BLOOD BANK DEPARTMENT

STANDARD OPERATINGP ROCEDURES

(SOPs)

April 2016

اهداء:

❖ الى أرواح شهدائنا الأبرار والى أرواح شهدائنا خاصة في مهنة التحاليل الطبية

الشهيد/رامي السلوت

والشهيد/حسام راضي

❖ وكذلك الى روح الزميل/حسام أبو شمالة

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❖ والى مرضانا الزملاء/مهند الشنطي

الميكروبيولوجي) SOPs والزميل محمود الجرو (وهو عضو فريق اعداد

نسال الله لهم الشفاء العاجل وللشهداء الفردوس الأعلى .

❖ الى كل من ينتمي الى هذه المهنة الانسانية من زميلات وزملاء

نهدي هذا العمل رمزاً للوفاء

شكر وتقدير

يتقـــدم فريــق عمل مختبرات وبنوك دم المستشفيات بجزيل الشكر والتقدير إلــى كل من **الأخ الدكتور/ يوسف ابو الريش "وكيل وزارة الصحة"**، وإلى **الأخ الدكتور/ عبد اللطيف الحاج" مدير عام المستشفيات"** لما قدموه من دعم وتسهيل من اجل انجاز هذا العمل وكذلك إلى **الاستاذ/ شاكر ابو شعبان" مدير دائرة مختبرات وبنوك دم المستشفيات سابقا"** لما قدمه من دعم ومشورة في جميع مراحل انجاز هذا العمل .

كما نتقدم بجزيل الشكر والتقدير الى كل من فريق الاعداد وفريق المراجعة لما بذلوه من جهد من اجل اتمام هذا العمل وكذلك الى جميع الاخوة العاملين في مختبرات وبنوك دم المستشفيات اللذين سيكون لهم الدور الرائد في تطبيق هذه الاجراءات.

وكذلك نتقدم بجزيل الشكر والعرفان الى مؤسسة العون الطبي للفلسطينيين لرعايتهم طباعة هذا الدليل.

بسم الله الرحمن الرحيم

قال تعالى: (و قل اعملوا فسيرى الله عملكم ورسوله و المؤمنون) صدق الله العظيم

الأخوة والأخوات الزملاء الأكارم...

السلام عليكم ورحمة الله وبركاته..... أما بعد

انه لمن دواعي سروري أن أضع بين أيديكم (دليل طرق الفحوصات المخبرية الموحد) والذي يتضمن توثيقاً وتفصيلاً لطرق عمل (Standard Operating Procedure SOPs) الفحوصات التي تقدمها مختبرات وبنوك دم المستشفيات، وذلك من أجل تنظيم العمل وضمان جودته في جميع جوانب خدمات المختبرات وبنوك الدم.

تأتي الحاجة إلى هذا العمل تأكيداً وترسيخاً لمبدأ العمل بروح الفريق الواحد وتوثيق وتوحيد طرق العمل المبني على أسس علمية والذي تنتهجه وزارة الصحة والإدارة العامة للمستشفيات في كافة مناحي العمل وتطلعاً للرقي بمهنة التحاليل الطبية خاصةً، و بجودة الخدمات الطبية المقدمة في الوزارة بشكل عام.

كما يعتبر هذا الدليل الأول والموحد لجميع مختبرات وبنوك دم المستشفيات و الذي سيكون له بمشيئة الله الأثر الايجابي على جودة الخدمات المخبرية ومجمل الأداء الفني من أجل الارتقاء بالخدمات المقدمة للمواطن.

في النهاية لا يسعني إلا أن أتقدم بخالص الشكر و التقدير لفريق عمل دائرة مختبرات وبنوك دم المستشفيات وجميع من ساهم في انجاز هذا العمل سواءً في الإعداد أو المراجعة أو الطباعة والإخراج.

د. عبد اللطيف الحاج

مدير عام المستشفيات

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Model SOP on Donor Room

STANDARD OPERATING PROCEDURE (SOP)

Donor Room (DR)

Contents

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Criteria for donor selection

SOPs\HGA \.....H\BB\DR \101

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

This SOP describes the criteria for a donor to be accepted for blood donation, for ensuring safety of donor as well as recipient.

2. Responsibility

The donation room staff 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 examination including the results of pre donation screening tests.

3. Material required

- Donor Questionnaire
- Donor identification (Donor Card , Donor ID , ….)

4. Procedure

1) Donation frequency

- Whole Blood donors may donate every 90 days.
- Plasma donors may donate once in 4 weeks.
- Platelet donors may donate a maximum of 24 times per year.
- Other specialized donations are subject to other rules.

2) Criteria for selection of blood donors

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

1. The interval between blood donations should be no less than 12 weak.
2. The donor shall be in good health, mentally alert and physically fit.
3. Age: in the age group of 18 to 60 years .
4. Weight: not less than 55 kilograms for male and 50 kilograms for female.
5. Pressure: The systolic and diastolic blood pressures are within normal limits
6. Temperature and pulse of the donor shall be normal
7. Hemoglobin shall not be less than 13.5 g/dl for male and12.5 g/dl for female
8. Hct > 38%.
9. The donor shall be free from any skin disease, skin punctures or scars at the site of phlebotomy.

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 (major)	12 months
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 on treatment with insulin or with complications
6. Hepatitis B and C infection
7. Chronic nephritis
8. Signs and symptoms, suggestive of AIDS
9. Liver disease
10. Tuberculosis

11. Polycythemia Vera
12. Asthma
13. Epilepsy
14. Leprosy
15. Schizophrenia
16. Endocrine disorders

N.B. See the attached (BB\ Annex 1)

5. Documentation

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

Pre-donation test

SOPs\ HGA \.....H \ BB\DR\ 102

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To perform an examination on the donor for confirming fulfillment of the criteria

which ensure safety of the donor as well as the recipient.

2. Responsibility

It is the responsibility of the donor room staff to perform the examination on the donor.

3. Materials required

1. Weighing scale
2. Sphygmomanometer
3. Clinical thermometer
4. CBC counter or spectrophotometer
5. Microhematocrit centrifuge
6. Clay
7. Capillaries
8. Donor card
9. Lancet

4. Procedure

Medical Examination: (If available)

1. General Appearance: Defer a donor who appears ill or do not appear to be providing reliable answers to medical history.
2. Check and enter donor's weight. The weight should be >55 kg to collect

450 ml.

3. 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 > 90 mm of Hg;
    - Pulse regular, between 60 and 100 beats / minute.
    - Oral temperature 37.5 C +/- 0.2C .

Hemoglobin estimation:

- Blood donation can be accepted only if the hemoglobin is > 13.5 g/dl for male and12.5 g/dl for female.
- Hct >38 %
- Test for hemoglobin by CBC method (Refer SOP of hematology).

5. Documentation

Documents all test of donor data in the donor card /computer

Automated measuring CBC parameters

SOPs \HGA\.....H\ BB\DR \ 103

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To find a fit and healthy donor and to determined CBC parameters. This also helps in assuring the quality of the product.

2. Responsibility

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

For more details see SOPs no.(01,02,03,04) of hematology department

Estimation of donor's Hematocrit Hct measurement

SOPs \HGA \.....H\ BB\DR \ 104

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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. Materials required

- Microhematocrit tube approximately 75 mm long with an inner bore of approximately 1.2mm.
- Clay-like sealing compound.
- Microhematocrit centrifuge.
- Microhematocrit tube reader.

4. Principle

Whole blood is centrifuged for maximum red blood cell packing. the space occupied by the red blood cells is measured and expressed as a percentage of the whole blood volume .

5. Procedure:

(1) Allow the capillary or well-mixed anticoagulated whole blood to enter two microhemtocrit tubes until they are approximately two-third filled with blood

(2) Seal one end of the microhematocrit tube with the clay material by placing the dry end of the tube into the clay in a vertical position .

(3) Place the two microhematocrit tubes in the radial grooves of the centrifuge head exactly opposite each other, and centrifuge for 5 minutes .

(4) Remove the hematocrit tubes and determine the results by using microhematocrit reader.

6. Sources of error:-

1- The EDTA (dipotassium salt for choice) should be in a concentration of 1.5 mg/ml. This concentration will be exceeded if a reduced amount of blood is added to a standard specimen container or if the blood is taken up in a capillary which contains anticoagulant. This will cause shrinkage of the red cells with falsely low MCV.

2- Storing blood beyond 6-8 hours results in an arte factual increase in MCV, especially in hot climates.

3- Inadequate mixing of blood before sampling.

4- A clot in the specimen.

5- Inadequate packing in prescribed time (see 'Maintenance' above).

6- Including the Buffy-coat layer in the reading of the red cell level.

7- Evaporation of plasma during centrifugation, especially if the centrifuge over-heats, or if the spun sample

Vein puncture procedure

SOPs\HGA\.....H \ BB\DR \ 105

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Collection of blood units under aseptic technique

2. Responsibility

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

3. Materials required

- Sterilizing tray.
- 70% methyl alcohol.
- Cotton/gauze/swabs.
- Tourniquet.

4. Procedure

1. After selection of the vein for vein puncture, apply alcohol and spirit swab, in this order, to the skin at the phlebotomy site.
2. Start disinfection of the skin of about an area of 5 cm diameter from the centre outwards in a circular motion.
3. Do not touch the site prepared for vein puncture. Should it be necessary, touch the skin away from the point of needle insertion.
4. If the puncture site is touched, repeat skin preparation procedure as detailed earlier.
5. Discreetly check the used swab. If it is physically soiled /contaminated, take a new Swab and repeat skin preparation [1]procedure as detailed

earlier.

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

Selection of Bags

SOPs\HGA\.....H \ BB\DR \ 106

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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 in the donor area coordinates with the component room for deciding the type of blood bags to be used. The head of blood bank department is consulted in case of difficulty in making a decision or to optimize the availability of components.

3. Materials required

Different types of blood bags in use.

4. Procedure

Select the bag as per the following chart:

DONOR		COMPONENTS	BAGS	
Weight	**Aspirin intake**	**Required**	**Type**	**Qty. (ml) of Blood**
>55 Kg	**No**	**PC+FFP+PLT**	**Triple or Quadruple**	**450ml**
>55 Kg	**Yes**	**PC+FFP PC+FVIIID+CRYO**	**Double**	**350/450ml**
50-55 Kg	**No**	**PC+FFP PC+FVIIID+CRYO PC-PLT**	**Double**	**350ml**
50-55 Kg	**Yes**	**PC+FFP PC+FVIIID PC+FVIIID+CRYO**	**Double**	**350ml**

PC: Packed Cells, **FFP:** Fresh Frozen Plasma, **PLT:** Platelets, FVIIID**:** Factor VIII Deficient Plasma, **Cryo:** Cryoprecipitate

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

5. Documentation

Enter the following details on donor card and computer

- Type of bag.
- Donor serial no.
- Donation date
- Expiry date

Blood collection procedure

SOPs\HGA\.....H \ BB\DR \ 107

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Blood collection from the donor with a correct performance of venipuncture is essential for the quality and safety of the blood donation .and contributes to the comfort and satisfaction of the donors thus encouraging re-attendance.

2. Responsibility

The technician in the donor area is responsible for blood collection from the donor.

3. Materials required

1. Cotton/Gauze swabs.
2. Disposable plastic syringes (2ml).
3. Disposable needles.
4. Pilot tubes: Plain and EDTA.
5. Tourniquet.
6. Rubber gloves.
7. First aid tray.
8. Electronic tube sealer.
9. Blood collecting bags.
10. Discard jar with 10% sodium hypochlorite.
11. Scissors.
12. Blood bag mixer (Bio mixer).
13. Comfortable donor chair.

4. Procedure

1- Prior to phlebotomy, write unit number ,date, blood group and donor name on the main collection bag and all transfer bags,
2- Make the donor lie down with a pillow under the head or recline in a comfortable Donor chair. Loosen tight garments.
3- Ask the donor if he/she is in a comfortable position. Give the donor a hand roller/

squeezer to hold.

4- Clean the venipuncture site.(Sop 05)
5- Set the biomixer for the required volume of blood (350/450ml) to be collected and place the bag on it.
6- Apply the tourniquet on donor arm.
7- 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.
8- Keep the level of the needle facing upward and the shaft at an angle of 15 to the arm.
9- Once the needle is beneath the skin, release the clamp.
10- Insert the blood bag needle into the vein for about 1 to 1.5 cm by a bold single.
11- Prick to strips.
12- Advise the donor to gently squeeze the hand roller to improve blood flow. If the venipuncture is unsuccessful do not make further attempt In the same arm.
13- Take the donor's permission for a second attempt. Use a new bag.
14- 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 biomixer automatically clamps the tubing.
15- 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.
16- 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.
17- Seal the bag tube with tube sealer.
18- Burn the needle of the bag in the needle incinerator. Discard the tubing with the burnt needle in a container of sodium hypochlorite solution.

5. Documentation

Record all the data in the donor register/ computer.

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

During and Post donation care and management of adverse reactions

SOPs\HGA\.....H \ BB\DR \ 108

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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

2. Responsibility

It is the responsibility of the technician working in the donor area until the donor goes out.

3. Material required

1. Sterile swabs.
2. Adhesive tape.
3. Leaflet for post donation instructions.
4. Ice bag

4. Procedure

1. Ask the donor not to get up from the chair /cot for 5 minutes even if he feels perfectly all right.
2. Observe for another 10 minutes in the refreshment area whilst having juice.
3. Inspect the venipuncture 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 venipuncture, apply pressure with a dry, sterile cotton swab. Inform the donor about the expected change in skin color. If the pain persists, ask him/her to apply ice.
4. Instruct the donor to drink adequate fluid in the day and avoid strenuous activities.

5. Donor Reactions

What are donor reactions?

- Signs (what you observe).
- Symptoms (what donor tells you).
- Changes in vital signs (blood pressure, pulse and respiration).
- They occur in two to four percent of donors.
- They are classified as mild, moderate or severe according to what happens and how long it lasts.

