S.No.	Point Discussed	Action Plan	Responsibility	Review Date
1.	Observation of internal Audit held on ----- were reviewed	CAPA has been undertaken for all the deviations	Director & QMgr	
2.	Validity of Equipment------ Calibration of equipments---	Deviation to be rectified after recalibration due for pipettes	Equipment Management I/C	ASAP
3.	Approval of new Equipment	To be taken from budget Monitoring committe	I/C blood bank	Next MRM
4.	Status of Statutory Requirements	Meets all Statutory requirements apply for pollution certificate for diesel Gen set/ noise monitoring		Next MRM
5.	Verification of LIS Software	No discrepancies have been reported from any areas of service	-	-
6.	Q I indicators Assessment TTI Reactive units Discard rates Utilization review	Within defined range except for discard rates of platelets	QM, AQM, Admin	Next MRM
7.	Review Bio Medical waste Management Practices	Documentation Found Satisfactory		
8.	Consolidated feed back report including all non conformities and complaint from patient / clinician discussed in detail	CAPA has been discussed	Director Admin Mgr	Next MRM
9.	Evaluation of suppliers by Purchase Manager	Found Satisfactory	Purchase Manager	
10.	External Validation of Reports Of EQA	To be done before NABH assessment positively	Director / QMgr	
11.	Annual health check up for staff	Health check up in process vaccination for hepatitis B to be Given to all the staff members		Follow up before next MRM
12	It has been decided to apply for NABH accreditation and to submit the application at the earliest	Completion of all formalities for NABH application to be undertaken	Director Qmgr AQ, Mgr Admin Mgrs	To be submitted with in one month

Quality Manager

Copy to:

CHAPTER 25

Accreditation Process- National Accreditation Board of Hospitals (NABH)

- NABH is a constituent board of Quality Council of India.
- It is set up to establish and operate accreditation and allied programs for healthcare organizations.
- The accreditation program by NABH strives to maintain the quality and safety of blood and blood products.
- It assesses the quality and operational systems in place within the facility before accreditation is awarded.
- The basis for assessment of Blood Banks/blood centers includes compliance with the accreditation standards and guidelines set by National AIDS Control Organization (NACO)
- The independent assessment under accreditation helps the facility to prepare comprehensively for regulatory requirements as well as accreditation standards
- It ensures safety as well as quality culture within the facility.
- Accreditation is granted for collection, processing, testing, distribution and administration of blood and blood components

Procedure for Accreditation

NABH has a website : www.nabh.co

- Blood Bank should obtain a copy of NABH Standard from NABH office and other documents from NABH website.
- Blood Bank should prepare Quality Manual as per NABH standard and implement the requirements.
- The application form should be Submitted online .
- After the application is accepted, copy of internal audit and minutes of Management Review along with requisite fees should also be submitted.
- All the information should be filled. The e mail ID provided in this form, should be used for all the future login.
- Once Blood Bank application form is received, NABH would activate login and provide password on the Blood Bank's e-mail.
- On using Blood Bank login and password, application form for blood bank should be filled, after which rest of the process would be through the software.

REFERENCES

1. Drug and Cosmetic Act (D & C Act) 1940 with modifications
2. National Blood Policy, Ministry of Health and Family Welfare, Govt. of India
3. NACO Standards for blood banks and blood transfusion services 2007
4. NABH - Accreditation Standards for Blood Banks
5. ISO 15189:2012 : Quality Management System Requirements
6. NBTC and NACO Hand book for implementation of QMS in blood banks
7. WHO - Quality Management Training modules for Blood Banks
8. WHO - Distance learning modules on Safe blood and blood products
9. WHO guidelines for quality assurance programs for BTS
10. WHO - Aide Memoire for national blood program on Quality systems for blood safety
11. Bio Medical Waste Management (BMW) Rules 2015
12. NACO Guidelines on PEP and Spill Management

ANNEXURES

Annexure A

XYZ Blood Bank **BB/QS/FM/00**

Master List of Documents

S. No	Document Name / Description	Document No.
1.	Quality Manual	BB/QM/01
2.	Quality System Procedures	BB/QSP/02
3.	Human Resource Manual	BB/HR/03
4.	Infection Control Manual	BB/ICM/04
5.	Safety Manual	BBSM/05
6.	Master List of Documents	BB/06
7.	Master List of Records	BB/07
8.	Document & Data Control	BB/08
9.	Standard Operating Procedures	Bb/SOP/1-XX/Donor Area
10	Standard Operating Procedures	BB/SOP/1-XX/IH/Issue
11.	Standard Operating Procedures	BB/SOP/1-XX Component Area
12	Standard Operating Procedures	BB/SOP/1-XX/TTI
13	Standard Operating Procedures	BB/SOP/1-XX/Storage Area
14	Standard Operating Procedure	BB/SOP/1-XX/QC
15	Standard Operating Procedure	BB/SOP/1-XX/ Stock and Inventory
16	Formats	BB/16
17	Checklist	BB/17
18	Scope of services	BB/18
19	List of Equipments	BB/19
20	Blood bank licence	BB/20
21	Blood Inventory	BB/21
22	Calibration validation of equipments	BB/22
23	List of Personal Files (Ref individual files)	BB/23

BB/QS/FM/00

XYZ Blood bank

Document Control Sheet

Name of the Document

Document No

S.No	Distribution	Rev. No	Issue date	Remarks

Approved By:

XYZ Blood Bank

BB/QS/FM/

Format For Document Change

Reference Document No:

Proposed Change

Reason for Change

Requested by:

Date:
Department:

Comments HOD

Signature

Date

Approved/Rejected by Quality Manager

Signature
Date

XYZ Blood bank

Amendment Sheet

Sl. no	Page No.	Clause No.	Date of Amendment	Amendment made	Reasons	Signature QM	Signature Director
1							
2							
3							
4							
5							

Sign of Quality Manager

Dated:

OBSOLETE DOCUMENTS RECORDS

S.No.	Document no	Date of issue	Description of Documents	Received from	Date of Receiving	Signature QM

XYZ Blood Bank

DOCUMENT REVIEW

Name of Department……..

