |
| VDRL Test | - Supervisor in charge of TTI Testing Laboratory - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCE

Kit Package insert.

4. PROCEDURE

4.1 Principle:

- Venedex is an antigenic cardiolipin based emulsion for detecting syphilis regains (antibodies) in serum, plasma and spinal fluid.
- Venedex emulsion contains cardiolipin, lecithin and cholesterol as its active components which produces a flocculation reaction with serum or plasma that contain syphilis antibodies(regains).

Reagent Storage:

Reagent is stable at 2-8°C. Bring to room temperature before use and gently stir the reagent.

Method:

1. Samples do not need in activation.
2. Centrifuge the samples to be tested.
3. Take a VDRL slide i.e. slide with twelve concave depressions, thoroughly clean and dry it.
4. Arrange samples to be tested in a tube rack and label them serially.
5. Using a pipette transfer 0.05ml of serum or plasma of the 1st sample on the concave depression.
6. Discard the tip.
7. Attach a new tip to the pipette and deliver 0.05ml of the 2nd sample.
8. Repeat this step for all the samples.
9. Note the position of the samples added.
10. Lastly add the negative and positive controls.
11. Mix the Venedex reagent and add one drop to all the test samples, negative and positive controls contained in a VDRL slide.
12. Rotate the VDRL slide at 180 rpm for four minutes.
13. Examine macroscopically and microscopically for flocculation.
14. Repeat reactive and doubtful results again alongwith controls.

6. INTERPRETATION

Test results are reported by comparing it with positive control and negative control results.

- **REACTIVE:** Presence of flocculation indicates the presence of anti-lipoidal antibodies in test samples. Strength of flocculation depends upon the degree of positivity of the test samples.
- **NON-REACTIVE:** Absence of flocculation indicates the absence of antilipoidal antibodies in test samples. Strength of flocculation depends upon the degree of positivity of the test samples.

7. DOCUMENTATION

The details of the VDRL test done each day is written in the VDRL register. The following entries are made:

- The date on which the test is run.
- The name of the kit used.
- Lot number and expiry date of the kit.
- Initials of the technologist who performed it.

The units tested are recorded in the register as per the arrangement in the test tube rack. The controls used are also recorded.

“R” (Reactive) is written across the reactive unit in red.

“NR” (Non Reactive) is written across the non-reactive units.

Results of controls in use are also recorded.

I.P.C.:Reactive (Internal Kit Positive Control).
I.N.C.:Non Reactive (Internal Kit Negative Control).
E.P.C.1:Reactive (Lab. External Strong Positive Control).
E.P.C. 2:Reactive(Lab. External Weak Positive Control).
E.N.C.Non Reactive (Lab. External Negative Control).

The record is then transferred to donor grouping register.

8. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
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| SP 020 | | 3 | | |
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| LOCATION | SUBJECT |
|--|---|
| TTI Testing Laboratory | HBsAG Testing |
| FUNCTION | DISTRIBUTION |
| Samples tested for Hepatitis B Surface Antigen by ELISA method | - Supervisor in charge of TTI Testing Laboratory - Master File |

1. SCOPE & APPLICATION

HBsAg is a mandatory test for blood unit screening before it is transfused. This is carried out on all donor units' samples.

2. RESPONSIBILITY

It is the responsibility of technician from TTI Testing lab to carry out the test and report as required.

3. REFERENCE

- Kit Package inserts.
- Technical Manual of American Association of Blood Banks 13th edition 1999 Pgs 152-153

4. MATERIALS REQUIRED

- Elisa Reader
- Elisa Washer
- Microshaker
- Incubator
- Micropipettes and disposable tips
- Timer
- Disposable gloves
- Disposal container with Na Hypochlorite
- Absorbant tissue
- Distilled water
- 1 mol / litre Sulphuric acid
- Kit

5. PROCEDURE

5.1 Principle:

In the monoclonal EIA procedures microplate wells are coated with monoclonal antibody to Hepatitis B Surface Antigen (Anti HBs) are incubated with serum or plasma and Anti-HBs peroxidase (Horse radish) conjugate in one step assay. During the incubation period HBsAg if present is bound to the conjugate (Anti-HBs-HRPO). Unbound material is aspirated and washed away. On the addition of substrate colour develops in proportion to the amount of HBsAg which is bound. The enzyme reaction is stopped by the addition of stopping solution.

5.2 Method:

1. Carry out the test as per manufacturer's instructions given in the package insert.
2. Remove reagents from the fridge 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.
3. Bring reagents and samples to room temperature before testing.
4. Arrange all donor unit test tube samples, apheresis samples, serially in ascending order in a test tube rack. Add required number of internal kit controls and external lab controls.
5. Discard all disposable tips into hypochlorite solution.
6. Place the tray in front of the test tube rack.
 - Dispense test sample 100 μ l volume using an auto pipette and fresh disposable tip for every sample.
 - Add kit internal positive control.
 - Add kit internal negative control.
 - Add Lab. External negative control.
 - Add Lab. External strong positive control.
 - Add Lab. External weak positive control.
 - Agitate using microshaker speed 900 rpm for 15 seconds
 - Incubate at 37°C for 90 minutes.
 - Wash and soak each well four times with PO4 buffer. Check buffer before use. If salt crystals have formed, resolubilise by warming at 37°C until crystals dissolve.
 - Pipette 100 μ l substrate in each well. Do not mix or agitate discard any unused substrate.
 - Incubate at 37°C for 30 minutes.
 - Stop reaction by adding 100 μ l 1 mol/L Sulphuric Acid to each well.
 - Ensure thorough mixing by tapping side of plate
 - Read the plates within 15 minutes
 - Blank the reader or air and read the absorbance in each well at 450 \pm 5nm.