Classification of reactions:

A. Mild.

B. Moderate.

C. Severe.

A. Mild

- Signs and symptoms < 15 minutes.
- Unresponsiveness < 15 seconds.
- Pallor, sweating.
- Hyperventilation, rapid, pulse.
- Lightheadedness, weakness.
- Nausea.

B. Moderate

- Signs, symptoms 15 – 30 minutes.
- Unresponsiveness 15 – 30 seconds.
- Slow pulse.
- Hypotension.
- Vomiting.
- Twitching movements.
- Fainting (standing, sitting).
- Difficulty in breathing.

C. Severe

- Signs, symptoms >30 minutes.
- Unresponsiveness > 30 seconds.
- Convulsions.
- Incontinence.
- Tetany.
- Chest pain.

What is vasovagal syncope?

Vasovagal syncope (stimulation of vagus nerve) due to emotional stress also called emotional fainting that results in:

- Generalized muscle weakness
- Inability to stand upright.
- Loss of consciousness.
- Bradycardia.
- Hypotension.
- Hyperventilation.

Which donors are most likely to have reactions?

It is important to know which donors are most likely to have reactions because many can be prevented by giving donors more attention and reassurance studies have shown that reactions occur more often in:

- First time donors.
- Young donors.
- Low body weight.
- Women.
- Donors who have reaction before.
- Donors who see others react.
- Donors who wait long before phlebotomy.

Other contributing factors are not eating for a few hours, not sleeping well, hot and overcrowded room.

What can you do to prevent reactions?

You can do a lot prevent reactions.

- Show that you care and reassure the donors.
- Be professional and nice.
- Try not to keep the donors to wait.
- Speak with donors.
- Observe donor who is pale, dizzy or staring on space.

What should you do if a donor has a reaction?

1-General:

- Remove the tourniquet.
- Stop vein section.
- Call for help (supervisor or any other colleague).

2-Fainting:

- Elevate donor legs.
- Be sure that the donor has clear airway.
- Apply ice bag.
- If the donor does not recover and if he/ she is still hypotensive calling with emergency department

3-Nausea, vomiting:

- Instruct the donor to breath slowly and deeply.
- Turn donor head to the side.
- Apply cold compresses.
- Provide a suitable emesis basin and cleaning towel.
- Prepare a cup of water for the donor to rinse his mouth.

4- Twitching and muscular spasm :

- Watch closely for these symptoms.
- Converse with donor.
- Let the donor rebreathe into a paper bag.

5- True convulsions are rare:

- Hold the donor and restrain him to prevent from injuring himself.

- Be sure the donor has clear airway.
- Call the physician to decide whether the donor needs any medication or not

6-Serious cardiac difficulties are exceptionally rare.

Call for emergency care unit

6. Documentation

- Give a leaflet of post donation instructions to the donor.
- Record any adverse reaction on computer.

Labeling of Blood Bags

SOPs \HGA\.....H \ BB\DR \ 109

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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 collecting the blood units to ensure proper labeling and recording of the requisite details, even if the donor area attendant affixes the labels.

3. Material required

Sticker labels (with Blood group and Unit Number).

4. Procedure

1- Identify each unit with serial number

2- Write donor's name on his/her blood bag and sample tube.

3- Fix the sticker label of blood group on the blood Unit which contain:

- Unit serial number.
- Donation date.
- Donor name.

4- Write unit number on the primary bag and on all the satellite bags in case of multiple bags

5- Verify the donor's identity by tallying with the name, Telephone, date, birth date, address and ID no. on the master registration record

book/computer.

6- Cross check the numbers on the bag pilot tubes to ensure identity.

7- Transcribe this number on all records hence forth for storage, testing and distribution.

8- While 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

Quality control in donation

SOPs \HGA\.....H \ BB\DR \ 110

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To make sure that all the procedures in the collection room are safe for donor and blood unit

2. Responsibility

It is the responsibility of the supervisor of the blood bank .

3. Procedure

1- The number of units checked every month is 1-1.5% of the total; this number is divided over the four weeks of each month.

2- Quality control should be done on a different day each week so that QC is performed on most days of the week.

3- Check the questionnaire of the donor contains all the personal information of the donor namely; name, age, sex, address, ID number and date of last donation. Make sure that all questions are answered and medical examination is recorded.

i.e. Temperature, blood pressure, Hb level, and the signature of the authorized personal.

Check the No. of the blood unit and on the sample tubes.

1. Check the blood unit for the following data:

- Signature of the phlebotomist on the blood unit .
- The duration of donation is written (it should not exceed 15 min maximally).
- The collection date is written down on blood unit.

2. Examine the blood unit for the following:

- Right red ⟶ Arterial blood
- Dark or purple/ black ⟶ Bacterial contamination.
- Clots. ⟶ Not properly mixed with anticoagulation during donation
- .Leaks / air. ⟶ Open system to be discarded.

Weight of the blood unit should not exceed 495 ml .

3. Check for the arrangement of ice-packs and blood units in ice boxes, the following should be considered :

- Ice packs should be frozen .
- Arrangement of ice packs should ensure that temperature of blood is between 2-8 ^{0}C .
- Ice packs should be placed around blood units not on top or beneath blood units.
- Blood units must not touch the frozen ice packs. (this will cause hemolysis)

4. Check the temperature of blood units on arrival of mobile blood campaign:

This is done by sandwiching a thermometer between 2 blood units.

Blood units from which platelets are prepared should have their temperature at 20-22 ^{0}C .

Model SOP on Component separation

STANDARD OPERATING PROCEDURE (SOP)

Component Separation (CS)

Contents

S No	Subject	SOP No
1.	Calibrating Refrigerator centrifuge	SP 201
2.	Separation of packed cells and FFP (using double bag)	SP 202
3.	Separation of packed cells ,platelets and FFP(using triple bag)	SP 203
4.	Preparation of Cryoprecipitate	SP 204
5.	Labeling of Blood Bags and Blood Components	SP 205
6.	Preservation of Blood and Blood Components	SP 206
7.	Inventory of Blood Bags and Blood Components	SP 207

Calibrating Refrigerator Centrifuge

SOPs\HGA\.....H \BB\ CS \ 201

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To operate a Refrigerator centrifuge in a good manner to insure good manufacturing practice by getting the exact required blood components concentrate.

2. Responsibility

It is the responsibility of the supervisor of the blood bank.

3. Programming procedure

1. Turn power switch on.
2. Turn the key to switch to the normal position .
3. Press program into in – out the (desired program No. eg, 1 ,2 ,3 .. etc) .
4. Put the program name.
5. Insert the desired speed .
6. Insert the desired time .
7. Insert the specific acceleration time
8. Insert the specific deceleration time
9. Adjust temperature as required
10. Press save key to store the entire entered data

4. Calibrating centrifuges for Platelets Separation

Each centrifuge should be calibrated upon receipt & after adjustment or repair**.**

1. Collect from the donor an EDTA tube in addition to the specimen drawn for routine processing.
2. Perform a platelet count on the EDTA specimen, if the donor has a platelet count below 133000/mm, this unit of blood shouldn't be used for calibration.

3. Calculate the number of platelets in the unit of the whole blood (WB)

Number of platelet in WB = platelet per mm x1000 x volume of WB

4. Prepare platelet rich plasma (PRP) at a selected speed & time.
5. place a temporary clamp on the tubing so that one satellite bag is closed off. Express platelet rich plasma into the other satellite bag. Seal close to primary bag & disconnect the two satellite bags. Don't remove the temporary clamp to the satellite bag until the next step.
6. Strip the tubing several times so the tubing contains a representative sample of platelet rich plasma.
7. Seal off of the tubing & disconnect so the bag of platelet rich plasma remains sterile.
8. Perform a platelet count on the sample of platelet-rich plasma in the segment & calculate the number of platelets in the bag of platelet-rich plasma

no. of platelets in PRP= platelets count/mm x1000xvolume of PRP.

9. Calculate % yield

$$\% \text{ yield} = \frac{\text{no. of plt in PRP}}{\text{no. of plt in WB}} \times 100\%$$

10. Repeat the above process three or four times with different donors, Using different speeds & times of centrifugation
11. Compare the yields for each set of centrifuge conditions.
12. Select the shortest time & lowest speed that result in the highest %
13. yield of platelets in platelets rich plasma.
14. Centrifuge the platelets rich plasma at a selected time & speed to prepare platelets concentrate
15. Express the platelets poor plasma into the second attached satellite bag & seal the tubing , leaving along section of tubing attached to platelets concentrate bag
16. Place the platelets product on an agitator & leave at least for one hour to ensure that the platelets are evenly re- suspended. Platelets count cannot be performed accurately on a product immediately after centrifugation.

17. Strip the tubing several times, mixing its contents well with the contents of the platelets concentrate bag . let the concentrate flow back into the tubing . seal off a segment of the tubing so that the platelet concentrate bag remains sterile.
18. Perform a platelet count on the platelet concentrate. calculate the number of platelets in the platelets concentrate

No. of plt in pc = plt count /mm X 1000 X volume of pc

19. calculate **% yield = no. of plt in pc X 100 %**
no. of plt in PRP
20. Repeat steps 13 through 18 using different speeds & times of centrifugation.
21. Compare the yields for each set of centrifuge conditions.
22. Select the shortest time & lowest speed that result in the highest % yield of platelets in the platelets concentrate .

Once each centrifuge has been calibrated , it is not necessary to recalibrate unless there is a problem with the mechanical function of the centrifuge

Definitions :

1. **Acceleration time**: The required time for centrifuge to reach the maximum programmed speed
2. **Deceleration time**: The required time for centrifuge to come to complete stopping.
3. **Light spin** :This spin is used for plasma separation to prepare platelets rich plasma (PRP)

   PRP = 2000 x g. 3minites

4. **Heavy spin** : This spin is used for :
   a. Packed RBC PREPARATION = 500XG. 5 MINUTES .
   b. Platelets concentrate= 500XG. 5 MINUTES .
   c. Cell-free plasma= 700XG. 5 MINUTES .
   d. Cryoprecipitate= 700XG. 5 MINUTES .

To calculate the relative centrifuge force :

$$RCF = 28.38 \times R \times (RPM/1000)2$$

where:

RCF = relative centrifugal force (× g).

R = radius of centrifuge roster in inches.

RPM = revolutions per minute.

Different Component Separation Programs

Program items	PRP	Platelets Concentrate	Cryoprecipitate
Spin	Light spin	Heavy spin	Heavy spin
Sped	2600 rpm	3500 rpm	3500 rpm
Time	8 min	8 min	8 min
Temperature	21 °C	21 °C	4 °C
Acceleration time	4 min	3.5 min	3.5 min
Deceleration time	12 min	14 min	12 min

5. Centrifuge Maintenance

1. Daily external and internal cleaning of the machine .
2. Immediate cleaning of any spilling either external or internal .
3. Weakly cleaning of the machine filter .
4. Recalibration the centrifuge in case of :
   - Machine repair .
   - Machine adjustment .
   - Platelets concentrate fall below the acceptable level .

6. Safety

I. Electrical safety :

1. Make sure that the machine wall outlet receptacle is properly wired and earth ground .
2. Do not place containers holding liquid on or near the chamber door . If they spill liquid may get into centrifuge and damage the electrical or mechanical components .

II. Mechanical safety :

1. Before starting the centrifuge make sure that rotor tie down device .
2. Do not exceed the maximum rate of the rotor in use .
3. Never attempt to solve or stop the rotor by hand .
4. Never run the centrifuge when door is opened .
5. Never attempt to override the door interlock system while the rotor is spinning.
6. Do not lift or move the centrifuge while drive motor is spinning .
7. In case of power failure do not attempt to retrieve the sample from the centrifuge for at least one hour .

III. Biological safety :

1. Leakage spills or loss of sample containment may generate aerosols observe all Proper safety precaution .
2. Handle body fluid with care because they can transmit diseases (HIV , HCV , and HBV)
3. Handle all infectious samples according to good laboratory procedures to prevent spread of infectious diseases .

IV. Safety against risk of fire :

1. Fuse protects electrical circuit within the centrifuge against over current conditions .
2. For continued protection against the risk of fire , replace only with the same type and rating specified .
3. The centrifuge is not designed for use with materials capable of developing flammable or explosive vapors. Don't centrifuge such materials (for example ,chloroform or ethyl alcohol) neither in the machine nor handle or store them within 30-cm clearance envelope surrounding the centrifuge

Separation of packed cells and FFP (using double bag)

SOPs \HGA\.....H \ BB\ CS \ 202

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Fore utilizing use of blood it is necessary to use the components as per the need rather than using whole blood.

2. Responsibility

All staff at blood components department
All trained staff at both blood donation and blood issuing department who are authorized of blood collection and blood separation.

3. Equipments and material requirements

1. Metal clips and hand sealer.
2. Refrigerated centrifuge.
3. Plasma expresser.
4. Electronic weighing scale.
5. Double pan weighing balance.
6. Double bags (450ml).

4. Procedure.

Preparation of packed cells and FFP 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 bucket 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.
4. 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 50-60 ml of plasma back along with the red cells in the primary bag and this component is Packed Red Cells (PC).

5. Cut the segment of FFP bags short.
6. Store the units of packed cells in quarantine refrigerate at 2-8C
7. Store the units of FFP in quarantine freezer at (-30 —- -80C)

5. Documentation

a. Record the following details in the Component Register

1. Date of separation.
2. Unit number.
3. Blood group and serology results.
4. Signature of technician.

b. Record in stock register of red cells, FFP and platelets after the testing is completed and the units are labeled.

c. Incident reporting: If there are any problems encountered during the component processing write the incident report form and inform the supervisor.

Separation, packed cell, platelets and FFP (using triple bag)

SOPs \HGA\.....H \ BB\CS \ 203

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Fore utilizing use of blood it is necessary to use the components as per the need rather than using whole blood.

2. Responsibility

All staff at blood components department
All trained staff at both blood donation and blood issuing department who are authorized of blood collection and blood separation. .

3. Equipments and material requirements.

1. Metal clips and hand sealer.
2. Refrigerated centrifuge.
3. Plasma expresser.
4. Electronic weighing scale.
5. Double pan weighing balance.
6. Triple bags (450ml).