Name of Document…… Document ID No……

Adopted	Date	Sign of Quality coordinator	Sign of HOD

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

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

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

1. SCOPE AND APPLICATION

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

2. RESPONSIBILITY

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

3. REFERENCE

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

4. MATERIALS REQUIRED

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

5. PROCEDURE

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

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

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

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

STANDARD OPERATING PROCEDURE

(Name of the Blood Centre)

Number	Effective Date	Pages	Author	Authorised by
SP 031		4		
Version	**Review Period**	**No. of Copies**	**Approved by**	**Date**
1	1 Year			

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

1. SCOPE & APPLICATION

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

2. RESPONSIBILITY

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

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

    - o Preventive.
    - o Routine.
    - o Extra maintenance.
    - o Cleaning and sanitation.

3. REFERENCES

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

Societies, 1998, Pages 23-24.
3. The Gazette of India extra ordinary notification G.S.R. 245 (E) dated 5th April 1999, new Delhi, Part II Sec. 3 (i), Page 40.

4. PROCEDURES

4.1 Maintenance overview:

4.1.1 Identify each item of equipment in the unit that requires maintenance. Ensure all items have an Asset Number.

4.1.2 Include clear outline of the relevant procedures, routine maintenance and preventive maintenance and cleaning of equipment. Write operator instructions for each item of equipment. Also include those responsible and names of service personnel. Maintain a documented log of servicing for all items.

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

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

- **Equipment name / description.**
- **Asset Number.**
- **Serial Number.**
- **Model Number.**
- **Operation:**
  - Operating Range.
- **Calibration:**
  - Frequency.
  - Referenced documents.
  - Performed by
- **Performance Check:**
  - Frequency.
  - Referenced documents.
- **Preventive maintenance:**
  - Frequency.
  - Referenced documents.
  - Performed by.
- **Routine maintenance:**
  - Frequency
  - Referenced documents.

- **Cleaning:**

  - Frequency.
  - Referenced documents.

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

4.2 Maintenance Schedules:

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

4.3 Service contracts:

4.3.1 Contracts need to be in place for all equipment items maintained by an external agent.

4.3.2 Each service contract shall define exactly what is carried out / the frequency and by whom it is completed.

4.3.3 At the completion of the service, a maintenance report is to be supplied, signed by the contractor and the officer in charge. The report shall detail the work carried out by the contractor.

4.4 Repair & breakdown:

4.4.1 Operating instructions for each item of equipment shall identify the steps required to be taken in the event of a fault or breakdown, and shall identify who is responsible for organising service or replacement.

4.4.2 A log book of errors and corrective actions is to be maintained for all equipment items. In the event of equipment breakdown, it is essential that it be clearly labelled and identified as being “OUT OF SERVICE”.

4.5 Maintenance overdue:

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

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

5. DOCUMENTATION

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

6. END OF DOCUMENT

Annexure B

	Things to be Checked	Time	Month :..... Year :.....Frequency of check : Daily																
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
1	Floor Cleaning	Morn																		
		Even																		
2	Dust bin Cleaning	Morn																		
		Even																		
3	Cleaning of tables and chairs	Morn																		
		Even																		
4	Dirty linen	Morn																		
	Removed	Even																		
5	Magazines	Morn																		
	Organised	Even																		
6	Water dispenser	Morn																		
	Functional	Even																		
7	Cleaning of walls	Weekly																		
8	Cleaning of webs	Monthly																		
Sign: House Keeping																				
Sign: Supervisor																				

XYZ blood bank Checklist - Infection Control

S. No.	Things to Check	For the Month of ..... Frequency of check: Thrice a week											
		1st - 7th			8th - 15th			16th - 23rd			24th - Last		
	Day----												
	Date --												
1	Adequate PPE are available												
2	PPE is being used by staff												
3	Personal hygiene												
4	bio-medical waste disposal												
5	Hand Hygiene practiced by staff												
6	Hand washing facility is clean												
7	Availablity of alcohol based hand rub, where necessary												
8	Use of alcohol based hand rub in practice												
9	Staff aware of needls stick injury												
10	Needle disposal												
11	Floor cleaning												
12	Staff take care of infectious patient and post cleaning / changing of linen												
13	Dirty linen are kept separetely												
14	Floor area is clean												
15	Toilets are clean												
16	Working tables are clean												
Sign:Infection Control Supervisor													

XYZ Blood bank

BB/Gen/FM/00

Humidity & Temperature Record

Month:…….. **Area :**……

Date	Morning (8.00 AM - 11:00 AM)			Evening (4:30 PM - 6:00 PM)		
	Humidity	Temp.	Signature	Humidity	Temp.	Signature
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
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21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

XYZ Blood Bank

Bb/QS/FM/00

List of Statutory Requirement

S.No.	Name of Document	Registeration / Licence No.	Valid From	Valid Upto
1	Blood bank license	Drug Controller General of India		
2	Ownership	Property papers		
3	Building Completion	MCD		
4	Fire safety clearance	Fire deptt		
5	Bio Medical Waste management	DPCC/BMW/AUTH/		
6	Fire Fighting Arrangement	NOC From Ceasefire Industries Ltd		
7	DPCC(Noise Monitoring Report for Generator)	DPCC/Comm/N/		
8	DPCC(Noise Monitoring Report for Generator)	DPCC/Comm/N/		
9	Pollution control clearance	PCB		
10	Blood Mobile Van	RTO		
11				

XYZ Blood Bank **REFRIGERATOR I**

Temperature Maintenance Record

Month & Year:

Acceptable range

Refrigerator: 2 to 8°C

Deep Freezer: -15 to -20°C

Date	08:00 am	Deep freezer 08:00 am	04:00 pm	Deep freezer 04:00 pm	Defrosting done on	Signature
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Sign of HOD/QM