5.3 Validation:

If the run fails to meet criteria as per package insert consider the test is invalid and repeat the whole test again. Examine absorbance values of the controls before the sample results can be interpreted.

Check the validity of the blank (if used) Negative and positive control absorbance value as per package insert of the kit.

Cut off O.D. is automatically calculated.

5.4 Interpretation:

Check the printout carefully for absorbance value:

- (i) The samples below the cut off are considered non-reactive.
- (ii) Equal to cut off are considered initial reactive
- (iii) Above cut off are considered initial reactive
- (iv) Those with asterik are in grey zone. Repeat all samples showing grey zone result.

6. DOCUMENTATION

6.1

Paste the printout in the HBsAg Register and also record the following details:

- (a) The date on which the test is run.
- (b) The name of the kit used.
- (c) Lot No. and expiry date of the kit.
- (d) Initials of the technologist who performed the test.
- (e) Initials of the Supervisor who verifies the result.
- (f) Reactive units are marked in red.

6.2

Transfer the results to donor grouping register.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
|---------|----------------|---------------|-------------|---------------|
| SP 021 | | 3 | | |
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| LOCATION | SUBJECT |
|--|---|
| TTI Testing Laboratory | Anti HIV Testing |
| FUNCTION | DISTRIBUTION |
| Sample tested for Anti HIV antibodies by EIA | - Supervisor in charge of TTI Testing Laboratory - Master File |

1. SCOPE & APPLICATION

Anti HIV antibodies testing is carried out on all bag samples before these are released for transfusion. Pre-donation samples of pheresis donors are also tested.

2. RESPONSIBILITY

It is the responsibility of technician from TTI Testing lab; to carry out the test and report as required.

3. REFERENCE

- Kit package insert.
- Technical Manual of American Association of Blood Banks 13th Edition, 1999. Pages 152-153.

4. MATERIALS REQUIRED

- Reagent kit
- Micropipettes and disposable pipette tips
- Timer
- EIA reader
- EIA Washer
- Incubator 37°C
- Vortex Mixer
- Glassware
- Distilled water.

5. PROCEDURE

5.1 Principle

Human serum or plasma diluted in specimen diluent and incubated with the proteins of HIV 1 HIV 2, coated auto microplate wells and incubated. If the HIV antibodies are present in the sample that are tested, it will bind with the proteins coated on the microwell. After washing off the unbound analyte, horse radish peroxidase conjugated with anti human IgG antibodies is added. Enzyme conjugate binds through the antigen antibody complex if present. Unbound analyte is washed and substrate solution is added. Colour will develop in proportion to the amount of HIV antibodies present in the specimen. Stopping solution is added at the end of the incubation to stop the reaction. The reaction is read by EIA reader.

5.2 Method

The anti HIV antibody test is carried out as per the instructions given in the package insert of the kit.

1. Remove reagents from the fridge 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.
2. Bring the samples to room temperature before testing.
3. Arrange all samples to be tested serially in ascending order in which they are to be tested in a test tube rack.
4. Place the plate in front of the test tube rack
 - Add 100 l of the sample diluent to A-1 well as blank
 - Add 100 l negative control in each well No. B-1, C-1 respectively.
 - Add 100 l positive control in D-1, E-1 and F-1 wells
 - Add 100 l of each sample diluted in sample diluent (1:11) in each well, starting from G1 well.
 - Apply cover seal
 - Incubate at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 30 min. ± 2 min.
 - While the samples are incubating, prepare working wash solution and working conjugate as specified in package insert.
 - Take out the plate from the incubator after the incubation time is over and wash the wells 5 times with working wash solution.
 - Add 100 l of working conjugate solution in each well including A-1.
 - Apply cover seal
 - Incubate at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 30 min. ± 2 min.
 - Aspirate and wash as described in step No. (h).
 - Add 100 l of working substrate solution in each well including A-1.
 - Incubate at room temperature ($20-30^{\circ}\text{C}$) for 30 min. in dark.
 - Add 50 l of stop solution.
 - Read absorbance at 450 nm within 30 minutes in Elisa Reader after blanking A-1 well.

Printer prints out all nos. fed in and their OD values. Reactive is printed across that particular reactive sample number according to the O.D. value of the cutoff.

5.3 Validation:

- Check the validity of the Blank (if used) as well as negative and positive control absorbance value as per pack insert of the kit.
- Examine absorbance values of the controls before the sample results can be interpreted. If the run fails to meet the criteria as per package insert consider the test as invalid and repeat the whole test again.
- Cut off O.D. is automatically calculated.

5.4 Interpretation:

Check the printout carefully for absorbance values:

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

Samples with grey zone results are repeated in one well.

6. DOCUMENTATION

6.1

Paste the print out in the HIV register and also record the following details:

- (a) The date on which the test is run.
- (b) The name of the kit used.
- (c) Lot No and expiry date of the kit.
- (d) Initials of the Technologist who performed the test and the Supervisor who verified the results.
- (e) The reactive units are marked in red.