4. Procedure.

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. Balance the bags in the buckets using dry rubber or unused bags.
4. Keep equally balanced buckets diagonally opposite each other in the refrigerated centrifuge.
5. Position the bags in buckets parallel to the direction of the spin.

6. Keep the bag on the separator on the laminar flow.
7. Break the seal of the tubing connecting to the satellite bag.
   a. Express the plasma into the satellite bag leaving 50-60 ml plasma along with the red cells.
   b. If the bag with additive solution is used, remove all plasma in satellite bag before clamping.
   c. 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 21°C in refrigerated centrifuge after balancing the buckets.
12. Place the bag containing PRP on the expresser stand.
13. Express the plasma into the empty bag leaving 40-60 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 and transfer to deep freezer in issue area when the tests are completed after labeling and entering in the inventory.

Weight Chart for Blood Drive

According to the following equation:

Volume of any component = Wt . of component pack - Wt. Of empty pack
Density of Component

- Density of plasma = 1.03
- Density of RBCs = 1.09
- Density of plat = 1.03
- Density of WB = 1.06

Ideal Weight	405 – 495 ml	→ Prepare RBCs & FFP.
Low Weight	less than 300 ml	→ Discard the unit .
Low Weight	300– 405 ml	→ PRBCs only & Discard Plasma.
Over Weight	495– 630 ml	→ Plasma only & Discard PRBCs
Over Weight	more than 630 ml	→ Discard the unit

5. Documentation

a. Enter following details in the Component Register

1. Date and time of separation.
2. Unit number.
3. Type of bag used.
4. Blood group and serology results.

b. Enter in stock register of red cells, FFP and platelets after the testing is completed and the units are labeled.

c. Incident reporting: If there are any problems encountered during the component processing enter the incident report form and inform the supervisor of blood bank.

Preparation of Cryoprecipitate

SOPs \HGA\.....H \ BB\CS \ 204

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To prepare Cryoprecipitate obtained from fresh frozen plasma.

2. Responsibility

All staff at blood components department

All trained staff at both blood donation and blood issuing department .

3. Equipment and materials required

1- FFP ≥200 mL
2- Metal clips and hand sealer.
3- Sterile blood transfusion bags.
4- Refrigerated centrifuge.
5- Plasma expresser.
6- Electronic weighing scale.
7- Double pan weighing balance.

4. Procedure

A - Preparing of FFP:

1. Collect fresh whole blood into a unit with two integrally attached transfer containers.
2. Using heavy spin program, centrifuge the blood units at 1-6°C to separate plasma.
3. Collect at least 200 ml of cell free plasma and rapidly freeze at (- 70°C) in will monitored freezer.

Notes:

- Starting of plasma separation must take place as soon as possible
- Plasma must be frozen at least under (- 70°C).

- Plasma must reach this core temperature within 7-8 hrs. of exposure to the target temperature.

B - Preparing of Cryoprecipitate:

1 - After freezing plasma for (3) days at (- 70°C) thaw the frozen FFP at 1-6°C in a blood bank refrigerator overnight.

2 - Separate liquid FFP (when it has a slushy consistency) using heavy spin program (at 5000 rpm for 15 minutes at 4°C) to sediment the cryoprecipitate.

3 - Using plasma extractor, cryoprecipitate depleted plasma into a separate satellite bag.

4 - Leave at least from 10-20 ml of plasma to cover the cryoprecipitate.

5 - Store the two products (CDP and cryoprecipitate) at (- 70°C).

Notes:

- Cryoprecipitate may be prepared from FFP at any time within 12 months of collection
- The expiration date of Cryoprecipitate is one year from the date of blood collection, not from the date it was prepared.
- The cryoprecipitate should be refrozen within 1 hour of thawing. Store at –18°C or colder, preferably at –30°C or colder, for up to 12 months from collection.

C- Labeling:

The labeling must contain the following information:

- ABO and Rh grouping.
- Original blood unit's number.
- Components' name.
- Date of collection and expiration.

5. Documentation

Enter following details in the Component Register

1. Date of separation.
2. Unit number.
3. Blood group and serology results.

Labeling of Blood Bags and Blood Components

SOPs \HGA\.....H \BB\CS \ 205

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Before blood bags are taken on inventory for use they should be labeled depending on their blood groups.

2. Responsibility

- Head of blood components department and a second technician to double check
- All trained staff at blood bank department

3. Material required

1. Preprinted adhesive labels for all components printed as per regulator requirement.
2. The labels are printed and color coded for all components as per blood groups.
3. Group O have red labels, Group A yellow labels, Group B green labels, and Group AB have blue labels.
4. Negative labels also have the same color labels except the color is pale.

4. Procedure

1. After collection and processing whole blood and component units remain in quarantine storage areas.
2. Once all the reports of blood group and TTI testing are ready, place the bags on a table in chronological order.
3. 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 labeling.
4. Write clearly the unit number, date of collection and expiry and the

volume on each label as per the grouping register records.

5. Date of collection and date of expiry is very important. The expiry date depends on the type of bag and component :
   a) In case of a triple and quadruple bag with additive solution, the expiry date is 42 days,
   b) For double and single bags, it is 35 days.
   c) 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.
6. The day of blood collection is considered the day zero for calculating the expiry dates.
7. After the bags are labeled ask a second technician to double check the number and group on the bags tallying them with the records.
8. Enter all labeled 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.
9. Label FFP and Cryo deficient plasma, and platelet concentrates in the same manner.
10. All plasma components have an expiry date of one year.
11. The expiry date of platelet concentrate is 3 days with PVC bags and 5 days if special bags are in use.

5. Documentation

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

Preservation of Blood and Blood Components

SOPs \HGA\.....H \ BB\CS \ 206

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To preserve optimal viability and function of blood and blood component during the storage period

2. Responsibility

It is the responsibility of head of blood components department and all trained staff at both blood donation and blood issuing department who are authorized of blood collection and blood separation.

3. Materials requires

1. Storage Equipment.
2. Blood bank Refrigerator.
3. Deep Freezer.
4. Platelet agitator with incubator.

4. Procedure

1. All untested units should be kept in the quarantine refrigerator
2. After testing is over, release the fully tested. Transfer those deemed suitable for clinical use from quarantine refrigerator to the stock area after labeling. (Refer table).
3. 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 refrigerator (4-6^{0} C).
4. Each shelf is reserved for a particular group having its label stuck on the outer side.
5. Arrange the blood bags according to the expiry dates .
6. 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.

7. Use red cells prepared in open system within 24 hours of preparation.
8. 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°– -80°C) immediately after separation.
9. The shelf life of all these plasma components is 1 year. FFP once thawed and then refrozen is used only as FVIII deficient plasma.
10. Place Random donor platelets (RDP), Single Don^{2}or Platelets (SDP) in a platelet incubator at 20-22^{0} C on an agitator which has shelves to store them.
11. Store the concentrates prepared in PVC bags up to 3 days and those prepared in special platelet bags up to 5 days.
12. Take due care to maintain sterility of all components by keeping all storage areas clean.
13. Monitor and record the temperature to ensure the storage conditions to be appropriate and correct for each product with continuous graphic recorder. Change the charts every week, and achieve them. Check the alarm system every month.
14. Carry out physical stock taking every day and rewrite the inventory.

5. Documentation

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

Table

BLOOD COMPONENT STORAGE					
Product	packed cell (P.C.)	Fresh frozen Plasma (FFP)	Cryopoor Plasma	Platelets	Cryoprecipitate
Storage Temperature	**2-6 C**	**-30C^0 to-80 C^0**	**-30C^0 to-80C^0**	**22 C^0 with Gentle agitation**	**-30 C^0 to-80 C^0**
Shelf life collection from time of	**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**

Inventory of Blood units and Blood Components
SOPs \HGA\.....H \ BB\CS \ 207

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

In order to avoid outdating according to hospital need and to make optimum use of available blood, it is important to maintain a day to day inventory of tested and untested blood

2. Responsibility

Head of blood components department

3. Materials required

Inventory Register

4. Procedure

1. Inventory is maintained on a day to day basis. After labeling the units, enter the numbers of whole blood or packed cells numbers
2. Enter the units group wise and according to the date of collection in the inventory register.
3. After labeling the FFP, enter the unit's numbers group wise in the stock register of FFP similar to blood units.
4. Enter FVIII Deficient Plasma unit's labeled group wise in the stock register similar to plasma register.
5. Enter the labeled cryoprecipitate unit numbers in the register.
6. Clearly mark the inventory of bags that have less volume of blood collected or are reserved for specific patients with specific instructions.

5. Documentation

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

Model SOP on Immunohematology

STANDARD OPERATING PROCEDURE (SOP)

Immunohematology room (IR)

Contents

S No	Subject	SOP No
1.	ABO grouping by forward method	SP 301
2.	Subgroup of A antigen	SP 302
3.	Rh Typing (D –antigen)	SP 303
4.	Weak D Antigen or (Du)	SP 304
5.	ABO grouping by reverse method	SP 305
6.	Preparation of red cell suspension	SP 306
7.	Direct antiglobulin test (DAT),Direct Coomb's Test (Manual)	SP 307
8.	Indirect antiglobulin test (IAT),Indirect Coomb's Test (Manual)	SP 308
9.	Panel Test (Antibody Identification) (Manual)	SP 309
10.	Antiglobulin cross match (Manual)	SP 310
11.	Cross match by **Dia Med –ID Card**	SP 311
12.	Direct antiglobulin test (DAT) by **Dia Med –ID Card**	SP 312
13.	Indirect antiglobulin test , Antibody screening by **Dia Med –ID**	SP 313
14.	Dia Med –ID Panel test	SP 314
15.	Cross match by Biovue Card	SP 315
16.	Cross match by BIO-RAD Card	SP 316

ABO Grouping by forward Method

SOPs \HGA\.....H \BB\IR \ 301

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To determine the correct ABO group of an individual and ensure the reliability of the result

2. Responsibility.

- All staff at blood collection, issuing and separation departments
- Head of blood bank department must be able to resolve any:
  1. Problems with the process.
  2. Difficulties in using the SOP.
  3. To identify and interpret the correct results of the forward and reverse blood grouping methods and to insure that those results match each other without any discrepancy of the results.

3. Definition:

The test procedure is based on the principle of agglutination of RBC possessing the antigen will agglutinate when tested with the corresponding antibody.

4. Materials and equipment required:

1. Freshly collected RBC from either blood donor or patients.

Note: Blood sample should not be older than 24 hours at room temperature (R T), or for 3 days at 2-6°C.

2. Anti-sera Anti-A and Anti-B.
3. Test tubes 12x75 mm.
4. Sero-fuge.
5. Droppers.
6. Racks.
7. Storage refrigerator

8. Microscope.
9. Glass slides.
10. Wooden applicator.

5. Procedure:

A. Technique tube test:

1. Prepare 2-3% cells suspension in isotonic puffer saline (0.9%).
2. Label two tests tubes 12x75 mm A and B.
3. Add 1 drop of anti-A and Anti-B respectively.
4. Add 1 drop of 2-3% cells suspension respectively.
5. Mix well and centrifuge at 1000 RCF for 1 min.
6. Gently re-suspend the cells and examine macroscopically for agglutination.

B. Technique slide test:

1. Place on a clean glass slide at room temperature (18-25°C).
2. 1 drop of ant-A and anti-B reagent.
3. 1 drop of 35-45% of freshly prepared cells suspended in their own group compatible serum or plasma[3].(Consult the reagent manufacturer's instructions to determine the correct cell concentration to be used.
4. Using a clean wooden applicator, mix the reagents and cells over an area of approximately 20x40 mm.
5. Slowly tilt the back and forth and observe for agglutination for a period not exceeding two minutes.

6. Reporting of results:

Forward Grouping		
Anti-A	**Anti-B**	**Interpretation of result ABO Grouping**

-	-	O
+	-	A
-	+	B
+	+	AB

7. Interpretation

1- Strong agglutination or hemolysis of red cells in the presence of any ABO typing reagent constitutes a positive result.

2- A smooth suspension of red cells at the end of 2 minutes is a negative result.

3- Samples that give weak or doubtful reactions should be retested using reverse blood group.

Reagents			Cells Suspension				ABO
Anti-A	Anti-B	Anti-AB	A_1 Cells	A_2 Cells	B Cells	O Cells	Group
+	-	+	-	-	+	+	A
-	+	+	+	+	-	-	B
+	+	+	-	-	-	-	AB
-	-	-	+	+	+	-	O

Subgroups of (A) antigen

SOPs \HGA\.....H \ BB\IR \ 302

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To detect the subgroups of A antigen that differs from other of the same ABO group with the respect amount of A antigen carried on the RBC, and to transfuse the accurate and specific subgroup of A1 and A2 to patients carrying these subgroups in order to avoid any transfusion complications.

2. Responsibilities

All staff at blood collection , issuing and separation departments.

Head of blood bank department must be able to resolve any:

1. Problems with the process.
2. Difficulties in using the SOP.
3. To identify and interpret the correct results of the tested of subgroups of A antigen and to specify the accurate blood group of A1 and A2.and to avoid any results discrepancy .

3. Definition

Subgroups of A are phenotypes that differ from other of the same ABO group with respect to the amount of A antigen carried on the RBC. Subgroup A1 differs quantitatively and qualitatively than A2 antigen. A2 and weak A subgroups can possess an anti-A1 in serum or plasma, which will react with A1 reagent cells during reverse or serum grouping.

4. Materials and equipments required:

1 – Freshly collected RBC from either blood donor or patients. Blood sample should not be older than 24 hours at RT , or for 3 days at 2-6°C

2 – Anti A1 (Dilicohs Bliflorus) 3 – Test tubes 12x75 mm.

4 – Serofuge 5 – Droppers.

6 – Racks.

7 - Storage refrigerator.

8 - Microscope.

5. Procedure:

When there is suspicion of subgroup of (A) (weaker reaction of RBC's with anti(A).