XYZ Blood Bank

Temperature Maintenance Record

Room Temperature – Lab

Month & Year: Acceptable Range: 18-24°C

Date	08:00 am	04:00pm	Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
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22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

Sign of HOD/QM

Annexure C

XYZ Blood Bank						BB/GEN/FM/00
Fire Extinguisher Inspection Record						
FE Sr. No.:_____			**Type:**	**_____**	**Capacity:_____**	
Installation Site: _____				**Manufacturing Date:_____**		
Inspection frequency - Quarterly						
	Next	**Status of**	**Status of**	**Status of**		
Inspection	**Inspection**	**Safety**	**nozzle**	**Instruction**	**Indicator**	**Remarks &**
Date	**Due on**	**Seal**	**Seal**	**sticker**	**position**	**Signature**

Annexure D

XYZ BLOOD BANK

Check List - Documents in Personal File

Name of Employee: _____			**Sign with Date**
1	CV	Yes / No / NA	
2	Appointment letter / Contract Copy	Yes / No / NA	
3	Permanent address / temporary address	Yes / No / NA	
4	Photograph 2 nos.	Yes / No / NA	
5	Qualification / degree certificates - photocopies signed by employee	Yes / No / NA	
6	Certification or Licences, if required (e.g. MCI, MC registration)	Yes / No / NA	
7	Confidentiality agreement	Yes / No / NA	
8	Previous employer reference, if required	Yes / No / NA	
9	Job description, signed	Yes / No / NA	
10	Record of identification of signature & initials	Yes / No / NA	
11	Annual medical check-up record	Yes / No / NA	
12	Vaccination record	Yes / No / NA	
13	Police verification, if required	Yes / No / NA	
14	Training record	Yes / No / NA	
15	CME record, if required (mainly for doctors)	Yes / No / NA	
16	Competency Evaluation	Yes / No / NA	
17	Renewal / promotion records	Yes / No / NA	
18	Annual performance review	Yes / No / NA	
19	Appreciation / disciplinary record	Yes / No / NA	
20	Complaint / grievances records	Yes / No / NA	
21	Record of benefits	Yes / No / NA	
22	ESI record, if applicable	Yes / No / NA	
23	PF record, if applicable	Yes / No / NA	
24	Authorities & Privileges	Yes / No / NA	
25	Background Assessment	Yes / No / NA	

XYZ Blood Bank

EXAMPLE OF JOB DESCRIPTION

Job Title	:	Technologist , TTI Lab
Department/Directorate	:	Blood bank
Grade	:	
Main Function	:	To undertake confirmatory testing of donor samples referred to the laboratory
Accountable	:	Head of blood bank
Liaises with	:	Other sections of blood bank
Minimum Qualifications	:	DMLT/BSC MLT
Staff Responsibilities	:	Together with senior laboratory staff, supervision and training of technical staff as required

1. Key Tasks

1.1 Perform confirmatory testing of samples referred to the laboratory

1.2 He/She is responsible for organising their own workload and, within the framework of the agreed confirmatory algorithms, determining and performing the investigations required to determine the true status of the referred samples

1.3 Play an active role in any other areas of investigation or evaluations performed by the laboratory

1.4 As required by the head of the laboratory, check and authorise final reports

1.5 As required by the head of the laboratory, maintain and calibrate the equipment used in the laboratory

1.6 Help to develop both the scientific and quality aspects of the laboratory

1.7 Help to obtain relevant accreditations for the laboratory

1.8 Help in the training and teaching of other staff seconded to the laboratory or external visitors to the laboratory

2. General

2.1 The post holder is managerially responsible for the resources within their span of control.

2.2 The post holder is required to keep themself informed about developments and best practices in their areas of activity and to apply such information to the benefit of the Service as appropriate.

2.3 To promote and implement the spirit and intention of the Service's Mission Statement and to comply with and promote all The Blood Service's policies and supporting procedures.

2.4 To make positive efforts to promote your own personal safety and that of others by taking reasonable care at work, by carrying out the requirements of the law or following recognised codes of practice provided or advised by management to ensure safe working practices.

2.5 To be responsible for the adequate appraisal training, development and motivation of staff within the posts span of control, to include the provision of clear objectives and relevant and up-to-date job descriptions.

2.6 To observe the Service's standards on confidentiality of information at all times.

2.7 To observe, maintain and promote quality standards in accordance with The Blood Service policy, and to continuously improve the quality of patient support and donor care provided.

2.8 To be responsible for budgetary control to enable efficient and effective management of resources and the identification and implementation of cost improvements.

2.9 To develop and expand own area of responsibility to enable the service to explore and market new opportunities consistent with business objectives.

2.10 To undertake ad hoc duties and/or hours of work as may be required of you at your initial place of work or at any of the Service's other establishments.

TERMS AND CONDITIONS

All other terms and conditions of employment are subject to Admin and Clerical terms and conditions of service unless otherwise indicated in your Statement of Main Terms and Conditions of Employment

XYZ Blood bank

Authorities & Privileging

Name: _____
Department: _____
Designation: _____

I. Authorities:

II. Privileging:

XYZ Blood Bank

CONFIDENTIALITY DECLARATION

This is to state that I Dr. /Mr./Ms./Mrs. _____

S/D/W/o_____give an undertaking that

a) I will not involve in any activity that may diminish confidence in the Blood bank competence or operational integrity.

b) I will not come under any undue commercial, financial or other pressures and influences that may adversely affect the quality of my work.

c) I shall openly and appropriately declare any existing potential conflicts in competing interest.

d) I shall maintain confidentiality of information at all times and shall not discuss any data pertaining to SSDUC with any outsider.

Date:_____ Name & Sign of Employee

XYZ Blood Bank

C/FM/ADMIN/09

Induction Training Records

Name: _____ Date of Joining: _____

Admin Given By:……

General introduction to Organisation:

Department: ……..……

Working under supervision

Assessment before being given
independent charge

Fit/Unfit

Signature

XYZ Blood Bank

C/FM/ADMIN/09

Induction Training Records

Name: _____

Date of Joining: _____

Admin

Given By:……..