6.2

Transfer the record to donor records.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| LOCATION | SUBJECT |
|--|---|
| TTI Testing Lab | Anti HCV Testing |
| FUNCTION | DISTRIBUTION |
| Sample tested for HCV antibodies by EIA Method | - Supervisor in charge of TTI Testing Laboratory - Master File |

1. SCOPE & APPLICATION

Anti HCV is a mandatory test for blood unit screening before it is transfused. This is carried out on all donor units samples and pre-donation samples of pheresis donors.

2. RESPONSIBILITY

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

3. REFERENCE

1. Kit package insert.
2. Technical Manual of the American Association of Blood Banks- 13th edition, 1999 pgs. 152-153.

4. MATERIALS REQUIRED

- Elisa Reader
- Elisa Washer
- Microshaker
- Incubator
- Micropipettes and disposable tips
- Timer
- Disposable gloves
- Disposal container with Na Hypochlorite
- Absorbant tissue
- Distilled water
- 1 mol / litre Sulphuric acid
- Kit

5. PROCEDURE

5.1 Principle:

In HCV Eia, the microwell are coated with recombinant Hepatitis C Virus encoded antigens as the solid phase. If the HCV antibody is present, it becomes bound to the solid phase and can be detected by a complementary anti-human IgG conjugated to an enzyme (capable of acting on a chromogenic substrate). When substrate is added to the bound complex, the presence of antibody can be detected by development of a coloured end product.

5.2 Method:

Anti-HCV EIA test is carried out as per kit manufacturer's instructions. The details of the kit procedure and interpretation of results are as per the pack insert of the kit in use.

Remove reagents from the fridge 30 minutes prior to testing. Mix the reagents gently by inverting the vials without foaming.

- Bring samples to room temperature before testing.
- Prepare wash buffer solution as per pack insert.
- Discard all disposable tips in a container with hypochlorite solution.
- Arrange the samples so that well I A is blank I B, C & D as negative control and I E + F as positive controls.
- Dispense 100 ul diluent to each well except the blank well.
- Add 10 ul of controls and specimens to appropriate wells.
- Mix the plate gently and cover with a seal.
- Incubate at 37°C for 60 minutes.
- Remove seal and wash 5 times.
- Invert the plate and tap on a clean paper towel to remove excess wash buffer.
- Dispense 100 ul conjugate to all wells except blank.
- Cover the plate with sealer and incubate at 37°C for 30 minutes.
- Prepare substrate 10 minutes prior to use.
- Wash wells 5 times
- Dispense 100 ul of substrate to all wells including blank.
- Incubate at 15-30°C in dark for 30 minutes.
- Dispense 100 ul of 4 N sulphuric acid to all wells.
- Remove moisture from bottom of plate and read at wavelength of 490 nm.

5.3 Validation:

- Cut off O.D. is automatically calculated.
- Examine absorbance values of the controls before the sample result.
- Check the validity of the Blank (if used) Negative and positive control absorbance value as per pack insert of the kit.
- If the run fails to meet the criteria as per package insert consider the test invalid and repeat the whole test.

5.4 Interpretation:

Check the printout carefully for absorbance value:

- The samples below the cut-off are considered non-reactive.
- Equal to cut off are considered initially reactive
- Above cut off are considered Initially reactive iv Retest ii and iii in duplicate. If one or both positive record the result as positive. If both negative record as negative

6. DOCUMENTATION

6.1

Paste the print out in the HCV register and record the following details

- (a) The date on which the test is run.
- (b) The name of the kit used.
- (c) Lot number and expiry date of the kit.
- (d) Initials of the Technologist who performs the test and Supervisor who verifies the results.
- (e) Write the numbers of samples to be repeated below the print out. After these samples are repeated again then reactive or non-reactive is written across that unit below the print out.
- (f) The reactive units are marked in red.

6.2

Transfer the record to donor records and grouping register.

7. END OF DOCUMENT

***Model SOPs on
Labelling,
Preservation &
Storage of Blood
Components***

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
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| SP 023 | | 2 | | |
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| LOCATION | SUBJECT |
|-------------------------|---|
| Storage Area | Labelling of Blood Bags and Blood Components |
| FUNCTION | DISTRIBUTION |
| Ensure safe Transfusion | - Supervisor in charge of storage and distribution - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCES

Technical manual of the American Association of Blood Banks - 13th edition, 1999 Pgs. 156-158.

4. MATERIAL REQUIRED

- Preprinted adhesive labels for all components printed as per regulatory requirement.
- The labels are printed and colour coded for all components as per blood groups. Group A have yellow labels, Group B pink labels, Group O blue labels and Group AB have white labels. Negative labels also have the same colour labels except the printing is in red colour.