1- Place 1 drops of anti A1 (Dilicohs Bliflorus) into a labeled test tube 12x75 mm.
2- Add 1 drop of 2% - 5% of patient's or donor cells suspension.
3- Control the anti-sera by testing against A1 and A2 cells.
4- Mix thoroughly and centrifuge for one minute at 200g / OR 1min at 1000RPM.
5- Gently shake the test tubes and observe macroscopically agglutination.
6- Read negative results microscopically.
7- Record results and interpretation.

6. Result Interpretation:

- Anti-A1 positive result: A1 and A1B.
- Anti-A1 negative results: A2 and A2B.

Anti A_1 (Dilicohs Bliflorus)	Interpretation
+	A_1 and A_1B
-	A_2 and A_2B

- About 80% of group A are A1 or A1B.
- About 20% of Group A is A2 or A2B.

Therefore the Anti-A1 is occurred at:

- 1-8% of the A2 persons.
- 23-35% of the A2B persons.

Rh Typing (D –antigen)

SOPs \HGA\.....H \ BB\IR \ 303

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

To detect the presence or absence of the D-antigen for the purpose of typing, and correct blood and components transfusion.

2. Responsibility.

-All staff at blood collection, issuing and separation departments.

Head of blood bank department must be able to resolve any:

1- Problems with the process.
2- Difficulties in using the SOP.
3- To identify and interpret the correct results of the tested group of D antigen and to avoid any results discrepancy .

3. Definition

The Rh system is composed of a series of antigens and their corresponding antibodies which together form a highly and complex group system. The methods of detection are basically the same for the detection of the D-antigen and antibodies.

This methods of detection (D-antigen) by using specific anti-D reagent of a high specificity and sensitivity.

4. Materials and equipment required

1- Freshly collected RBC from either blood donor or patients. Blood sample should not be older than 24 hours.
2- Anti-D.
3- Test tubes 12x75 mm.
4- Serofuge.

5- Droppers.

6- Racks.

7- Storage refrigerator

8- Microscope.

9- Control reagent.

10-Glass slides.

11-Wooden applicator.

5. Procedure:

A. The tube technique.

1- Prepare 2-3% cells suspension in physiological saline (0.9%).

2- Place 1 drop of anti-D into a clean, labeled test tube.

Note: The addition of the reagent to the tube before the addition of the red cell suspension acts as a visual check for the presence of the anti-D to eliminate false-negative reactions caused by failure to add the reagent.

3- Place 1 drop of tested RBC suspension.

4- Mix gently and centrifuge 1min at 1000 RPM ,Or for the time, and at the speed, specified by the manufacturer.

5- Gently re-suspend each tube button and read microscopically and macroscopically for the presence of agglutination.

6- Any tubes to be tested showing a negative or questionable test result must be incubated for 15 minutes at 18-25°C for more studding, following incubation, repeat steps 3 and 4.

Results Interpretation:

Anti-D	Results Interpretation
4+ agglutination	Rh positive (D+)
≥ 2+ agglutination	Rh positive (D+)
< 2+ agglutination	Rh must be tested for D weak or Du
1+ agglutination	Test must be repeated using another anti-D reagent.
No agglutination	Rh negative (D-)

B. The slide technique:

1- Prepare a 40-50% suspension of test RBC in autologous serum or plasma of the patient or donors.

2- Place on a labeled glass slide 1 drop of anti-D reagent and 2 drop of tested RBC suspension.

3- Using a clean wooden applicator stick, mix the reagent and cells over an area of about 20x40 mm.

4- Slowly tilt slide back and forth for at least 30 seconds, with occasional further mixing during 2 minutes of time.

5- Read microscopically after 2 minutes over a diffused light. Do not mistake fibrin strands as agglutination , drying of the reaction mixture or rouleaux for agglutination.

6- Any weak reaction should be repeated by tube technique or by any other available technique.

C. The Dia-Med-ID-Micro Typing Technique:

1 - Prepare 0.8% suspension of RBC in a Dia-Med ID diluents.

2 - Using Dia-Med-ID card, remove the aluminum foil from as many as required micro-tubes.

3 - Place in a labeled micro-tube 50 µl of tested RBC suspension and 25 µl of anti-D reagent.

4 - Centrifuge the ID-card for 10 minutes in an ID-centrifuge.

5 - Read macroscopically for agglutination.

6. Recommended sample collection:

1- Freshly collected RBC from either blood donor or patients. Blood sample should not be older than 24 hours.

2- If the test is delayed store the specimen at 2-6°C for 3 days.

3- Specimen collected into EDTA or heparin should be tested within 48 hours of being collected.

4- Specimen collected into ACD, CPD, or CPDA-1 can be tested up to their expiration date.

Testing for Weak D Antigen or (Du)

SOPs \HGA\.....H \ BB\IR \ 304

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose:

To detect the presence of some D-antigen that is expressed so weakly that they are not directly agglutinated by of the most (anti-D reagent) .

2. Responsibility:

All trained staff at blood collection , issuing and separation departments.

Head of blood bank department must be able to resolve any:

1- Problems with the process.
2- Difficulties in using the SOP.
3- To identify and interpret the correct results of the tested of D-antigen or weak D-antigen (Du), and to differentiate between the strong and weak D-expression.

3. Definition:

Some RBC's carry a D-antigen that is expressed so weakly that they are not directly agglutinated by most of anti-D sera, so it is the responsibility of both collection and blood issuing departments staff to screen and differentiate the presence of strong or weak D-antigen through using this SOP.

4. Materials and equipment required:

1 - Freshly collected RBC from either blood donor or patients. Blood sample should not be older than 24 hours.

2 - Anti-D.

3 -Test tubes 12x75 mm..

4 - Serofuge.

5 - Droppers.

6 - Racks.

7 - Storage refrigerator.

8 - Microscope.

9 - Control reagent.

10- Anti-IgG.

11- IgG coated RBC's.

5. Procedure:

1 - Place 1 drop of anti-D reagent in a well labeled and clean test tube 12x75 mm.

2 - Add 1 drop of 2- 5% cell suspension in 0.9% saline to be tested.

3 - Mix and incubate for 15-30 minutes at 37°C.

4 - Centrifuge for 30 seconds at 1000 rpm.

5 - Gently re-suspend the RBC's bottom and examine for agglutination.

6 - If strong agglutination is observed at this point of the test, record the result as D+.

7- Wash the red cells at least three times with saline.

8- Add ant globulin reagent according to the manufacturer's directions.

9- Mix gently and Centrifuge for 30 seconds at 1000 rpm.

10- Gently re suspend and examine for agglutination, grade, and record.

11- Add IgG-coated control cells to confirm the validity of negative antiglobulin test results (If available)

6. Interpretation

1- Agglutination in the anti-D tube before adding anti globulin reagent indicates that the red cells are D positive. It is incorrect to report the results as "Du positive" or "D negative, Du positive."

2- No agglutination of the red cells in the anti-D tube before adding anti globulin reagent then positive agglutination indicate Du positive

ABO grouping by reverse method

SOPs \HGA\.....H \ BB\IR \ 305

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose:

To confirm the results of ABO grouping performed by Forward grouping method .

2. Responsibilities:

All trained staff at blood collection , issuing and separation departments.

Head of blood bank department must be able to resolve any:

Problems with the process.

1- Difficulties in using the SOP.
2- To identify and interpret the correct results of the forward and reverse blood grouping methods and to insure those results match each other without any discrepancy of the results.

3. Definition:

Blood grouping results obtained from forward method using anti-A, anti-B sera should be considered valid if confirmed by using a reverse ABO grouping method at the same time.

4. Materials and equipment required:

1- Serum or plasma from collected blood sample should not be older than 24 hours.
2- RBC A1, A2, B, and O cells in ready to use 2-5% suspension (Commercial or locally prepared).
3- Test tubes 12x75 mm.
4- Serofuge .
5- Droppers.
6- Racks.
7- Storage refrigerator.

5. Procedure:

1. Mark four tubes 12x75 mm A1, A2, B, and O.
2. Add 2-3 drops of patients or donor serum to each tube.
3. Add 1drop of RBC A1, A2, B, and O in ready to use 2-5% suspension respectively.
4. Gently mix and centrifuge for 1 minute at 1000 RPM.
5. Re-suspend the cells by gentle shaking of the tube.
6. Observe the presence of any agglutination or hemolysis macroscopically and microscopically.
7. Compare serum test results with those obtained in testing red cells

6. Results interpretation:

Reaction with cells A1	A2	B	O	Isoagglutination	Blood group
-	-	+	-	Anti B	Group A
+	+	-	-	Anti-A	Group B
-	-	-	-	Non	Group AB
+	+	+	-	Anti-A and Anti-B	Group O
- = No Agglutination or no hemolysis				+ = Agglutination or hemolysis	

Positive reactions characteristically show (+3 to +4) agglutination by reagent ABO antibodies; reactions between test serum and reagent red cells are often weaker. The serum tests may be incubated at room temperature for 5 to 15 minutes to enhance weak reactions.

7. Quality control for cell suspension:

1. **Check** A1, A2 cells against Anti A1:
   - A1 cells must be positive.
   - A2 cells must be negative.
2. **Check** B cells Against Anti-B:
   - B cells must be negative.
3. **Check** O cells against Anti-A and Anti-B:
   - O cells must be negative.

Preparation of A1, A2, B and O cells:

1 – Label 4 clean tubes of A1, A2, B and O cells Respectively.

2 – Add to each tube 5 ml of confirmed blood group respectively.

3 – wash the cells 3 time using physiological saline 0.9%.

4 – After washing suspend the cells at 2-5% in physiological saline 0.9%.

5– Add preservative solution.

6 – Store the cell's containers at 2-6◦C.

Preparation of Red Cell Suspensions

SOPs \HGA\.....H \ BB\IR \ 306

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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 morning shift duty technician must prepare A, B & O red cell suspension for the day's use.

3. Material

A- Equipment:

Calibrated centrifuge

B- Reagents:

0.9% saline.

C- Specimen:

- Anticoagulated blood specimen of donor.
- Anticoagulated blood specimen of patient.
- Donor unit segment.

D- Glassware:

- Pasteur pipettes.
- Serum tubes

E- Miscellaneous:

- Discard box.
- plastic beakers.
- Rack to hold tubes.

4. 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) labeled tube.
3. Place 1 drop of red cells each from 3 of B group sample tubes or segment into the (B) labeled tube.
4. place 1 drop of red cells each from 3 of O group sample tubes or segment into the (O) labeled tube
5. Fill the tube ¾ 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 color comparable to that of the reagent red cell suspension.
8. If the color is too dark, add additional isotonic saline to the tube until the suspension color is right.
9. If the color 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.

5. Donor/ Patients' sample

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

6. Limitations:

- 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.

7. Documentation

- Hemolysis of the red blood cells from improper washing may result in false results.[4]
- A cell suspension that is too heavy or too light may produce false positive or false negative results.
- For best results use red cell suspensions on the day of preparation only unless stability for a longer time has been validated.

Direct antiglobulin test (DAT)

Direct Coombs Test (MANUAL)

SOPs\HGA\.....H \ BB\IR \ 307

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose:

To determine whether or not a patient's RBC have become sensitized by anti-bodies complexes, which have formed in vivo.

2. Responsibilities:

- All trained staff in blood bank department can use this SOP
- Head of blood bank department must be able to resolve any:
  1- Problems with the process.
  2- Difficulties in using the SOP.
  3- To identify and interpret the correct results of DAT test.

3. Restriction:

Reject of all clotted , hemolysed and lipemic samples

4. Definition:

It is the responsibility of the blood issuing department's staff to perform the required DAT test to exclude the following:

- Hemolytic disease of newborn.
- Autoimmune hemolytic anemia.
- Drug induce hemolytic anemia.
- Transfusion reaction.

5. Materials and equipment required:

1 - Freshly collected EDTA Blood from patients. Blood sample should not be older than 24 hours.

2 - Anti-human globulin.

3 -Test tubes 12x75 mm.

4 - Serofuge.

5 - Droppers.

6 - Racks.

7 - Storage refrigerator.

8 - Microscope.

9 - Control reagent (IgG coated RBC's).

6. Test procedure:

1. Place 2 drops of the patient's RBCs in a well-labeled test tube.
2. Wash 3 time using physiological saline 0.9% by filling the tube with saline and centrifuging and discarding the supernatant. Resuspend the cells each time before adding the saline for washing
3. Prepare 2% to 5% cells suspension.
4. Place 2 drops of the cell suspension in a well-labeled test tube.
5. Add 2 drops of anti-human globulin (the amount may be referred to the manufacturer).
6. Centrifuge for 1 minute at 1000 rpm and shake gentle to see any agglutination
7. Read under microscope

7. Result interpretation:

The DAT is positive when agglutination is observed after immediate centrifuge or after centrifugation that followed room temperature incubation.

The DAT is negative when no agglutination is observed at either test phase.

NOTE:

False negative result with DAT may be cause by:

1. Inadequate washing.
2. Elution of the antibodies due to a delay in completion of the test.
3. Improper storage of cells or serum.
4. Contamination of antihuman globulin.

5. Failure to add antihuman globulin .
6. Shaking the tube very vigorously.

False positive reaction resulting in:

1. Adding anti Rh instead of AHG.
2. Improperly cleaned glassware.
3. Bacterial contamination of cells or blood sample.
4. Marked reticulocytosis which absorb the AHG.
5. Prolong storage of saline in glass or storage saline in metal containers.

8. Quality control

You must confirm the negative DAT by adding globulin coated cells to the DAT test tube at end of the test .If the globulin are not agglutinated the negative DAT result is considered invalid and the test must be repeated.

Indirect antiglobulin test (IAT)

Indirect Coombs test (Antibody screening) (MANUAL)

SOPs \HGA\.....H \ BB\IR \ 308

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose:

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 in blood issuing department 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 for Antibody Identification.

3. Restrictions:

Hemolysis sample
Lipemic sample.