General introduction to Organisation:

Department: ……..……

Working under supervision

Assessment before being given independent charge

Fit/Unfit

Signature

XYZ Blood Bank

In Service Training Record

Date of Training :

Area of Training :

Name of Participants:

Duration :

Trainer :

Summary :

XYZ Blood bank

Employee Grievance Form

Employee Name:_____ Date:_____

Designation:_____

Date & Time of event leading to grievance
Detailed account of event (include name of persons involved if any):
Please state policies,procedure or guidelines that you feel have been violated:
Proposed solution to grievance:

The Grievant should retain a copy of the form for his/her record.

The signature below indicates that all information given by the grievant is truthful.

Employee Signature _____ Date:_____

Received by _____ Date:_____

XYZ Blood Bank

Employee Grievance Redressal

Date:…..……..

Name of the Employee:……

Department:……..

Nature of Grievance :

……

……

……

HOD's Comments:

……

……

Action Taken to Resolve the Grievance

……

……

……

Director's Remarks:

……

……

Director's Signature HOD's Name & Signature Employee's Signature

XYZ Blood bank

Sexual Harassment Complaint Form

Employee Name			
Department		Designation	
Age		Sex	

Date of Incident		Time of Incident	
Person(s) you allege committed the sexual harassment			
Name		Position/Designation	

Please describe the incident in detail including your reaction to incident

Person(s) who witnessed the incident, if any

Additional Notes

Employee Signature…… Date……

Received by …… Date……

XYZ Blood Bank

Sexual Harassment Redressal

Date:…..……..

Name of the Employee:……

Department:……..

Nature of Sexual Harassment:
.....……

.....……
……

……
……....

Committee Member's Comments:
……
……

……
……

Action
Taken:……

……
…….

……
……

Presiding Officer's Remarks:
……

……
……

Presiding Officers Signature Committee Member's Signature Employee's Signature

XYZ Blood bank **BB/CL/00**

Annual Health Checkup - Record

Employee Name :

_____

S. No.	Investigation / Tests	Results of the Investigation				
		Ist Year	2nd Year	3rd Year	4th year	5th year
1	BP - Blood Pressure					
3	Complete Blood Count					
4	Urine R/M					
5	Stool RE					
6	X-Ray Chest					
7	HBSAg					

Comments:

XYZ Blood Bank

Blood Donation Camp Information Form

Status of camp New Repeat

Camp Date Camp Code……

Starting Time…… to …….

Organized by …….

Contact Person Name……..Phone No. …….

Site Address: ……..Phone No. …….

Site Visited: Yes / No If yes name of person……

Sanitation condition:

Adequate area Yes / No Cleanliness: Yes / No

Continue/uninterrupted electric supply for Equipment used in the camp Yes / No

Adequate lighting Yes / No Hand washing facilities for staff Yes / No.

Refreshment facilities for Donor Yes / No

Expected No. of Donor…… No. of Donor in camp……..

Name of duty Doctor ……..Name of camp in charge ……..

Other Staff: Name of phlebotomist……
……
Bag made by …… Hb and Group done by……

Number of Repeat Donor (In. Blood Bank)……

Number of Deferral ……..due to 1. Low Hb 2. Jaundice 3. Infection
4. BP 5. Malaria 6.Weight
7. Any other 8. Age

Phlebotomy failure No Unit No. 1. ……2 ……..3……

Total number of Adverse reaction …….. Name and Unit No. ……

Name and Unit No.(If Report not to send by post)……

Blood dispatch Time: 1……

Voluntary Card given to Send by post Organizer Donor

Camp In charge Signature of MO Blood Bank In charge

XYZ Blood bank					BB/QS/FM/0	
AMBULANCE LOG BOOK						
AMBULANCE NO:-						
Date	Starting Meter (Km/Time)	Place	Purpose	ClosingMeter (Km/Time)	Maintenance	Checked By

Annexure E

IQ, OQ AND PQ

INSTALLATION QUALIFICATION

Instrument Type : ABC	**Manufacturer Name :**
Model Name :	**Supplier Name :**

Installation report

Name of the customer :	**Instrument Type: ABC**
Model Number:	**Serial Number:**
Date of receipt:	**Date of installation .**

Power check:

Power supply	AC 229V-50 Hz
Plug top	5 Amps
Earth voltage	1.2 Volt

Environmental check:

Parameter	Working range	Site conditions
Room temperature	5-40*C	27*C
Humidity	10-90%	53%

Physical check of the equipment:

Check for damage	Checked	No damage found
Visual & functional inspection	Checked	OK
No damage on internal assembly	Checked	No damage found

System configuration check:

Positioning of the equipment-flat stable surface	Checked	Found OK
Adequate space around the tube sealer	Checked	Found OK
Interference to other equipments	Checked	No interference

Result:

Installed the Tube sealer satisfactorily and is ready for operational verification

Installed by:	**Checked by** :
Signature :	**Signature :**
Date :	**Date** :

PERFORMANCE QUALIFICATION

Instrument Type :	**Manufacturer Name :**
Model Name :	**Supplier Name :**
Installed on :	**Service Engineer:**
Placed in service from :	

Performance Verification Report

Name of the customer :	**Instrument Type:**
Model Number:	**Serial Number:**
Date of receipt:	**Date of installation:**

Sample Performance Check:

Without tube, initiate tube detection lever.	Checked	Working OK-sealing motion and electrode going back very fast.
20 continuous seals to check the consistent sealing quality	Checked	Found OK
False triggering	Checked	No false triggering
LED indications after continuous sealing	Checked	Found OK
Functional test	Checked	Found OK
Limit switch functions	Checked	Found OK
Tear ability of tubes after continuous sealing	Checked	Easy separation of tube segments found OK

Result:

The performance verification of Tube sealer has been completed satisfactorily and instrument is ready to be placed in service.