5. PROCEDURE

- After collection and processing whole blood and component units remain in quarantine storage areas.
- Once all the reports of blood group and TTI testing are ready, place the bags on a table in chronological order.
- Segregate those which are found reactive for any TTI or found unsuitable for use and keep them in the area for disposal. Leave those found suitable for use on the bench for labelling.
- Write clearly the unit number, date of collection and expiry and the volume on each label as per the grouping register records.
- Date of collection and date of expiry is very important. The expiry date depends on the type of bag and component. In case of a triple and quadruple bag with additive solution, the expiry date is 42 days, and for double and single bags, it is 35 days. In case of a triple or quadruple bag if for some reason, the components could not be separated, then label the expiry date as 21 or 35 days depending on the anticoagulant present in the primary bag. The day of blood collection is considered the day zero for calculating the expiry dates.
- After the bags are labelled ask a second technician to double check the number and group on the bags tallying them with the records.
- Enter all labelled bags group wise in the stock book which is also maintained group wise. In the stock book keep a footnote for any autologous blood that is reserved for the patient's own use.
- Label FFP and Cryo deficient plasma, and platelet concentrates in the same manner. Cryoprecipitate labels do not indicate blood groups.
- All plasma components have an expiry date of one year. The expiry date of platelet concentrate is 3 days with PVC bags and 5 days if special bags are in use.

6. DOCUMENTATION

Enter all labelled bag numbers in the inventory of units for use.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 024 | | 3 | | |
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| LOCATION | SUBJECT |
|---|---|
| Storage Area | Preservation of Blood and Blood Components |
| FUNCTION | DISTRIBUTION |
| Optimum Storage of Blood and Blood Components | - Supervisor in charge of Storage and Distribution - Master File |

1. SCOPE & APPLICATION

Blood components prepared are stored in conditions designed to preserve optimal viability and function during the storage period. (Table 1)

2. RESPONSIBILITY

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

3. REFERENCES

- Technical Manual of American Association of Blood Banks 13th Edition, 1999. Pages 166-167, 182-183, 84, 86.
- Introduction to Transfusion Medicine, Zarin Bharucha & D.M. Chauhan, 1ST Edition, 1990, Pages 111-112.

4. MATERIALS REQUIRES

- Storage Equipment
- Blood bank Refrigerator
- Deep Freezer
- Platelet incubator
- Platelet agitator

5. PROCEDURE

- All untested units should be kept in the quarantine area.
- After testing is over, release the fully tested. Transfer those deemed suitable for clinical use from quarantine area to the stock area after labelling. (Refer table No. 1).
- Label those found unsuitable for use with a biohazard label and keep for disposal.
- Store whole blood and Red Cell concentrates on metal rack stand in the Cold Room (4-6°C). These stands have shelves. Each shelf is reserved for a particular group having its label stuck on the outer side. Arrange the blood bags in chronological order, group wise and according to the expiry dates in trays and then stack the trays on the shelves. This makes it very easy for the technologists on duty to remove the bags for issuing, whenever required.
- Store blood collected in CPD-A1 and the red cells separated in a closed system up to 35 days. Store the red cells suspended in additive solutions up to 42 days. Use red cells prepared in open system within 24 hours of preparation.
- Keep Fresh Frozen Plasma, cryoprecipitate and FVIII deficient plasma bags in over wrap bags and then arrange in plastic trays in the Deep Freezer (-40°C) immediately after separation. The shelf life of all these plasma components is 1 year. FFP once thawed and then refrozen is used only as FVIII deficient plasma.
- Place Random donor platelets (RDP), Single Donor Platelets (SDP) in a platelet incubator at 20-22°C on a agitator which has shelves to store them. Store the concentrates prepared in PVC bags up to 3 days and those prepared in special platelet bags up to 5 days.
- Take due care to maintain sterility of all components by keeping all storage areas clean.
- Monitor to ensure the storage conditions to be appropriate and correct for each product. Monitor the temperature of all storage areas with continuous graphic recorder. Change the charts every week, and achieve them. Check the alarm system every month.
- Similarly, after labelling the plasma bags, enter the unit numbers group wise in the stock register. Make FFP entries on the right hand page of the stock register, whereas Factor VIII-D plasma & Cryo units on the left hand page. Carry out physical stock taking every night and rewrite the inventory.

6. DOCUMENTATION

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

7. END OF DOCUMENT

| BLOOD COMPONENT STORAGE | | | | | |
|------------------------------------|--|---------------------------|-----------------|-------------------------------------|-----------------|
| PRODUCT | PACKED CELLS (P.C.) | FRESH FROZEN PLASMA (FFP) | CRYOPOOR PLASMA | PLATELETS | CRYOPRECIPITATE |
| Storage Temperature | 2-6°C | -30°C to -80°C | -30°C | -22°C with gentle agitation | -30°C |
| Shelf life from time of collection | 35 days without additive solution. 42 days with additive solution "SAGM" | 1 Year | 1 Year | 3 to 5 days according to bag in use | 1 Year |

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| SP 025 | | 2 | | |
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| LOCATION | SUBJECT |
|---------------------------------------|---|
| Storage Area | Inventory of Blood Bags and Blood Components |
| FUNCTION | DISTRIBUTION |
| Availability of Blood for Transfusion | - Supervisor in charge of Storage and Distribution - Master File |

1. SCOPE & APPLICATION

In order to avoid outdated and make optimum use of available blood, it is important to maintain a day to day inventory of tested blood which helps selection of blood to be cross matched for patients requiring transfusion.

2. RESPONSIBILITY

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

3. REFERENCES

1. Technical Manual of American Association of blood banks 13th Edition, 1999. Pages 83-84, 86.

4. MATERIALS REQUIRED

Inventory Register

5. PROCEDURE

- Inventory is maintained on a day to day basis. After labelling the units, enter the numbers of whole blood or packed cells numbers group wise on the right hand page of the inventory register kept in the main red cell laboratory. In case of packed cells units, write the alphabet "PC" above the unit number. PC denotes packed cells without additive solutions. PCS denotes packed cells with additive solution. The inventory bears columns for A group, B group, AB

group, O group as well as negative groups of these four groups.