4. Sample:

Serum free of hemolysis and lipids

5. Items Required:

1- Plastic Tubes.
2- Manufacture RBCs I, II, III reagent.
3- Microscope.
4- Glass slides.
5- Micropipette (10-200 µ).
6- Centrifuge.
7-Water Bath.
8- Yellow tips (200 µ).
9- Gloves with latex.
10- Timer.
11- Sample: Serum.
12- Bovin Albumin.
13- Anti human globulin.

6. Procedures:

1- Label 3 plastic tubes as I, II, III.
2- Take 1 drop of each manufacture RBCs reagent in its own tube.

3- Add 2 drops from serum patient to all tubes.
4- Then add 2 drops of Bovine albumin to each tube.
5- Mix and incubate at 37°C for 15-30 minutes.
6- Centrifuge the tube for 1 minute.
7- Shake gentle to see any agglutination, if not continue.
8- Wash 3 times with saline, to discard unbounded Abs and excess Bovin albumin.
9- Add 2 drops of antihuman globulin and incubate for 5 minutes.
10- Centrifuge for 1 minute at 1000 rpm then Read the result.

7. Results:

Read by Vision :

Shake the tube gently and see if there is agglutination or not.

Read by Microscope:

- On a glass slide take one drop and see under microscope if there is agglutination or not.
- Finely if there is agglutination in any tube the Indirect Coombs test is Positive, and if there is no agglutination the Indirect Coombs test is Negative.

Panel test

Antibody Identification (Manual)

SOPs \HGA\.....H \ BB\IR \ 309

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose:

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

2. Responsibilities:

It is the responsibility of the technician in blood issuing department to perform the Antibody screening (IAT) and Antibody Identification using proper cell concentrations. One technician performs all tests and another checks it. If any unexpected blood group antibody is detected, inform the head of blood bank for further investigations..

3. Restrictions:

Hemolysis sample.

Lipemic sample

4. Sample:

Serum free of hemolysis and lipids

5. Items Required:

1- Plastic Tubes.

2- Manufacture RBCs 1 - 11 reagents.

3- Microscope.

4- Glass slides.

5- Micropipette (10-200 µ).

6- Centrifuge.

7- Water Bath.

8- Yellow tips (200 µ).

9- Gloves with latex.

10- Timer.

11- Sample: Serum.

12- Bovine Albumin.

13- Anti human globulin.

6. Procedures:

1- Label 11 plastic tubes as 1 to 11.
2- Take 1 drop of each manufacture RBCs reagents in its own tube.
3- Add 2 drops from serum patient to all tubes.
4- Then add 2 drops of Bovine albumin to each tube.
5- Mix and incubate for 15-30 minutes.
6- Centrifuge the tube for 1 minute at 1000 rpm.
7- Shake gentle to see any agglutination, if not continue.
8- Wash 3 times with saline to discard unbounded Abs and excess Bovin albumin.
9- Add 2 drops of antihuman globulin and incubate for 5 minutes.
10- Centrifuge for 1 minute at 1000 rpm then Read the result.

7. Results:

Read by Vision :

Shake the tube gently and see if there is agglutination or not.

Read by Microscope:

- On a glass slide take one drop and see under microscope if there is agglutination or not.
- Finely to determine the type of antibody follow up the chart that found in the kit.

Antiglobulin Cross-match –Manual

SOPs \HGA\.....H \ BB\IR \ 310

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

This procedure is applied for compatibility testing of all patients requiring transfusion especially for 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 blood issuing department to perform anti-globulin cross match using quality controlled reagents and proper cell concentrations and document the results. If any unexpected antibody is detected, Antibody screening (IAT) and Antibody Identification should be performed.

3. Material required

a) Equipment:

1- Refrigerator to store samples & reagents at 2- 6°C.
2- Table top centrifuge.
3- Automated Cell Washer.
4- Microscope.
5- Dry bath.

b) Specimen:

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

c) Reagents:

1- 22% bovine albumin.

2- Antihuman globulin reagent(anti-IgG+anti-C3d).
3- IgG sensitized control cells.
4- 0.9% Saline.
5- Distilled water.

d) Glassware:

1- Serum tubes.
2- Coombs' tubes.
3- Pasteur pipettes.
4- Glass slides.

e) Miscellaneous:

1- Rubber teats.
2- Disposal box.
3- plastic beakers.
4- Aluminum racks to hold serum and coombs' tubes

4. Procedure

A. Principle:

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

B. Anti-Globulin Cross-Match:

1. Label tube with patient/unit and test identification.
2. Add 2 drops of patient serum to each tube.
3. Prepare a 2-5% cell suspension in saline from each donor unit segment. (Sop\IR\06)
4. Add 1 drop of donor's 2- 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 15-30 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- sensitized control cells. Centrifuge, re-suspend and read for agglutination. Grade and record test results. After the addition of IgG-sensitized control cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.(If available)

C. Interpretation:

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

D. Limitations:

The anti-globulin cross- match will not:

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

5. Documentation:

Enter all results on the transfusion record card and on computer.

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.

Cross match by Dia Med –ID Card

SOPs \HGA\.....H \ BB\IR \ 311

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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

2. Responsibility

It is the responsibility of the technician in blood issuing department to perform advanced cross match and document the results. If any unexpected antibody is detected, Antibody screening (IAT) and Antibody Identification should be performed.

3. Reagent

1- ID-Card "LISS/Coombs" with 6 micro tubes containing polyspecific AHG (rabbit anti-IgG and monoclonal anti-C3d, cell line C139-9) within the gel matrix.

2- ID-Diluent 2:modified LISS for red cell suspension.

4. Sample material

1- For optimal results, the determination should be performed using a freshly drawn sample, or In accordance with local laboratory procedures for sample acceptance citrate, EDTA or CPD-A anticoagulant.

2- Samples drawn into plain tubes (no anticoagulant) may also be used.

3- When the use of serum instead of plasma is required, the serum must be well cleared by centrifugation at 1500 g for 10 minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

5. Restrictions:

- Clotted sample rejected if used anticoagulated sample

- hemolyzed and lipemic sample.

6. Preparation of blood sample

a) Red cell suspension for DAT or auto control .

- Prepare a 0.8% red cell suspension in ID-Diluent 2 as follows:
- Allow the diluent to reach room temperature before use .

1- Dispense 1.0ml of ID-Diluent 2 into a clean tube .

2- Add 10 µL of packed red cells, mix gently .

The cell suspension may be used immediately

b) Plasma or serum for indirect antiglobulin test (IAT) procedure .

Where samples are not for immediate testing they should be stored at 2-8°C after separation (see also under "Sample material") for a maximum of 48 hours, thereafter -20°C

7. Procedures

Note: Do not use ID-Cards which show sins of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the micro tubes or on the underside of the aluminum foil.

1- Identify the appropriate micro tubes of the ID-Card "LISS-Coombs" with recipient's and donor's name or number.
2- Remove the aluminum foil from as many micro tubes as required by holding the ID card in the upright position.
3- Pipette 50 µL of the donor red cell suspension to the appropriate micro tube.
4- For the auto control, pipette 50 µL of the patient's own red cell suspension to the appropriate micro tube
5- Add 25 µL of the patient's plasma or serum to each micro tube .
6- Incubate the ID-Card for 15 minutes at 37^0C in the ID-Incubator .
7- Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge .
8- Read and record the results

8. Interpretation of the results

1. Principle

a) **Positive** : Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.

Too heavy or too week red cell suspensions can causes aberrant results.

b)**Negative:** Compact button of cells on the bottom of the micro tube.

2. Reaction

- A negative reaction indicates compatibility of the donor blood with the recipient
- A positive reaction indicates incompatibility of the donor blood with the presence of antibodies directed against antigens on the donor red cells. Further investigation to identify the antibody specificity should be performed.

9. Limitation

1- ID card which show air bubbles or gel drops in the upper part of the micro tubes and/or the seal, must be centrifuged before use.

2- Certain drugs are known to cause positive reactions in anti-human globulin procedures.

3- Some pathological conditions are also reported as causing positive reactions in anti-human globulin procedures.

4- Cells that have become polyagglutinable, due to crypt antigen exposure e.g. T antigen, either in vivo or in vitro may react with all human sera. Father investigation of such reactions is required .

5- Bacterial or other contamination of materials used can causes false positive or false negative result.

6- Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the micro tube after centrifugation.

7- Use of suspension solution other than ID-Diluent 2 may modify the reaction.

8- The use of the test cell reagent than "ID-Dia Cell" or "ID-Dia Panel" may modify the reaction patterns.

Direct antiglobulin test (DAT) by Dia Med –ID Card
SOPs \HGA\.....H \ BB\ IR \ 312

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

This procedure applies to determine sensitized RBCs for patient's pre-transfusion blood and prenatal specimens in vivo with immunoglobulin and/or complement.

2. Responsibility

All trained technicians in blood bank department can use this SOP.

The Head of the blood bank must resolve any problem with the process and difficulties in using this SOP.

3. Reagent :

a. ID-Card "LISS/Coombs" with 6 micro tubes containing polyspecific AHG (rabbit anti-IgG and monoclonal anti-C3d, cell line C139-9) within the gel matrix .

b. ID-Diluent 2:modified LISS for red cell suspension .

4. Sample material

For optimal results, the determination should be performed using a freshly drawn sample, or In accordance with local laboratory procedures for sample acceptance citrate, EDTA or CPD-A anticoagulant

Restrictions:

1- Clotted sample rejected.

2- Hemolysis sample.

3- Lipemic sample

5. Preparation of blood sample

Red cell suspension for DAT or [auto control (If available)]

Prepare a 0,8% red cell suspension in ID-Diluent 2 as follows:

Allow the diluent to reach room temperature before use.

1. Dispense 1,0 mL of ID-Diluent 2 into a clean tube.
2. Add 10 µL of packed red cells, mix gently.

The cell suspension may be used immediately.

6. Procedures

Do not use ID-Cards witch show sins of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper of the micro tubes or on the underside of the aluminum foil

Direct antiglobulin test (DAT) :

1- Identify the appropriate micro tubes of the ID-Card "LSS/Coombs" with the patients or donors name or number.
2- Remove the aluminum foil from as many micro tubes as required by holding the ID card in the upright position.
3- Pipette 50 µL of the red cell suspension to the appropriate micro tube.
4- Centrifuge the ID-Card for 10minutes in the ID-Centrifuge.
5- Read and record the results

Note:

A positive DAT generally indicates that the red cells are coated in vivo with immunoglobulin and/or complement.

7. Interpretation of the results

a) Principle

- **Positive** : Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.
- **Negative** : Compact button of cells on the bottom of the micro tube.

b) Reaction for : Direct antiglobulin test (DAT) :

- **A negative reaction** indicates absence of detectable IgG antibodies or C3d complement component on the red cells .
- **A positive reaction** (± to ++++) indicates that the patient's red cells are sensitized (red cells coated with IgG antibodies and/or C3d) .

8. Limitation : See SOP\IR\ 311

Indirect antiglobulin test Antibody screening by Dia Med –ID

SOPs\HGA\.....H \ BB\IR \ 313

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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 in blood issuing department to perform the antibody screening using proper cell concentrations. One technician performs all tests and another checks it. If any unexpected blood group antibody is detected, inform the staff for Antibody Identification

3. Reagent :

c. ID-Card "LISS/Coombs" with 6 micro tubes containing polyspecific AHG (rabbit anti-IgG and monoclonal anti-C3d, cell line C139-9) within the gel matrix .

d. ID-Diluent 2:modified LISS for red cell suspension .

e. ID-DiaCell, I ,II ,III : Test cell reagent .

4. Sample material

1- For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.

2- When the use of serum instead of plasma is required, the serum must be well cleared by centrifugation at 1500 g for 10minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

Restrictions:

- Reject both Hemolysed and Lipemic sample.

5. Preparation of blood sample

Plasma or serum for indirect antiglobulin test (IAT) procedures

Where samples are not for immediate testing they should be stored at 2-8 °C after separation (see also under “Sample material”) for maximum of 48 hours, thereafter at -20 °C.

6. Procedures

Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper of the micro tubes or on the underside of the aluminum foil.

Antibody screening (IAT)

1- Use ready-to-use test cell reagents "ID-Diacell".

2- Allow the test cell reagents and samples to reach room temperature before use.

3- Identify the appropriate micro tubes of the ID-Card "LSS/Coombs" with the patients or donors name or number

4- Remove the aluminum foil from as many micro tubes as required by holding the ID card in the upright position

5- Pipette 50 µL of each "ID-DiaPanel" test cell to the appropriate micro tube (marked with the corresponding test cell).

6- When an auto control is to be included, pipette 50 µL of the sample's own red cell suspension to the appropriate micro tube .

7- Add 25 µL of the patients or donors plasma or serum to each micro tube .

8- Incubate the ID-Card for 15 minutes at 37^0C in the ID-Incubator .

9- Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge .

10-Read and record the results .

Note:

For the indirect antiglobulin test (IAT), labour intensive washing procedures are eliminated, due to the fact that the red cell suspension is added to the micro tube before the plasma/serum, creating a barrier over the gel suspension, thus avoiding neutralization of the AHG by serum IgG proteins.

7. Interpretation of the results

a) Principle

- **Positive** : Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.
- **Negative** : Compact button of cells on the bottom of the micro tube .

b) Reaction for : Antibody screening :

1- A negative reaction indicates absence of detectable irregular antibodies in the patient's or donor's serum or plasma .

2- A positive reaction indicates the presence of irregular antibodies .

3- Enter the reaction obtained on the antigen table .

4- Following the reaction pattern and the antigen configuration, the type of antibody present may be indicated. Perform the usual further test to identify the antibody.

5- A positive reaction with one or more test cells and a negative auto control suggest the presence of a specific antibody.

6- A positive reaction with all cells and a positive auto control may be due to non-specific reaction.

7- A positive reaction with all cells and a positive auto control but with one or more test cells showing a stronger positive reaction than the auto control, the patient sample should be submitted for further testing, to investigate the possibility of an underlying allo-antibody.