Performance check done in presence of:	HOD : Signature : Date:
Performance check Performed by	Checked by :
Signature :	Signature :
Date :	Date :

Installation, Operational and Performance Qualification certificate

The equipment Tube sealer XS 1000, Serial no: 0011127 is installed and commissioned. The operational and performance verification is done and observations are:

All system components are working in normal condition.

All tests were carried out in accordance with qualification protocol and standard operating procedure.

The performance of the Tube sealer XS 1000,Sl.no-0011127 is as per the acceptance criteria.

Date :

Sales & service Engineer

OPERATIONAL QUALIFICATION

Instrument Type :	**Manufacturer Name :**
Model Name :	**Supplier Name :**
Installed on :	**Service Engineer:**

Operational Verification report

Name of the customer :	**Instrument Type:**
Model Number:	**Serial Number:**
Date of receipt:	**Date of installation:**

Sample Operational Check:

Turning ON of POWER & indication	Checked	POWER LED is glowing
Activation of Moving Electrode while the lever is operated	Checked	Moving electrode pushes the tube for sealing
Sealing of tube & turning ON of SEAL LED indication simultaneously READY LED goes OFF	checked	Seals the tube and electrode going back to normal position & SEAL LED indication while sealing.
Turning OFF of SEAL LED after sealing	Checked	Found OK
Visual inspection of Sealing pattern	Checked	Good sealing pattern and equal width on both sides fro the centre mark.
Leakage	Checked	No leakage

Result:
Operational verification of Tube sealer has been completed satisfactorily and it is ready for the performance verification

Operations performed by:	Checked by :
Signature :	Signature :
Date :	Date

PERFORMANCE QUALIFICATION

Instrument Type :	**Manufacturer Name :**
Model Name :	**Supplier Name :**
Installed on :	**Service Engineer:**
Placed in service from :	

Performance Verification Report

Name of the customer :	**Instrument Type:**
Model Number:	**Serial Number:**
Date of receipt:	**Date of installation:**

Sample Performance Check:

Without tube, initiate tube detection lever.	Checked	Working OK-sealing motion and electrode going back very fast.
20 continuous seals to check the consistent sealing quality	Checked	Found OK
False triggering	Checked	No false triggering
LED indications after continuous sealing	Checked	Found OK
Functional test	Checked	Found OK
Limit switch functions	Checked	Found OK
Tear ability of tubes after continuous sealing	Checked	Easy separation of tube segments found OK

Result:

The performance verification of Tube sealer has been completed satisfactorily and instrument is ready to be placed in service.

Performance check done in presence of:	HOD : Signature : Date:
Performance check Performed by :	Checked by :
Signature :	Signature :
Date :	Date :

Installation, Operational and Performance Qualification certificate

The equipment Tube sealer XS 1000, Serial no: 0011127 is installed and commissioned. The operational and performance verification is done and observations are:

All system components are working in normal condition.

All tests were carried out in accordance with qualification protocol and standard operating procedure.

The performance of the Tube sealer XS 1000,Sl.no-0011127 is as per the acceptance criteria.

Date :

Sales & service Engineer

.

Equipment History Card

Name of the equipment :

Instrument ID :

Serial no :

Date of Last Calibration :

Next calibration due :

Last PM done :

Next PM due :

Name of Engineer :

Contact no :

Primary Operator :

Secondary Operator :

XYZ Blood bank

BB/QS/FM/00

Equipment Calibration Schedule

S.No.	Name of Equipment	Make / Model	QA done on	QA Valid Upto
1				
2				
3				
4				
5				

XYZ Blood bank

BB/QS/FM/00

S. No.	Equipment Name	Make	Model	Service Provider	(AMC/ CMC	No. of Visits	Validity		Respon-sibility	Comments
							From	To		
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										

XYZ Blood bank

EQUIPMENT BREAKDOWN LOG

Name Of The Equipment	Date & Time Of Break Down	Date And Time Of Information To The Engineer	Problem Identified	Corrective Action Taken	Date & Time Functional	Backup	TAT	Engineer Remarks	I/C BB Signature

XYZ Blood bank

DAILY START UP & SHUT DOWN LOG

DEPARTMENT:

MONTH:

EQUIPMENT:

YEAR:

Parameter	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Start up at																															
Sign of tech																															
Shut down at																															
Sign of tech																															

SIGN OF I/C BLOOD BANK

XYZ Blood Bank

QC Pipettes

Date	Type of pipette	Capacity of pipette	Weight of aspirated water (gm)	Weight of aspirated water by standard (gm)	Result	
					Pass	Fail

Annexure F

BB/PUR/FM/00

XYZ Blood Bank

Checklist for Receipt of Materials

Date	Name of the Material	Batch Number / Date of Manufacturing	Date of Expiry	Cold Chain Maintenance Yes/No	Condition of Pack Supplied Normal/Damage	Any Evidence of Leakage/ Breakage/ Soilage	Received By	Delivered from

XYZ Blood Bank

SUPPLIER EVALUATION FORM

Name of the vendor: **Items Supplied:**
Address
Period of Rating: Form……..to ……
Max. marks 40/10 marks each parameter)
I. **Quantity Rating**

Qty. Ordered	Qty. Received	Marks	Remarks

II. **Quality Rating**

Brief description of quality, including rejections if any:

Marks allotted:

III **Delivery Rating**

Brief description of Delivery, including detail of delays:

Marks allotted:

IV General Service

Brief description of general service

Marks allotted:

Total marks =
Please mark according to the total marks obtained.

	0 - 15	Shall be omitted from the Approved Vendor List
	16 - 20	Letters shall be issued to improve
	21 - 30	Need based letters shall be issued
	31 - 40	O.K Vendor

INCHARGE PURCHASE

Annexure G

XYZ Blood Bank

BB/QS/FM/00

Error in Investigation / Reporting

Department: .....