- Enter the units group wise and according to the date of collection in the inventory register (daily stock). The technologist on night duty is responsible for physical checking of the printed number tag with the hand written number on the label and enters in the inventory.
- After labelling the FFP, enter the donor units numbers group wise in the stock register of FFP similar to blood units.
- Enter FVIII Deficient Plasma units labelled group wise in the stock register similar to plasma register.
- Enter the labelled cryoprecipitate unit numbers in the register.
- Clearly mark the inventory of bags that have less volume of blood collected or are reserved for specific patients with specific instructions.

6. DOCUMENTATION

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

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 026 | | 2 | | |
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| LOCATION | SUBJECT |
|-------------------------------------|---|
| Red Cell Serology Laboratory | Supply of Safe Blood for transfusion |
| FUNCTION | DISTRIBUTION |
| Reissue of Blood & Blood Components | <ul style="list-style-type: none">- Technologist in charge of Issue Counter- Master File |

1. SCOPE & APPLICATION

The technologists have the duty to see that the blood is not wasted and made available to another patient of the same group. This is achieved by first-in-first-out (FIFO) policy.

2. RESPONSIBILITY

It is the responsibility of the staff to see that the blood which has returned and not used is once again cross matched and made safe for transfusion to another patient.

3. REFERENCES

1. Technical Manual of the American Association of Blood Banks 13th Edition, 1999. Pages 186, 491, 10.

4. MATERIAL REQUIRED

- Issue Register
- Inventory Register

5. PROCEDURE

- When blood is released from the Blood Bank to operation theatre or ward of the hospital or outside for transfusion, some times for some reason or the other, it may not be required by the patient and it is returned to the blood bank. If this unit of blood or blood component arrives within half an hour, it could be

reused for another patient. Take care to see that this unit of blood is kept erect in the cold room to look out for hemolysis. If there is no hemolysis seen after spinning or standing, issue this unit safely to another patient.

- In case of FFP, which comes to the blood bank unused, issue to another patient if there is a demand for that particular group immediately within 6 hours of the first issue. If no call arises, then use it later as FVIII deficient plasma.

6. DOCUMENTATION

- Make entries of returned units against the issue in the issue register.
- Re-enter the unit in the inventory before reissue.

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

| Number | Effective Date | Pages | Author | Authorised by |
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| SP 027 | | 2 | | |
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| 1 | 1 Year | | | |

| LOCATION | SUBJECT |
|------------------------------|--|
| Storage Area | Issue of blood for transfusion |
| FUNCTION | DISTRIBUTION |
| Optimum utilisation of blood | <ul style="list-style-type: none">- Supervisor in charge of storage and distribution- Master File |

1. SCOPE & APPLICATION

The blood and blood components are used as per the need of the patients. These are issued against the prescription of a medical officer after ensuring the compatibility and testing results.

2. RESPONSIBILITY

It is the responsibility of the technician on shift duty in Red Cell Laboratory to issue the blood for which requisition is received.

3. REFERENCE

4. MATERIALS REQUIRED

- Issue register
- Inventory register
- Request form
- Compatibility report

5. PROCEDURE

- In order to avoid outdating, implement FIFO policy
- Carry out compatibility testing using SP017/018
- Ensure that the compatible units are tested for TTI and found suitable for use
- Remove the correct unit from blood bank refrigerator and keep it in the thermal

box for transport

- Make entries in the issue register
- Instruct the individual to take the unit straight to OT/Ward for transfusion.

6. DOCUMENTATION

- Make following entries in issue register.
- Name of patient
- Hospital registration number
- Blood group
- Date and time of issue
- Unit No. issued
- Blood group of unit
- Component of blood
- Signature of technician who issues
- Signature of receiver

7. END OF DOCUMENT

Model SOPs on Quality Assurance

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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|---------|----------------|---------------|-------------|---------------|
| SP 029 | | 3 | | |
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| LOCATION | SUBJECT |
|---|--|
| Quality Control Laboratory | Optimum Quality Assurance |
| FUNCTION | DISTRIBUTION |
| Optimum Storage of Consumables, Reagents and Kits | <ul style="list-style-type: none">- Supervisor in charge of Donor Room- Supervisor - Red Cell Serology Laboratory- Supervisor - TTI Testing Laboratory- Supervisor - Quality Control Laboratory- Supervisor - HLA Laboratory- Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

It is the responsibility of all the staff members of different laboratories to store all the reagents and kits as per manufacturer's instructions.

3. REFERENCES

1. Indian Pharmacopoeia, Volume II, Annexure 29 (A-29), 1996.
2. Reagent manufacturer's instructions.

4. MATERIALS REQUIRED

- Domestic refrigerator
- Blood bank refrigerator
- Deep Freezer
- A.C. Store room
- Stock register or stock cards

5. PROCEDURE

(a) Donor Room:

- (i) Store disinfectants for preparation of phlebotomy sites at room temperature (22°C-25°C) in the donor room
- (ii) Store blood collection bags and apheresis sets in airconditioned room (22°C-25°C).