8. Limitation : See SOP\IR\ 311

Dia Med–ID Panel test

SOPs\HGA\.....H \ BB\IR \ 314

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

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

2. Responsibility

It is the responsibility of the technician in blood issuing department to perform the ; Antibody screening (IAT) and Antibody Identification using proper cell concentrations. One technician performs all tests and another checks it. If any unexpected blood group antibody is detected, inform the head of blood bank for further investigations

3. Reagent :

1- ID-Card "LISS/Coombs" with 6 micro tubes containing polyspecific AHG (rabbit anti-IgG and monoclonal anti-C3d, cell line C139-9) within the gel matrix

2- ID-Diluent 2:modified LISS for red cell suspension .

3- ID-Dia Panel: Test cell reagent .

4. Sample

- For optimal results, the determination should be performed using a freshly drawn sample, Samples drawn into plain tubes (no anticoagulant) .
- The serum must be well cleared, by centrifugation at 1500g for 10minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

- When sample are not for immediate testing they should be stored at 2-8 °C after separation for a maximum of 48 hours, thereafter at -20 °C.

5. Restrictions:

- Hemolysis sample.
- Lipemic sample.

6. Procedures

1- Use the ready-to-use test cell reagent "ID-DiaPanel".
2- Allow the test cell reagent and samples to reach room temperature before used .
3- Identify tow ID-Card "LISS/Coombs" with the patient's or donor's name or number.
4- Remove the aluminum foil from as many micro tubes as required by holding the ID card in the upright position.
5- Pipette 50 µL of each “ID-DiaPanel” test cell to the appropriate micro tube (marked 1 to 11).
6- Pipette 50 µL of the sample's own red cell suspension to the 12^{th} micro tube (auto control).
7- Add 25 µL of the patient's or donors plasma or serum to all 12microtubes.
8- Incubate the ID-Card for 15minutes at 37^{0}C in the ID-Incubator.
9- Centrifuge the ID-Card for 10minutes in the ID-Centrifuge.
10- Read and record the results.

7. Interpretation of the results

a) Principle

- **Positive** : Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.
- **Negative** : Compact button of cells on the bottom of the micro tube.

b) Antibody Identification

1- A positive reaction indicates the presence of irregular antibodies. Enter the reaction obtained on the antigen table. Verify that the lot number of the test

Cell reagents "ID-Dia Panel" corresponds to the lot number indicated on the antigen table.

2- Following the reaction pattern and the antigen configuration, the type of antibody present can in the most cases, be identified (auto control must be negative); (If available)

3- A positive reaction with all " ID-Dia Panel" test cells and a negative auto control may be due to non-specific reactions or may indicate the presence of an alloantibody directed against a high frequency antigen.

4- A positive reaction with all " ID-Dia Panel" test cells and a positive auto control may be due to non-specific reactions.

5- A positive reaction with all " ID-Dia Panel" test cells and the auto control but with one or more test cells showing stronger reactions than the auto control, may indicate an underlying allo-antibody and further investigation should be undertaken.

8. **Limitation : See SOP\IR\311**

Cross match by Biovue Card

SOPs\HGA\.....H \ BB\IR \ 315

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Column Agglutination Technique for Compatibility Test between donor's RBCs and patient serum to determine the suitable blood unit for patient.

2. Responsibilities:

- All trained staff in blood bank specially in issuing department can use this SOP.
- Head of blood bank must resolve any problems with the process and difficulties in using the SOP.

3. Sample:

Serum free of hemolysis, plasma of EDTA.

4. Restrictions:

- Clotted sample rejected if used EDTA.
- Hemolysis sample.
- Lipemic sample.

5. Items required:

1- Bio Vue system (Centrifuge, Incubator ,pipette, work station).
2- Centrifuge.
3- Glass tubes, markers & racks.
4- Sample to be tested.

6. Procedure:

1- Prepare the polyspecific cassette by labeling the name of the patient on one side and the user and date in the other side.
2- Open the wells according to the number of tests.

3- Make 2-5% cell suspension of the donor's unit.
4- 50µl of BLISS in each well used.
5- dispense 10µl of red cell suspension of the donor in each test well and of the patient in control well.
6- dispense 40µl of serum or plasma sample of the patient in each well.[5]
7- Incubate for 10 minutes.
8- Centrifuge for 5 minutes.
9- Comment and write the results.
10- Write the final result on the compatibility test results register.
11- Fill in a compatibility label.

	Donor	Patient
BLISS	50µl	50µl
Donor/Patient Cell Suspension	10µl	10µl
Patient Serum	40µl	40µl
Incubation	10 min	10 min
Centrifugation	5 min	5 min
Reaction		Auto control

7. Interpretation of the results :

If the IAT is confirmed as negative, the blood is compatible and can be issued for the patient after correct documentation and labeling has been completed.

Table: interpretation of result:

Cross matching	Auto control	Interpretation
Negative	Negative	**Compatible blood**
Positive	Negative	**Incompatible blood.(if multiple incompatible units proceed to antibody detection and identification)**
Positive	Positive	1- **Auto-antibody** 2- **If history of recent transfusion , perform DAT.** 3- **Abnormalities of patient's serum / or anomalous reagent-related serologic reaction.** 4- **Bad quality sample [taken from medication line].** 5- **Cold agglutinin.** **N.B [Seek advice of senior staff]**

Cross match by BIO-RAD Card

SOPs \...H \IR \ 316

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1. Purpose

Column Agglutination Technique for Compatibility Test between donor's RBCs and patient serum to determine the suitable blood unit for patient.

2. Responsibilities:

- All trained staff in blood bank specially in issuing department can use this SOP.
- Head of blood bank must resolve any problems with the process and difficulties in using the SOP.

3. Sample:

Serum free of hemolysis, plasma of EDTA.

4. Restrictions:

- Clotted sample rejected if used EDTA.
- Hemolysis sample.
- Lipemic sample.

5. Items required:

5- BIO - RAD system (Centrifuge, Incubator pipette, work station).
6- Centrifuge.
7- Glass tubes, markers & racks.
8- Sample to be tested.

6. Procedure:

a. Prepare the polyspecific cassette by labeling the name of the patient on one side and the user and date in the other side.

2. Open the wells according to the number of tests.

3. Make 0.8% red cell suspension of the donor's unit and patient sample (for auto control)
4. Despines 1.0 ml of ID – Diluent 2 into clean tube
5. Add 20 µl packed red cells , mix gently .
6. dispense 50 µl of red cell suspension of the donor in each test well and of the patient in control well.
7. dispense 25 µl of serum or plasma sample of the patient in each well.
8. Incubate for 15 minutes at 37ºc in ID incubator.
9. Centrifuge for 10 minutes in ID centrifuge .
10. Comment and write the results.
11. Write the final result on the compatibility test results register.
12. Fill in a compatibility label.

	Donor	Patient
Donor/Patient cell Suspension	**50µl**	**50µl**
Patient Serum	**40µl**	**40µl**
Incubation	**10min**	**10 min**
Centrifugation	**5 min**	**5 min**
Reaction		**Auto control**

7. Interpretation of the results

If the IAT is confirmed as negative, the blood is compatible and can be issued for the patient after correct documentation and labeling has been completed.

Table: interpretation of the result:

Cross matching	Auto control	Interpretation
Negative	Negative	**Compatible blood**
Positive	Negative	**Incompatible blood.(if multiple incompatible units proceed to antibody detection and identification)**
Positive	Positive	**1. Auto-antibody** **2. If history of recent transfusion , perform DAT.** **3. Abnormalities of patient's serum / or anomalous reagent-related serologic reaction.** **4. Bad quality sample [taken from medication line].** **5. Cold agglutinin.** **N.B[Seek advice of senior staff]**

Model SOPs on Quality Assurance

STANDARD OPERATING PROCEDURE (SOP)

Quality assurance (QA)

Contents

S No	Subject	SOP No
1	Personnel	SP 401
2	Standard tests, equipment and reagents	SP 402
3	Quality Assurance (QA): 1-Quality Control (QC) • Quality control of reagents (anti-sera) • Quality control of B.B equipment • Quality control of blood and blood components 2-Documentation 3- Corrective action 4-Training	SP 403

Personnel

SOPs\HGA\.....H \BB\QA \ 401

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1- The blood bank department shall have adequate number of personnel qualified by education, training and/ or experience.

2- The technical in-charge/supervisor of each section shall be responsible for the technical operation and to ensure quality assurance.

3- The staff shall receive on the job orientation/induction briefing and training specific to quality assurance and quality management for services offered.

4- All staff shall participate in continued medical education programs

5- All blood bank personnel shall be trained on the use and maintenance of the equipment.

Blood Bank Standard Operating Procedures (SOPs)

Standard tests, equipment and reagents

SOPs\HGA\.....H \ BB\QA \ 402

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

1- Each blood bank shall perform the required tests ,and must have standard equipment and standard reagents

Table: standard tests at blood bank department:

Blood Donation
ABO grouping (Direct and Reverse)
Rh D typing
Weak D test
Test for Donor Hemoglobin
Screening of donated blood for HIV, HBV, HCV
Donor Red cell phenotyping

Compatibility tests
ABO grouping
Rh typing
Cross-matching test
Antibody screening test to detect unexpected antibodies
Antibody identification test
Recipient Red cell phenotyping

Quality Control tests
QC tests on blood group serology reagents

QC tests on TTI reagents
QC tests on blood components
Other tests
Tests for transfusion reaction investigation

2- Equipment control process shall be in place for calibration, and periodic maintenance.

3- Quality controls of reagents and test kits shall be performed periodically.

4- Records of all installed equipment shall be maintained.

Quality Assurance (QA)

SOPs\HGA\.....H \ BB\QA \ 403

Version: …1……	Head of department: ……
Date effective: …… …..…...	Quality Officer: ……...
Copy number: ……	Director of : …….....

Blood and blood components are intended for use in the cure, treatment or prevention of diseases in humans and have been classified as medicinal products; all blood products shall be regulated and controlled

In-order to ensure that blood and blood components maintain consistent quality and safety standards, all blood bank departments shall implement the following elements of QA:

1- Quality Control (QC)

It refers to all the activities undertaken by the staff at periodic intervals to monitor the quality of the materials, reagents, equipment, methods, blood and blood components prepared to assure that they meet their minimum requirements.

Quality control (QC) shall be conducted for:-

- Reagents
- Equipment
- Techniques
- Whole blood and blood components

1) Quality control of reagents (anti-sera) shall include:

a) Checks for titer, antibody specificity and validity on every new batch or lot received.

b) These checks shall be conducted as below:

Table: Frequency of testing for reagents and solutions

Reagents and supplies	Frequency of testing with controls
Blood grouping anti-sera	Each day of use
Standard cells for serum grouping	Each day of use
Anti-Human Globulin	Each day of use
Coombs control cells	Each day of use
Bovine albumin	Each lot
HIV test assays reagents	Each run
Hepatitis test assays	Each run
Normal saline	Each day of use

c) Minimum quality requirements for anti-sera and red cell reagents are as follows:-

Table: Anti-sera (anti-A, anti-B and anti-AB)

Parameters	Quality requirement
Appearance on visual inspection	No turbidity, no particle or precipitates
Specificity with positive and negative controls and required strength of reactions	For Anti-A : hemolysis or positive reaction of grade 3+/ 4+ with A cell : negative reaction with B cell
	For Anti-B : hemolysis or positive reaction of grade 3+ /4+ with B cell :negative reaction with A cell
	For Anti-AB: hemolysis or positive reaction of grade 3+ /4+ with A cell and B cell : negative reaction with O cell

Avidity	**Macroscopic agglutinates seen in 10 seconds with whole blood on slide test**
Acceptable titer	**3+ reaction at 1:256 titer (to be carried out with every new lot , and with new annual procurement supply)**

ABO & Rh D Blood Grouping

- ABO & Rh D Blood Grouping must be determined on each blood donation. The primary and any derived component be labeled.
- Forward and reverse grouping must be performed on previously unknown ABO group.
- Only forward ABO grouping is sufficient for previously known ABO blood groups.

Quality Control of ABO Blood Grouping

- Only approved reagents should be used.
- QC of procedures recommended by reagent and equipment manufacturer should be followed.
- Before a blood grouping reagent is used, appropriate reactivity with control cells should be performed.
- The control cells should be prepared by pooling of 3 red cell samples of the same blood group.

Quality Control of Rh D Grouping

- Only approved reagents should be used.
- QC of procedures recommended by reagent and equipment manufacturer should be followed.
- Before a blood grouping reagent is used, appropriate reactivity with control red cell samples should be confirmed. For each series of Rh D blood grouping tests unequivocal appropriate reactions must be obtained with R1r red cells as a +ve control and rr or r1r as -ve control.

- Appropriate reactivity with control red cell samples expressing weak D should also be confirmed regularly during use, although not necessarily with each series of tests.

Table :Anti-D anti-sera

Parameters	Quality requirement
Appearance on visual inspection	**No turbidity, no particle or precipitates**
Validity	**Macroscopic agglutinates seen in 10 seconds with whole blood on slide test**
Acceptable titer	**3+ reaction at 1:64 titer (to be carried out with every new lot, and with new lot.)**

Note :

When the blood grouping is not performed in batches or series the appropriate reactivity of ABO & Rh D reagents should be checked at least once in the morning of each working day.

Quality Control of Anti Globulin Testing

- DAT is optional test on collected blood donations.
- Group O red cells sensitized with IgG antibody should be used as positive control.
- Blood & Blood components from DAT +ve donation should not be used.
- Donors with +ve DAT for more than 1 year should be removed from donor list and referred to physician.