S. No.	Reg. No.	Date	Patient Name	Investigation requested	Technician who performed the Investigation	Type & Nature of Error	Root Cause analysis of the error	Corrective Actions Taken	Error found by	Reviewd By & Sign

XYZ Blood Bank

Donor Adverse Reaction Form

Name of Donor:_____Blood Unit No:_____Date of Donation:__/__/____ Time of Donation:_____AM/PM

Donation

Adverse Reaction:	Immediate	Delayed
Site of Donation:	In Blood Bank Premises	In Out Door Camp
During Donation:	Yes	No
Donation Complete:	Yes	No
Type of Component:	Whole Blood	Platletphersis

Type of Adverse Reaction

Syncope (Fainting or Vasovagal syndrome)

Tetany (Twitching or Muscular spasm)

Nausea and Vomiting

Hematoma

Convulsions

Cardiac problem

Local reactions related to the veinpuncture

Thrombophlebitis

Arterial puncture

Local Allergic reaction

Accidental related to the vasovagal syndrome

Related to Apheresis Procedure

General Allergic reaction

Anaphylaxis

Haemolysis

Embolism

Cold feeling / Shivers

Citrate-related paraesthesia / tingling

Citrate-related tetany

TherapyAdministered:_____

Name of Phlebotomist **Medical Officer**

XYZ Blood Bank

NEAR MISS/ADVERSE EVENT RECORD

Date	S.No.	Error	Person responsible	RCA	CAPA	*Sign*

XYZ Blood Bank

BB/QS/FM/00

Analysis of Customer Complaint

S.No.	Date	Customer Name & Contact No	Donor Number	Nature of Complaint	Root Cause Analysis and Actions taken	Closure Date	Comments & Signature

XYZ Blood Bank

BB/QS/FM/00

Internal Audit Non Conformity

Audit No.	Date:	Auditor:
Department:	Activity Assessed:	Auditee:
NC No:	Ref To NABH-MIS Doc No. -	
Description of Non-Conformity: Sign of Auditor & Date		
Corrective Action Proposed: Sign of Auditee& Date		
Responsibility & Time Required for Corrective Actio Sign of Auditee& Date		
Corrective action verified & Comments: Sign of Auditor & QM & Date		

BB/QS/FM/00

XYZBlood Bank

Corrective Action and Preventive Action (CAPA)

S. No.	Date	Nature of Problem	Root cause Anaysis and Corrective & Preventive Actions Taken	Effectiveness verified by and Date	Remarks & Signature

XYZ Blood bank Sample Rejection

Reason for Rejection	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Incorect Request																															
Hemolysis																															
Inadequate Quantity																															
Inapropriate Container																															
Not Signed																															
Request form Incomplete																															

XYZ Blood Bank

REPEAT SAMPLE RECORD

MONTH & YEAR:

DATE	PATIENT ID	NAME	NAME OF THE INVESTIGATION	REASON FOR REPEAT TESTING	DATE AND TIME OF INFORMING THE PATIENT	DATE AND TIME OF REPEAT SAMPLE	FIRST VALUE	SECOND VALUE	REMARKS

SIGN OF THE HOD/QM

Annexure H

XYZ Blood Bank

DAILY QC FORM

RED CELL SEROLOGY:

1. QC of pooled cells: - Date : _____

   Dated of preparation: _____ Prepared by _____
   No. of sample pooled: A1 Cells ( ) B cells ( ) O Cells ( )
   (Minimum - 3)

2. Appearance of Pooled Cells: Hemolysis – Yes / No
   Turbidity – Yes / No

3. QC for LISS – ID Diluent – 2 + Pooled cells: Hemolysis ( ) Clean ( )
   pH of LISS – ID Diluent – 2:

4. Reactivity & Specificity of Pooled cells / Anti – sera / Gel Cards:

Red cell Suspension	Antiserum	Expected Reaction	Working Reaction
A1 cells	Anti A	Agglutination (+)	_____
A1 cells	Anti B	No Agglutination (0)	_____
B cells	Anti A	No Agglutination (0)	_____
B cells	Anti B	Agglutination (+)	_____
O cells	Anti A	No Agglutination (0)	_____
O cells	Anti B	No Agglutination (0)	_____
O cells	Anti H	Agglutination (+)	_____
CC cells	AHG	Agglutination (+)	_____
Rh Pos cells (R1R1)	Anti D – IgM + IgG	Agglutination (+)	_____
Rh Neg cells (rr)	Anti D – IgM + IgG	No Agglutination (0)	_____
CC cells	AHG – Gel Card	Agglutination (+)	_____
ID – Diacell – I	Anti D – (IgM) diluted (1 : 10)	Agglutination (+)	_____
ID – Diacell – II	Anti D – (IgM) diluted (1 : 10)	Agglutination (+)	_____
ID – Diacell – III	Anti D – (IgM) diluted (1 : 10)	No Agglutination (0)	_____
ID – Diacell – Pool	Anti D – (IgM) diluted (1 : 10)	Agglutination (+)	_____
ABO & Rh Gel Card	Know Group Cells & Serum	: _____	_____
(Any Known Group sample can be selected)			

5. QC Check of Antisera. Bovine albumin and Coomb's sera: -
   Appearance &Expirty:-

Name of Antiserum	Precipitate Yes / No	Turbidity Yes / No	Particles or Gel formation Yes / No	Lot No. / Batch No.	Date of Expiry
Anti – A					
Anti –B					
Anti AB					
Anti – A1 (Lectin)					
Anti – H (Lectin)					
Anti – D (IgG)					
Anti – D (IgM + IgG)					
Coombs (AHG) – Anti IgG + C3d					
Coombs (AHG) – Anti IgG (if used)					
Coombs (AHG) – C3d (if used)					
Gel Cards–AHG –LISS / COOMBS					
Gel Cards – ABO & Rh					
Gel Cards – Al & H (Sub Group)					
Normal Saline					
LISS – ID Diluent - 2					