(b) Red Cell Serology Laboratory (RCS):

- (i) Store ABO reagents Anti A, Anti-B, Anti AB, Anti D, bovine albumin, anti-human globulin, pooled A,B, and O red blood cells, papain and cystein powder in the cold room maintained at 4°- 6°C or as per manufacturer's instructions.
- (ii) Store 10ml aliquots of papain-cystein in the Deep Freezer at 70°C in RCS laboratory.

(c) Transfusion Transmissible Infections Testing (TTI):

Store Kits for HBsAg, HIV, HCV and VDRL at 4°C-6°C in the blood bank refrigerator in the TTI Laboratory or as per manufacturer's instructions.

(d) Quality Control Laboratory(QC):

- (i) Store Kits for Factor VIII assay at 4°-6°C in the QC laboratory or as per manufacturer's instructions.
- (ii) Store Copper sulphate stock and working solutions, 0.9% normal saline, and distilled water at RT (22°-25°C) in the QC laboratory.
- (iii) Store chemicals like copper sulphate, sodium chloride and calcium chloride powders at RT (22°-25°C) in the QC laboratory.

(e) HLA Laboratory:

- (i) Store Lyophilised HLA antisera, lyophilised rabbit complement, histopaque 1077, and RPMI 1640 powder at 4°-6°C in a refrigerator in the HLA laboratory or as per manufacturer's instructions.
- (ii) Aliquote reconstituted HLA antisera in 100ul quantities and store in the Deep Freezer at 70°C in the component room.
- (iii) Store HLA plates pre-dropped with HLA antisera in boxes kept in a Deep Freezer at 70°C in the component room.
- (iv) Store Aliquots of inactivated human AB serum and RPMI 1640 medium (pH7.2) at 70°C in the Deep Freezer in the component room.
- (v) Store 5% eosin solution, 0.5% phenol red solution, 1N HCl and sterile distilled water vials at 4°-6° C in the refrigerator in the HLA laboratory.
- (vi) Formaldehyde and phosphate buffered saline (pH 7.2) are stored at room temperature (22°-25°C) in the HLA laboratory.
- (vii) Powders of all the chemicals used are stored at room temperature (22°C-25°C) in the HLA laboratory.

6. DOCUMENTATION

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

N.B.:

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

7. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| LOCATION | SUBJECT |
|--|--|
| Quality Assurance Laboratory | Equipment Maintenance |
| FUNCTION | DISTRIBUTION |
| Preventive Maintenance contracts and schedules | - Quality Assurance Manager - Master File |

1. SCOPE & APPLICATION

This procedure applies to all the instruments and equipments used within the blood centre.

2. RESPONSIBILITY

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

- Where relevant, prepare specifications and validation reports for new and modified equipment.
- Write an individual SOP for all equipment which defines all the maintenance requirements (eg. Routine, Preventative, Calibration etc.) regardless of whether carried out by an external agent.
- The requirements may be defined in the service contract referenced in the SOP.
- Prepare the maintenance schedules for all equipment items. The schedule is to include:
 - o Preventive.
 - o Routine.
 - o Extra maintenance.
 - o Cleaning and sanitation.

3. REFERENCES

1. Technical Manual of American Association of Blood Banks 13th Edition, 1999, Page 5.
2. Quality Manual, International Federation of Red Cross and Red Crescent

Societies, 1998, Pages 23-24.

3. The Gazette of India extra ordinary notification G.S.R. 245 (E) dated 5th April 1999, new Delhi, Part II Sec. 3 (i), Page 40.

4. PROCEDURES

4.1 Maintenance overview:

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

Identify the relevant procedures for equipment maintenance determine the frequency of calibration and cleaning procedures clearly identifying the times eg., daily, monthly etc.

- 4.1.3 Prepare a complete equipment and instrumentation list consisting of the following headings:

- **Equipment name / description.**
- **Asset Number.**
- **Serial Number.**
- **Model Number.**
- **Operation:**

- Operating Range.

- **Calibration:**

- Frequency.
 - Referenced documents.
 - Performed by

- **Performance Check:**

- Frequency.
 - Referenced documents.

- **Preventive maintenance:**

- Frequency.
 - Referenced documents.
 - Performed by.

- **Routine maintenance:**

- Frequency
 - Referenced documents.

- **Cleaning:**

- Frequency.
- Referenced documents.

- 4.1.4 Maintain a list of all equipment and instruments used in all sections / departments in the QC lab to ensure all equipment within the department are documented.

4.2 Maintenance Schedules:

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

4.3 Service contracts:

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

4.4 Repair & breakdown:

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

4.5 Maintenance overdue:

The Quality Control Laboratory shall determine the suitability for ongoing use of any equipment that has passed its due date for routine maintenance (where this routine maintenance does not involve calibration). The laboratory must document their reasons for continuing to use an item of equipment that is overdue for maintenance. Where appropriate this should include explanation (and supportive evidence where available) that product quality has not been compromised by this delay in maintenance.

Where possible, documentary evidence from the manufacturer supporting this decision should be provided. Steps should be taken at the next instance of routine maintenance to evaluate whether any discernible damage has been caused to the equipment by the delay in maintenance.