Table : Anti-Human Globulin (AHG)

Parameters	Quality requirement
Appearance	No turbidity, no particle or precipitates.
Specificity and strength of reactions	Positive reaction of 2+/3+ / 4+ with negative reaction with any standard cell

Table : Bovine Albumin

Parameters	Quality requirement
Appearance	No turbidity, no particle or precipitates. (to be done daily)

Table: Red cell preparations (A cell, B cell, O cell and Coombs Control Cells)

Parameter	Quality requirement
Appearance on visual inspection	No hemolysis in the supernatant. If a single saline wash removes the hemoglobin-stained supernatant fluid, the red cells are appropriate for use. Otherwise, they must be discarded.
Specificity with positive and negative controls and required strength of reactions	A cell : positive reaction of grade 3+ /4+ with anti-A : negative reaction with anti-B B cell : positive reaction of grade 3+/ 4+ with anti-B : negative reaction with anti-A O cell : negative reaction with anti-A and anti-B

2) Quality control of Blood bank department equipment

a. For all new equipment, installation and operational qualification must be performed. After it is qualified for use, an ongoing quality control checks should be performed.

b. All critical equipment must be calibrated and adjusted:
   - before use- that is on installation
   - after activities that may affect the calibration
   - at prescribed intervals.

c. Safeguards are to be implemented to prevent adjustments that would invalidate the calibration setting and calibration equipment must have adequate accuracy and precision.

Table: Quality Control Performance Intervals

Equipment	Performance	Frequency
Blood collection monitor with shaker	Agitation Time displayed Volume displayed	Day of use Monthly
Spring balance for blood collection	Volume displayed	Day of use
Electronic balance for blood bags	Weight/Volume displayed	Monthly
Sealer	Adequate sealing	Day of use
Hemoglobinometer	Hb value with known control sample	Day of use

3) Quality control of blood and blood components

Blood and Blood Components

- Label on Bag.
- Name of the product.
- Donation Number or Donor Number.
- ABO & Rh Group.

- TTIs Screening Result.
- Volume of the Product.
- Expiry Date.
- Storage Temperature.

Table: Whole blood (100% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	350ml /450ml (± 10%)	Minimum of 4 units per month
Hematocrit value	30% to 40%	Minimum of 4 units per month
Sterility	No growth	Minimum of 4 units per month

Table: Packed red cell (100% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	280ml (±50ml)	Minimum of 4 units per month
Hematocrit value	65% to 75 %	Minimum of 4 units per month
Sterility	No growth	Minimum of 4 units per month

Table: Platelet concentrate (75% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	50 to 70 ml	Minimum of 4 units per month or 1% of prepared platelets ,
Platelet count	≥5.5 x 10^{10} platelet per bag in at least 90% of the units tested at the end of the storage period	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
pH at the time of expiry	6 to 7	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
Sterility	No growth	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher nits before issue
Physical examination	Swirling phenomenon demonstrated	Minimum of 4 units per month or 1% of prepared platelets , whichever is higher
Residual leukocytes	<0.2 ×10^{9}/single unit	at least 75% of the units tested

Table: Fresh frozen plasma (75% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	220 to 250ml	Minimum of 4 units per month
Factor VIIIc	0.7 IU/ml	Minimum of 4 units per month
Fibrinogen	200 to 400 mg	Minimum of 4 units per month
Visual inspection	No leakage, no clots, no abnormal color	All units before issue

Table: Cryoprecipitate (75% of the units tested should meet the below requirements)

Parameters	Quality requirement	Frequency of check
Volume	10 to 20 ml	Minimum of 4 units per month
Factor VIIIc	≥80 IU/ Unit	Minimum of 4 units per month
Fibrinogen	>150 mg /Unit	Minimum of 4 units per month
Visual inspection	No leakage, no clots, no abnormal color	All units before issue

2- Documentation

All blood bank activities shall be documented including all the tests performed and quality data. Confidentiality of both blood donors and blood recipients shall be ensured.

All records shall be maintained for period of 5 years. Accessibility to the information shall be restricted and a document control system where in development, approval, validation, reviews, revision and authorization shall be done by authorized personnel only.

Important activities in this regard include:

1) Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures.
2) Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required.
3) Generation and maintenance of complete and accurate records.
4) Development of a system to manage the issue, use and retrieval of documents.

3- Corrective action

All blood bank personnel shall be trained how to:

- Recognize, classify, analyze root cause, and document any such occurrence.
- Prioritize the necessary corrective action needed.
- Verify that the corrective action is performed.
- Take preventive action where possible to reduce the likelihood of future recurrence.
- Report to immediate higher authority when required.

4- Training

Comprehensive, appropriate and effective training is required for all blood bank staff. Important activities include:

1) Training policy
2) Training for all blood bank staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools.
3) Clear understanding of the role of the individual in the quality system and the consequences of quality failures.
4) Ongoing monitoring and evaluation of training and its impact.

Annex

Contents

S No	Subject	Annex No
1	Criteria for selection of blood donors	1
2	Blood transfusion in HDN	2
3	Biosafety and waste management in blood transfusion	3
4	Forms	4

Annex (1)

Criteria for selection of blood donor

Basic requirements

- Donor should be in generally good health and feeling well.
- Be at least 18 years of age; upper age 60.
- Weigh at least (50 kg) female (55 Kg) for male.
- Pulse: 80 to 100 beats/min and regular.
- Temperature: Should not exceed (37.5°c).
- Blood Pressure: acceptable range is 160/90 to 110/70.
- Skin: the venipuncture site should be free of any lesion or scar of needle pricks indicative of addiction to narcotics or frequent Blood donation (as in the case of professional Blood donors).

Donation Frequency (may vary)

- Whole Blood donors may donate every 90 days
- Plasma donors may donate once in 4 weeks
- Platelet donors may donate a maximum of 24 times per year.
- Other specialized donations are subject to other rules.

Medical conditions

- Accident & Injury: can donate if otherwise healthy
- AIDS: cannot donate
- Allergies: can donate if there is no infection present and there is no treatment ongoing
- Anemia: defer donation until no symptoms exist
- Arthritis: can donate if mild and not on medication
- Asthma: those with severe asthma requiring regular treatment cannot donate; can donate if there are no symptoms evident
- Blood disorders or bleeding tendencies: cannot donate

- Blood Pressure: acceptable range is **160/90** to **110/70**. (see medication section below for medication restrictions.)
- Brain or spinal surgery that required a transplant of brain covering (dura mater): cannot donate
- Bronchitis: defer donation until **four weeks** or after recovery
- CJD: When a Blood relative has been diagnosed with Creutzfeldt-Jakob Disease (CJD), or there is an increased family risk of CJD; cannot donate
- Cancer: Basal cell, squamous cell skin cancers and keratosis; cannot donate until removed and healed. Melanoma; cannot donate. Malignant tumors; can donate five years after removal of early stage contained solid tumor, no chemotherapy, and in remission
- Chicken Pox: defer donation until **four weeks** after recovery
- Chlamydia: like all other venereal diseases; a minimum of a one year deferral is required
- Colds, fever, flu, sore throat: cannot donate until symptoms (sore throat, cough, respiratory infection, headache) are completely gone
- Colitis: cannot donate
- Colostomy: cannot donate
- Dementia: cannot donate
- Dengue: defer donation until four weeks after recovery
- Dermatitis: can donate if mild; defer donation if severe
- Diabetes: can donate if treatment is by diet control and condition is stable; defer donation if on medication
- Diarrhea: defer donation until three weeks after recovery
- Eczema: can donate if mild. defer donation if severe
- Emphysema: cannot donate
- Filariasis: cannot donate
- Food Poisoning: defer donation for one week after full recovery
- Gastroenteritis: defer donation for one week after full recovery

- Gall Stone: can donate if not on medication
- Gonorrhea/Syphilis: defer donation for one year after complete recovery
- Gout: cannot donate
- Heart attack: can donate if greater than one year since, and no symptoms present, the attending Blood authority physician must carefully evaluate
- Heart surgery, Coronary artery bypass surgery (CABG) or angioplasty: can donate one year after surgery, if no history of heart attack, and the donor is on no medication for the heart (aspirin is okay)
- Hemochromatosis: cannot donate
- Hepatitis: Hepatitis or undiagnosed jaundice after age ten; can not donate. Positive hepatitis test: cannot donate. Can donate if the history of hepatitis is pertaining to mononucleosis or CMV infection
- Herpes (genital): can donate four weeks after lesions completely clear
- Leprosy: cannot donate
- Malaria; had Malaria in last three years: defer donation for three years after full recovery
- Pregnancy and Miscarriage: cannot donate
- Prostate: cannot donate
- Sexually transmitted diseases : cannot donate
- Sickle Cell Trait: cannot donate
- Seizures in the last five Years: cannot donate
- Spondylosis: can donate if feeling well and not under any treatment at all
- Strokes: cannot donate
- Surgery (all): can donate after healed and released from physician care.
- Syphilis: see Gonorrhea

- Thyroid: for Hypothyroid, can donate if feeling well and euthyroid on thyroxine for **six months**. For Hyperthyroid: cannot donate until euthyroid for **six months**.
- Tuberculosis: cannot donate until **two years** after complete cure
- Viral Infection: can donate after cure and off treatment
- Worms: can donate after complete cure

Medication guidelines

- Acetaminophen (e.g. Tylenol): may be taken in normal moderate doses before any Blood donation
- Accutane: four-week deferral
- Allergy medication: can donate
- Antibiotics: 72-hour deferral after infection is healed
- Anti-inflammatory drugs (Advil, Ibuprofen, Motrin and Naprosyn): may not be taken within 24 hours before a platelet donation (some other rules may apply)
- Aspirin-containing products or Feldene and Lodine XL: may not donate within 36 hours before platelet donation
- Birth control pills: can donate
- Blood pressure medication: can donate under control of the physician.
- Depression medication: can donate
- Diabetic medication - Injected bovine (beef) insulin; cannot donate
- Diet pills: can donate
- Diuretics: can donate
- Female hormone pills: can donate
- Any human pituitary-derived hormone (i.e. growth hormone): cannot donate
- Soriatane (Acitretin): three-year deferral
- Tegison (used to treat a severe skin disorder): can not donate if ever taken

- Thyroid medication: can donate if stabilized
- Immunization exclusions
- Polio, mumps, smallpox: two-week or more deferral
- Rubella or Rubella (types of measles): four week deferral
- Tetanus, diphtheria, flu, Hepatitis B: can not donate until any reaction is over

Other possible restrictions

- Acupuncture: one-year deferral
- Alcohol: defer donation if consumed in last 12 hours
- Body piercing: one-year deferral
- Cocaine: taking through the nose (snorting); one-year deferral minimum, local Blood authority will prevail
- Dental work - Cleaning and fillings: one-day deferral; Root canal: three-day deferral after work is complete
- Ear piercing: can donate if the piercing was performed in a doctor's office (with written verification) otherwise, one-year deferral
- Electrolysis: defer donation for one year
- Hepatitis exposure: one-year deferral
- Menstruation: can not donate
- Rape: one-year deferral
- Smoker: can donate
- Tattoo in the last 12 months: one-year deferral
- Transfusion: defer donation by one year if undergone transfusion with Blood products. Can donate if undergone autologous transfusion only

Donor deferrals

A. List of temporary deferrals

Conditions	Period of deferment
Abortion	Accept after 6 months
Antibiotics	Accept after completion of antibiotics
Allergies	Accept if mild seasonal allergy
Anemia	Accept only if it is iron deficiency anemia after it is Treated
Alcoholism	Accept if donor is sober and not under the influence of Alcohol
Arthritis	Accept after acute phase
Asthma / الأزمة	Accept after drug therapy
Blood transfusion history	Accept 6 months after the date of blood received
Bronchitis	Accept after 1 month of recovery
Breast feeding	Defer for 12 months after child birth
Chest pain/shortness of breath	Accept only if cleared by a medical doctor
Common cold	Accept if there is no fever
Cystitis (urinary tract Infection) التهاب المثانة	Accept 3 weeks after recovery
Dermatitis/skin infection	Accept if venipuncture site is clear of any infection and not on any oral medication like antibiotics
Dengue/مرض ابر الركب	Defer until 4 weeks after recovery
Diabetes	Accept only if diet controlled, or taking single antidiabetic oral drug.
Dysentery	Accept 1 month after recovery

Epilepsy	**Defer for 3 years after completion of treatment No deferral needed if h/o epilepsy in childhood**
Fractures	**Minor accept after 3 months Major accept after 6 months**
Fever, flu like illness	**Accept after 2 weeks**
Gall stones	**Accept if no symptoms of acute attack**
Gastro enteritis	**Accept after 1 month**
Gout / النقرس	**Accept if asymptomatic and not on treatment**
H/o Malaria or taken anti-Malarial drugs	**Accept after 3 years**
Visited an endemic area	**Accept after 6 months of return from malaria area**
Hypertension/high BP	**Defer temporarily and refer to a doctor**
Hypothyroidism	**Accept if 6 months of therapy have passed and thyroid levels are within normal limits**
H/o jaundice	**Accept after 12 months**
Menstruation	**Accept after menstruation is over**
Migraine/ الشقيقة	**Acceptable**
Peptic Ulcer / gastritis	**Accept if on diet control or on antacid treatment**
Surgery	• **Minor surgeries like appendicectomy, hernia repair, tonsillectomy accept after 3 months** • **Major surgeries like, gall stone removal,**
Syphilis or gonorrhea	**Accept after 12 months of completion of treatment**
Sexual contact with HIV/ Hepatitis B /C individual, drug addict, prisoner, homosexual	**Defer for 6 months**
Sexual contact with multiple partners or with commercial sex worker	**Defer for 6 months**

Tattoo, body piercing with unsterile sharps	Defer for 6months
Tonsillitis	Defer till completion of treatment with antibiotics
Tooth extraction	Defer for 1 week
Typhoid	Accept after 1 month
Tuberculosis/السل	Accept 5 years after recovery

B. List of conditions for permanent deferral

1	Abnormal bleeding tendency
2	Anemia's other than iron deficiency anemia
3	Asthma on steroid treatment
4	Cancers
5	Diabetes on treatment with insulin or with complications
6	Epilepsy
7	Hypertension with complications or heart diseases
8	Individuals with Hepatitis B, Hepatitis C or HIV/AIDS
9	Hyperthyroidism or thyrotoxicosis
10	Chronic kidney diseases or liver diseases

C. Special conditions

Special conditions	Accept
1. medicines/ antibiotics/aspirin	Accept three days after stoppage
2. vitamins, contraceptive pills/ حبوب منع الحمل	Accept the donor on same day
3. vaccines • Hepatitis A, hepatitis B (recombinant), Rabies (human diploid), Tetanus toxoid • Rubella vaccine • Hepatitis B immunoglobulin	• Accept after 48 hours • Accept after four weeks • Accept after 12 months

• tattooing, ear piercing or any body part piercing	Accept after 12 months
• history of syphilis or gonorrhea	Accept after 12 months from completion of treatment
• any individual who has been in a correction institution like jails or prisons for more than 72 hours	Accept after 12 months

ANNEX (2)

Blood Transfusion In HDN

HDN is often classified into three categories. In descending order of severity they are:

- D hemolytic disease caused by anti-D alone or, less often, in combination with anti-C or anti-E.
- "Other" hemolytic diseases caused by antibodies against other antigens in the Rh system or against antigens in other systems; anti-c and anti-K are most often implicated.
- ABO hemolytic disease possibly caused by anti-A,B in a group O woman or by isolated anti-A or anti-B.