6. Blood Spillage kit (Tray) available - Yes / No
   If not, action taken _____.

7. Plasma Thawing Bath:
   Water in Plasma bath working & clean - Yes / No

DAILY QC FORM

Date: _____

PRE – DONATION TESTING AREA:
To be filled by the Technician in Collection area:

23. QC of Antis era – Appearance & Expiry:

Name of Antiserum	Precipitate Yes / No	Turbid Yes / No	Particles or Gel formation Yes / No	Lot No. / Batch No.	Date of Expiry
Anti – A					
Anti –B					
Anti – D (IgM + IgG)					

Reactivity & Specificity of Pooled cells & Anti – sera:

5%Red cell Suspension	Antiserum	Expected Reaction	Working Reaction
A1 cells	Anti A	Agglutination (+)	_____
A1 cells	Anti B	No Agglutination (0)	_____
B cells	Anti A	No Agglutination (0)	_____
B cells	Anti B	Agglutination (+)	_____
O cells	Anti A	No Agglutination (0)	_____
O cells	Anti B	No Agglutination (0)	_____
Rh Pos cells (R1R1)	AntiD – IgM + IgG	Agglutination (+)	_____
Rh Neg cells (rr)	Anti D – IgM +IgG	No Agglutination (0)	_____

24. Work Instruction for cell counter ; Displayed: YES / NO

25. Cell counter – Work sheet updated: YES / NO

26. CBC Control run (minimum 2 controls / day) for Cell counter recorded: YES / NO
(Order to run controls: Low & Normal – Normal & High – High & Low)

Blood Collect Area:

27. Refreshments (Juice / coffee): [ ] Adequate [ ] Inadequate

If inadequate action taken
_____.

28. Antiseptic (Hand rub) Solution available: YES / NO

29. Vaccutainer Tuber & Needles: Adequate / Inadequate

30. Handy plaster (Spot): Adequate / Inadequate

31. Sterile Gauze: Adequate / Inadequate

32. Waster disposable: Correct / Incorrect

33. Sharp container available: Yes / No

34. Donor Weighing Scale working: Yes / No

35. Blood Collection Monitors working: Yes/ No

36. Table top Sealer – Working: Yes /No Clean: YES /NO

DAILY QC FORM

Date: _____

PRE – DONATION TESTING AREA:
To be filled by the Technician in Collection area:

23. QC of Antis era – Appearance & Expiry:

Name of Antiserum	Precipitate Yes / No	Turbid Yes / No	Particles or Gel formation Yes / No	Lot No. / Batch No.	Date of Expiry
Anti – A					
Anti –B					
Anti – D (IgM + IgG)					

Reactivity & Specificity of Pooled cells & Anti – sera:

5%Red cell Suspension	Antiserum	Expected Reaction	Working Reaction
A1 cells	Anti A	Agglutination (+)	_____
A1 cells	Anti B	No Agglutination (0)	_____
B cells	Anti A	No Agglutination (0)	_____
B cells	Anti B	Agglutination (+)	_____
O cells	Anti A	No Agglutination (0)	_____
O cells	Anti B	No Agglutination (0)	_____
Rh Pos cells (R1R1)	AntiD – IgM + IgG	Agglutination (+)	_____
Rh Neg cells (rr)	Anti D – IgM +IgG	No Agglutination (0)	_____

24. Work Instruction for cell counter ; Displayed: YES / NO

25. Cell counter – Work sheet updated: YES / NO

26. CBC Control run (minimum 2 controls / day) for Cell counter recorded: YES / NO
(Order to run controls: Low & Normal – Normal & High – High & Low)

Blood Collect Area:

27. Refreshments (Juice / coffee): [ ] Adequate [ ] Inadequate

If inadequate action taken
_____.

28. Antiseptic (Hand rub) Solution available: YES / NO

29. Vaccutainer Tuber & Needles: Adequate / Inadequate

30. Handy plaster (Spot): Adequate / Inadequate

31. Sterile Gauze: Adequate / Inadequate

32. Waster disposable: Correct / Incorrect

33. Sharp container available: Yes / No

34. Donor Weighing Scale working: Yes / No

35. Blood Collection Monitors working: Yes/ No

36. Table top Sealer – Working: Yes /No Clean: YES /NO

COMPONENT AREA:

37. Deep freezer (Minus 40°C): Working: YES / NO

38. Deep Freezer – (Minus 40°C): Working: YES / NO

39. Deep Freezer – (Minus 80°C) Working: YES / NO

40. Refrigerator: Working: YES / NO

41. Refrigerator Working:: YES / NO

42. Platelet AGITATOR – Clean & Working: YES/ NO
Swirling movement of RDP – checked: YES / NO

43. Platelet Agitator – Clean & Working:: Y es / NO
Swirling movement of PRC – checked : YES /NO

Platelets Expiry Today:

RDP Bag Nos.					
SDP Bag Nos.					

44. Temperature records – CMS (Instruments) updated & Daily printout taken & field: YES / NO

45. Centrifuge working: Cleanliness Checked YES / NO

46. Centrifuge working: Cleanliness Checked YES / NO

47. Electronic Weighing Scale – Clean & Working: YES / NO

48. Sterile connecting device Working: YES / NO

49. Sterile connecting device Wafers adequate: YES / NO

50. Laminar Air Flow working: YES / NO
UV light ( ) Air Flow ( ) Tubelight ( ) Cleanliness( ) Checked: YES / NO

Remarks if any:
_____

51. Humidity _____

Remarks if any:
_____

Checked by Component Area Technician: _____

Verified by Technical Supervisor: _____

XYZ Blood bank

ABO Discrepancy

Donor Number / Patient CR ---------- Brief history

Age / Gender---------- Transfusion history----------

Clinical diagnosis---------- Direct Antiglobulin test----------

Phase & incubation time	Cell grouping				Serum grouping				Auto Control	Additional tests
	Anti-A	Anti-B	Anti-AB	Anti-A1	A1c	A2c	Bc	Oc		
IS, 15 min										
RT, 30 min										
4^0, 30 min										
37^0, 15 min										

Interpretation:

XYZ BLOOD BANK

Blood Issue Instructions

Name…….