5. DOCUMENTATION

- Maintain individual files of service reports of all equipments.
- Enter the details of all routine as well as trouble-shooting service calls by the manufacturer's engineer in the equipment maintenance register.
- Maintain a file of all manufacturer's instructions and where required display them close to the equipment.
- Record the name, address and telephone number of the service engineer to be contacted in case of need.

6. END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| LOCATION | SUBJECT |
|------------------------------|--|
| Quality Assurance Laboratory | Equipment Manitenance |
| FUNCTION | DISTRIBUTION |
| Calibration | - Quality Assurance Manager - Master File |

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

It is the responsibility of the supervisor of the section to which the equipment belongs to:

- Plan, schedule, organise and maintain records of the calibration programmes for various equipment under their control.
- Ensure that equipment and instruments are continuously calibrated or are removed from use.
- The Supervisor should train staff for performing calibration/performance checks.

3. REFERENCES

Blood Programme Quality Manual IFRCRCS Page 23.

4. DEFINITIONS

Calibration:

A set of operations which establish under special conditions the relationship between values indicated by measuring instruments and standards.

Performance checks:

The routine checking of the performance of an instrument to verify that it has

remained within specified range of accuracy and precision.

Accuracy:

The closeness of agreement between the result of a measure and the true value of measurement. Calibration is used to determine the accuracy of an instrument.

Precision(Repeatability):

The closeness of agreement between the results of successive measurement of a defined procedure several times under prescribed conditions.

Measurement standard:

A measuring instrument or material which physically defines a unit of measurement or value of a quantity. Measurement standards used for calibration should be traceable to the SI units of standard measurements.

5. PROCEDURES

5.1 Calibration Schedules:

- Purchase each new piece of equipment or instrument according to specifications.
- Place new equipment on an Asset register prior to use.
- Ask the supplier prior to delivery or after installation to calibrate new equipment and provide a certificate of calibration.
- Maintain Calibration / Maintenance schedules for all equipment.

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

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

5.2 Reference standards, Traceability and Calibration Limits:

5.2.1 Reference Standards and Trace ability:

All measurement standards used to calibrate measuring devices should be traceable to a national standard of measurement either:

- (a) Directly through purchase of pre-calibrated certified standards. These shall be supported by calibration documents or certificate from the supplier stating the date, accuracy (assigned value and units of measure), traceability and conditions under which the results were obtained. These standards shall be re-calibrated at pre-determined intervals.
- (b) Indirectly by preparation of an internal working standard calibrated against a certified standard. These shall be supported by internal test reports and any other supporting documentation.
- (c) Where no recognised external standard exists an internal standard may be prepared and calibrated provided a written procedure is prepared and a

rationale for assigning values, accuracy and units is established. These standards shall be supported by suitable records of calibration as above.

5.2.2 Calibration Limits:

Calibration is concerned with the measurement of values and their comparison with acceptable limits of standards resulting in adjustment or correction, if necessary.

Compare calibration results with established limits for accuracy for the measuring device. If the device being calibrated does not fall within the limits then re-adjust and re-calibrate until it falls within pre-established limits. If not, remove from use.

The establishment of limits should be based on a combination of:

- Those specified at the time of purchase.
- Recommendations from the manufacturer.
- Limits established in reference standards.

The acceptable limits required for satisfactory calibration of each instrument should be identified or referenced in the relevant procedure.

5.3 Calibration and Performance Check Procedures:

Prepare documented procedures based on the instrument manufacturer's written instructions and use for the calibration and performance checks for all measuring instruments and measurement standards.

Calibration procedure should include:

- A list of equipment to which the procedure is applicable.
- Calibration points, environmental requirements and special conditions.
- Limits for accuracy.
- List and identity of traceable standards.
- Sequence of calibration steps.
- Instructions for recording data with reference to the relevant Standard Form.

Performance check procedures should follow a similar format.

5.4 Labelling:

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

- Date of last calibration.
- Signature of person who performed the calibration.
- Date next calibration due.

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

6. DOCUMENTATION

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

Calibration and Performance Check test records should include(where appropriate):

- Asset Register Number.
- Instrument Serial Number.
- Limits for calibration(refer 4.4.2).
- Date of calibration / performance check.
- Due date for next calibration.
- Any details of adjustment* or repair.
- Results of the calibration*/performance check.
- Statement of compliance, or details of non-compliance and action taken.
- Signature/initials of the person performing the calibration/performance check.

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

Maintain calibration and performance check records for five years.

7. CORRECTIVE ACTION

Conduct a review if any measuring device is found to be out of calibration and requires adjustment. Take corrective action where appropriate.

If the item can be adjusted back into calibration, it may continue to be used. If the item cannot be adjusted back into calibration, it must not be used until the situation is corrected. Under these circumstances attach an identifying label stating that the item is under repair and is not to be used.

The Supervisor must assess the likely impact of the inaccuracy of the affected measurement on the quality of current product and product produced since the previous satisfactory calibration. Factors influencing the degree of risk include:

- (a) Critical nature of the measurement.
- (b) Sensitivity of quality control testing to the consequences of the inaccuracy.
- (c) History of production records and performance checks.

Additional quality control testing may be instituted to determine whether quality has been compromised. Where it is likely that quality has been compromised this shall be communicated to senior management and document reports.

8. RELOCATION OF INSTRUMENTS

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

9. EXTERNAL CALIBRATION CONTRACTORS

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

- Use of standards and references traceable to national standards.
- Certification/licensing by the equipment manufacturer, if available.
- Check all certificates or reports supplied by approved external laboratories on receipt. Certificates and reports should contain the same information as required in 5.0 above.