Exchange transfusion

Exchange transfusion is the indicated treatment for severe HDN.

Selection of Blood

- In most cases the mother's serum is used for crossmatching and the red cells selected for transfusion are compatible with her ABO antibodies as well as the antibody(ies) responsible for the hemolytic process.
- If maternal blood is not available or is unsuitable for crossmatching, the infant's serum and/or an eluate from the infant's red cells can be used for crossmatching.
- In Rh D hemolytic disease, Rh D negative blood ABO compatible for both mother's serum and baby.
- In ABO hemolytic disease, the red cells used for exchange transfusion must be group O cells suspended in AB plasma.
- If the antibody is anti-D, the red cells must be D-negative, **but not every exchange transfusion requires group O,D-negative blood**. If mother and infant are ABO-identical, group-specific red cells can be used. If the implicated antibody is not anti-D, D-positive red cells may be given to a D-positive red cells may be given to a D-positive infant.

- In exchange due to another Rh antibody (e.g. anti-c) or non-Rh antibody (e.g. anti-Kell), blood selected negative to the particular antibody & of same ABO group as the baby.
- In exchange due to any cause of neonatal jaundice other than ABO or Rh D incompatibility, blood of the same ABO and Rh group as the baby should be selected and matched.

Subsequent Transfusion:

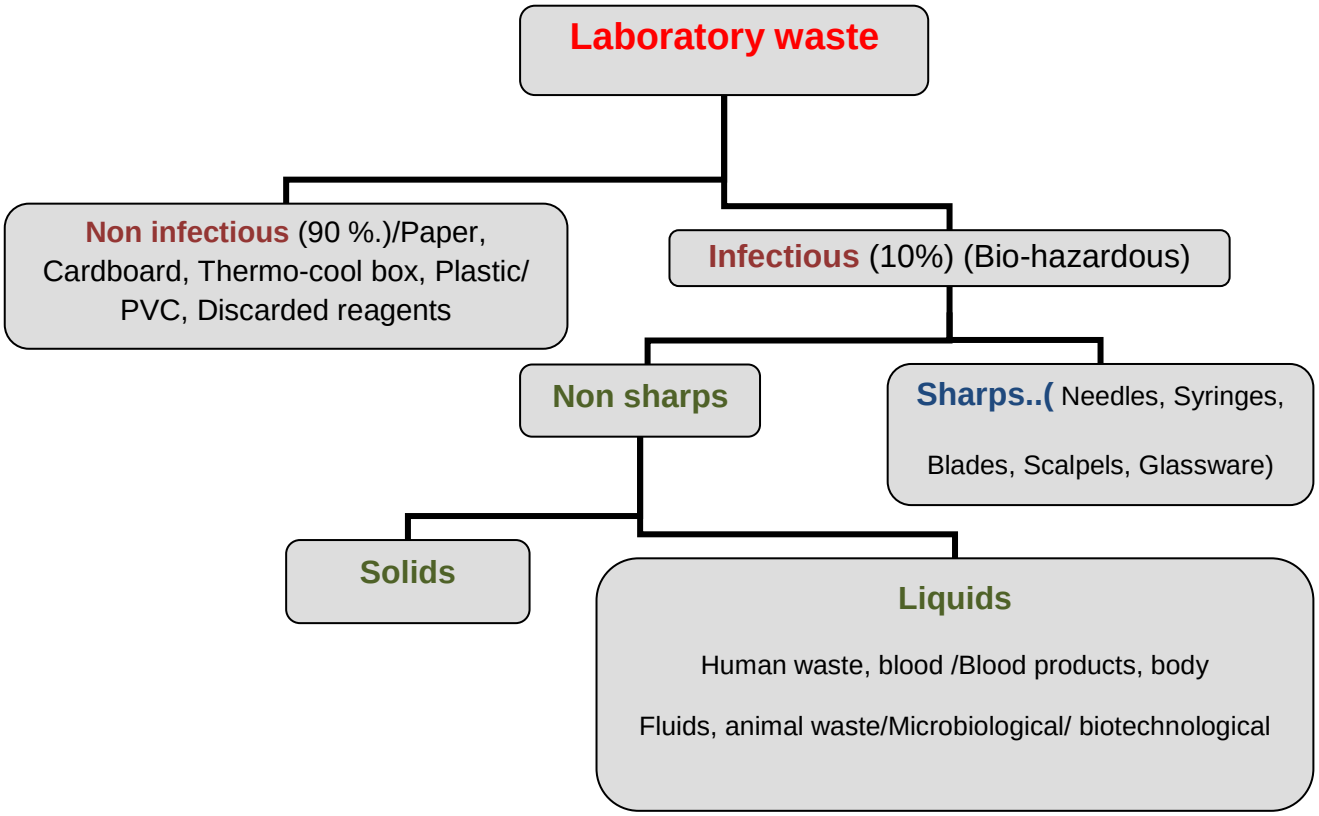
Bilirubin may reaccumulate rapidly after a successful exchange transfusion despite appropriate phototherapy, partly because bilirubin in extravascular fluid will follow the concentration gradient and enter the intravascular space, and partly because residual antibody coated cells continue to hemolyze. If rising Bilirubin levels make a second or third exchange transfusion necessary, the same considerations of red cell selection and crossmatching apply.

Annex (3)

Biosafety and waste management in blood transfusion

Classification of laboratory wastes:

Wastes generated in the laboratory are classified in fig.



The waste management in the blood transfusion service deserves special consideration as:

- Large volume of blood is collected and handled from apparently healthy asymptomatic donors
- Large volume of blood needs to be discarded due to various reasons like reactive, contaminated units outdated or unsuitable units.
- A greater degree of potential hazard among health workers through the use of wide-bore needles for blood collection.

Therefore following standards shall apply:

1- All Blood bank personnel shall be trained in national bio-safety guidelines, handling blood and well informed of the hazards including transmission of viral infections.

2- Incidental exposures to infected samples like bag breakage, splash, and needle stick injury shall be with the concerned authorities and action taken as per the guidelines on post –exposure prophylaxis.

3- Immunization against hepatitis B infection shall be mandatory before joining service after which their immune status will be determined.

4- The following safety instructions shall be followed at all times:-

a. All staffs are adequately trained in safety measures.
b. Staff must behave in a safe and responsible manner.
c. Appropriate protective clothing must be worn including apron and gloves.
d. Eating must be prohibited inside the laboratory.
e. Care must be taken to avoid formation of aerosols or splashing of materials.
f. All work surfaces must be decontaminated before and after the routine work is begun and after any spillage.
g. In-case of needle stick injury, squeeze out the blood, wash the hand with soap and water or anti-septic and prepare an incident report.

5- The waste that generated within the BTS should always follow an appropriate and well-defined process from its point of generation until its final disposal referred to as “cradle to grave” concept.

This process should consist of following steps:-

a. Generation
b. Segregation at source of generation of waste c. Collection
c. Storage
d. Transportation f. Treatment
e. Disposal

Table : Example of waste generated in a BTS

Non-risk waste	Infectious waste	Sharps	Chemical waste
Packages, boxes Wrappings	Gloves, gauze, swabs, used cuvettes contaminated with blood. Blood and blood component units discarded due to TTIs, expired and unsuitability. Used blood bags, transfer bags and accessories for component preparations. Segments from blood bag tubing. IV sets, used test tubes, micro- capillary tubes, and glassware, used syringes. Liquids from cell washers. Blood and serum samples. Red cell suspension for blood group serology testing	Needles from blood collection bags, blood administration sets and other disposable needles. Broken test tubes, glass slides. Broken glassware and ampoules, lancets, scissors wafers for sterile connecting devices	Anticoagulant solutions, Copper Sulfate, disinfectants, reagents, anti-sera, buffer solutions

Table : Waste segregation

Types of Waste	Color of container/ markings	Type of container
Infectious waste	Red polyethylene bag, marked "INFECTIOUS" or alternatively in plastic bins labeled with the international biohazard symbol.	Strong, leak proof plastic bags or containers capable of being autoclaved

Sharps	**Yellow plastic containers, marked "SHARPS" Yellow Cardboard boxes**	**Puncture-proof and leak-proof containers, fitted with covers and made of plastic, dense cardboard or metal**
General domestic waste	**Green**	**Plastic bags**

6- Treatment and disposal of infectious waste like blood units tested reactive for TTI

a. Autoclaving in a waste autoclave operating at a minimum temperature of 121º C for 30 minutes or at 138°C for 18 minutes is the recommended method.
b. After the sterilization, the waste should be buried in a secure landfill.
c. The other option is the use of double chamber pyrolytic incinerator with temperatures higher than 1200°C.
d. Where autoclave or incinerator is not available, burying of the infectious waste in a secured landfill is the method of choice.
e. Filled blood bags that are to be discarded should never be opened and the contents poured into the sink or bucket. Also never intend to inject disinfectant solution into the blood bags.

Glossary

AABB	American Association of Blood Bank
Ab	Antibody
ABO	American Board of Opticianry (Blood Group)
A.C	Store Room
Ag	Antigen
AHG	Anti Human Globulin
AIDS	Acquired Immuno -Deficiency Syndrome
AIHA	Autoimmune Hemolytic Anemia
ARC	American Red Cross
BBR	Blood Bank Refrigerator
BC	Blood Center
BD	Blood Donation
BLISS	Bovine low Ionic strength Solution
BP	Blood Products
BPQM	Blood Program Quality Manual
BTS	(Palestinian)Blood Transfusion Service
C	Clumps
C139-9	Cancer Tumor
C3d	Complement Component
CA	Central American
CABG	Coronary Artery Bypass surgery
CAT	Column Agglutination Technique
CBC	Complete Blood Count
CCC	Coombs Control Cells
CD4	Cluster of Differentiation(T-Cell)
CDC	Center for Disease Control
CJD	Creutzfeldt-Jakob Disease
Cm	Centimeters'
CMV	Cyto Megalo Virus
CPD-A1	Citrate Phosphate Dextrose Adenine

CPP	Cryo Poor Plasma
CRYO	Cryoprecipitate
DAT	Direct Antiglobulin Test
DCO	Document Control Officer
DF	Donation Frequency
DMT	Diamed micro typing
DR	Domestic Refrigerator
DW	Dental Workers
DW	Distilled Water
ECC	External Calibration Contractors
EDTA	Ethylene Diamino (dinitro) Tetra-Acetic acid
FDA	Food and Drug Administration
FFP	Fresh Frozen Plasma
FTR	Febrile Transfusion Reaction
FVIIID	Factor VIII Deficient Plasma
G	Gram
g/dl	Gram/Deciliter
GMP	Good Manufacturing Program
GPA	Global Program association
G.S.R	Gazette of Indian Extraordinary Notification
Hb	Hemoglobin
HBsAg	Hepatitis B surface Antigen
HBV	Hepatitis B Virus
Hct	Hematocrite
HCV	Hepatitis C Virus
H.C.W	Health Care Worker
HDN	Hemolytic Disease of Newborn
HIV	Human Immunodeficiency Virus
HLA	Human Leukocyte Antigen
HTR	Hemolytic Transfusion Reaction
IAT	Indirect Antiglobulin Test

ID	Identification
IFRC	International Federation Of Red Cross
IgG	Immunoglobulin G
IR	Incident Reporting
ISBT	International Standard Blood Transfusion
ISO	International Organization for Standardization
KG	Kilogram
L	Lysis
LISS	Low Ionic Strength Solution
M	Micron
MCD	Mad Cow Disease
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
MCV	Mean Corpuscular Volume
Min	Minutes
1N HCL	1 Normal Hydrochloride
NaCl	Sodium Chloride
NH(SO)2	Ammonium Sulphate
OOS	Out of service
PC	Packed Cells
PCD	Patient Care Department
PCS	Packed Cell without additive Solution
PLT	Platelets
PM	Preventive Maintenance
PNH	Paroxysmal Nocturnal Hemoglobuinuria
PRP	Platelet – Rich Plasma
QA	Quality Assurance
QC	Quality Control
QCL	Quality Control Laboratory
QM	Quality Manual
QUTY	Quantity

Rh	Rhesus Blood Group System
RBC	Red Blood cells
R	Radius of centrifuge rotor in inches
RBC	Red Blood Cells
RCF	Relative Centrifugal Force (× g)
RCS	Red cell serology
RCS	Red Crescent Societies
RDP	Random Donor Platelets
RPM	Revolutions Per Minute
RPM	Round Per Minutes
RR	Record Register
RT	Room Temperature
SA	South American
SAGM	Saline Adenine Glucose Manitol
SB	Safe Blood
SBTP	Safe Blood Transfusion Practice
SDP	Single Donor Platelets
SI	Standard International
SOP	Standard Operating Procedure
Temp	Temperature
TM	Technical Manual
TR	Transfusion Reaction
TTIs	Transfusion of Transmissible Infections
UK	United Kingdom
US	United States
VDRL	Venereal Disease Research Laboratory
WB	Whole Blood
WBC	White Blood cells
WE	Western Europe
WHO	World Health Organization
Wt	Weight

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