10.END OF DOCUMENT

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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| LOCATION | SUBJECT |
|--|--|
| Quality Assurance Laboratory | Incident Report |
| FUNCTION | DISTRIBUTION |
| Mechanism for correction and Prevention of error and incidents | <ul style="list-style-type: none">- Quality Assurance Manager- Supervisor in charge of Donor Area- Supervisor- Red Cell Serology Laboratory- Supervisor- TTI Testing Laboratory- Supervisor- Quality Control Laboratory- Supervisor- Component Laboratory- Master File |

1. SCOPE & APPLICATION

The procedure covers all incidents that would affect the quality of blood products & services. The procedure applies to all incidents, adverse reactions, equipment used in collection, testing & storage of blood products. The incident reporting process should be clearly defined so that information is tracked and acted on and feed back provided.

2. RESPONSIBILITY

- It is the responsibility of all the technical staff to report any incident/accident to the section supervisor who will submit the report to the Quality Assurance Supervisor/Manager.
- The Quality Assurance Supervisor/Manager is responsible to review the completed report and report to the Director for further investigation and implementation of remedial measures if any.

3. REFERENCES

- Technical Manual of American Association of Blood banks 13th Edition, 1999, Pages 3, 14-15.

4. DEFINITIONS

Incident Reporting:

- Is a process improvement tool that is used to identify problems, analyse the

cause, develop solutions, execute the solution and track the effectiveness.

Corrective Action:

- Is required for error and accident reports and is usually connected to a process improvement activity. It is an immediate remedial action taken to correct the effect of a defined event.

Preventive Action:

- Follow up action taken to prevent a defined event from re-occurring.

Incident:

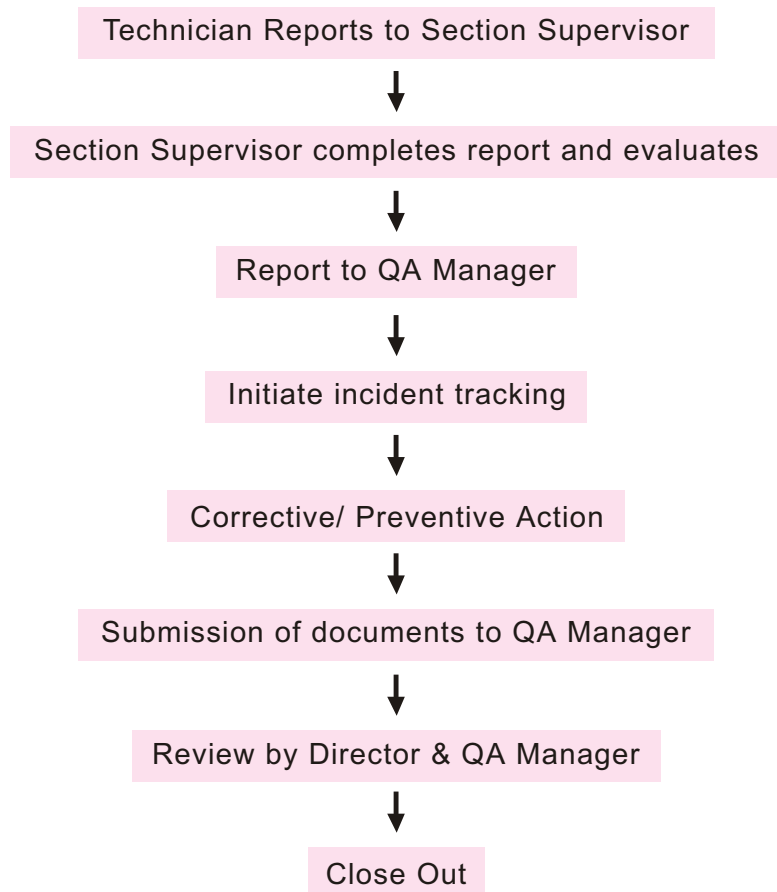
- An Event that results from a deviation from a system, process or procedure that may affect the:
 - (i) Safety, purity, potency or effectiveness of the product.
 - (ii) Health or safety of a donor, product recipient, member of staff/public.
 - (iii) Trace ability of records.

This event may have been identified either prior to or after distribution of a product or service.

5. PROCEDURE

- (i) Document all incidents on the standard form (Incident Report Form).
- (ii) Forward the incident summary report to the section supervisor for evaluation and completion.
- (iii) Initiate incident tracking.
- (iv) Develop corrective/preventive Action in consultation with Section Supervisor, QA Manager and the Director.
- (v) Forward original documents to the QA Manager within 3 working days of the event.
- (vi) The QA Manager reviews the report for completeness and appropriateness of corrective action.
- (vii) The status of an event remains active until effective action is taken and closed out. Record the details, date of action and close out and get the reports form signed by the Director.
- (viii) Notify the Director immediately in case of critical incidents such as those that could result in loss of life, product recall, failure to operate or adverse publicity
- (ix) Provide monthly summary reports to the Director.

5. FLOW CHART FOR INCIDENT REPORTING PROCESS



6. DOCUMENTATION

Record all incidents on a incident report form. File all record forms.

7. END OF DOCUMENT