Father's Name……...

Reg. No…….

Blood Group……Rh……

Unit No…….

X Match Report

Component	Unit No	Group	Rh	Major Cross Match		Minor Cross Match Saline
				Saline	Coombs	

Blood is Compatible with Recipient

Name and Signature of Cross-match Person

Date:___/___/_____ Time: ___/___AM / PM

Checklist for Issue of Blood Product from Blood Bank

Blood bag label and compatibility label / paperwork are all identical / compatible and correct
All the blood bag and patient details are identical and correct
Ask the attendant, spell patient full name
Requested of blood product including special requirements provided
Expiry date and time of blood bag (ensure cross match specimen current)

Visual inspection of the blood bag (mix gently before use)
Bag Intact - no leaks or evidence of tampering
No Clots, unusual discoloration or turbidity or haemolysis
No Significant color difference between tube segments and blood in bag

Issue No……

Name and Signature of Issue Person

Date:___/___/_____ Time: ___/___AM / PM

(Note: Once issued blood / blood component will not be taken back by Blood Bank.)

Instructions for Transfusion

Do not use it there is any visible evidence of deterioration

Store the product at appropriate temperature (as defined for each of the product) before use

(eg. Keep at 4°C ± 2°C / 22± 2°C)

Shake gently before use

Do not add any other medication to the blood/blood component

Check blood group on label and that of the recipient before administration

Use a fresh, clean, sterile and pyrogen-free disposable transfusion set with filter to transfuse blood

Do not dispense without a prescription

During the Transfusion

After the commencement of the transfusion, take observations at 15 minute intervals for 1 hour, then ½ hourly for one hour, and if within normal limits every hour for the duration of the transfusion. Complete the transfusion within 4 hours.

If a Transfusion Reaction Occurs

Stop the transfusion & notify medical officer

Keep the intravenous line open with suitable IV solution

Recheck patient identification and donor compatibility labels at the bedside to determine if the patient received the correct blood

Report the transfusion reaction to Blood Bank personal

Complete the Transfusion Reaction form (take fromBlood Bank)

Send post transfusion samples & blood product with giving set to Blood Bank

Note:

1. Complete Transfusion Reaction Form and forward with appropriate blood specimens and Blood Unit (IV tubing with sealed at both ends) send request to Blood Bank

2. Take Blood from opposite arm to transfusion

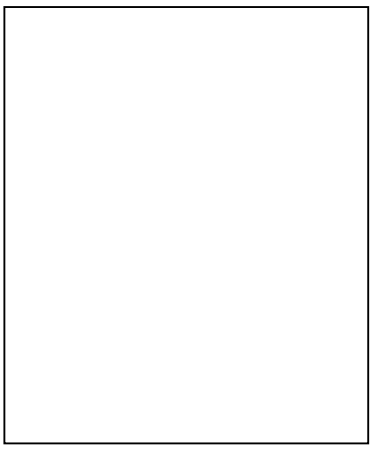
Red Top Vial	-	One
EDTA Vial(Lavender Top)	-	Two
Blood culture	-	One
Urine sample	-	Two

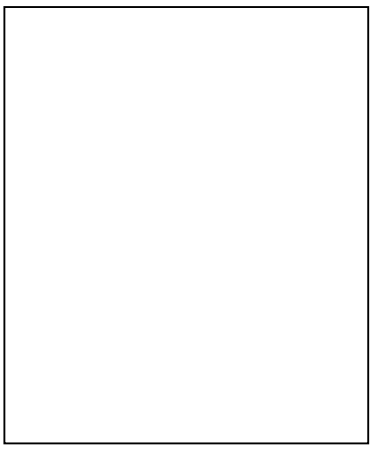
(Urine sample: At a time of Transfusion Reaction & after 4 hrs Post Transfusion)

XYZ Blood Bank

Record of STAT Issuing Blood (Un-cross-matched Blood/Components)

Stick Registration Barcode **Stick Issuing Barcode**





(Name & Signature) **(Name & Signature)**

Reason for STAT Issuing of Blood / Components: …….

Whom you talk for Issuing STAT:

Name: **Contact No.**

Date: **Time:**

STAT Issuing Directed By:

Name: **Contact No.**

Date: **Time:**

In case of In-compatible cross-match after issuing Blood/Components:

Inform to

Name: **Contact No.**

Date: **Time:**

XYZ Blood Bank
Transfusion Reaction Work up Form

Part I: Transfusion Reaction Investigation Request

1. **Patient Details:**

   Name _____ IPD/OPD/OUT .No_____
   Age/Sex_____

   Ward_____ Bed No ____ Name of Hospital _____Referred by _____

   Blood Group (as per record) _____Clinical Diagnosis _____

2. **Patient's History /Examination:**

   History of previous transfusion reaction: Yes/ No **If yes**: Date_____ No of Unit_____

   Obstetric History_____History of atypical antibody in serum _____

   Pre-transfusion haemglobinLevel_____Volume of urine passed (post transfusion) _____

3. **Transfusion Details :**
   Request No _____ Issue No (Blood Bank No)_____

   Indication of transfusion _____ Cross match by_____

   Component issued by (Name) _____Date / Time of issue_____

   Component transfused: Whole Blood PRC RDP FFP SDP CRYO

   Blood bag No._____ Date of Preparation___/__/_____ Date of expiry ___/_____/_____

   Date and time of starting transfusion _____

   Date and time of Reaction_____Volume of Product transfused_____

   Blood / Component was stored in (Ward):

   Freezer Refrigerator Room Temperature Incubator (22 to 24° C)

   History of warming: Yes No

   Method of warming: Room Temperature Water bath Incubator (37° C) Blood warmer

   History of injection in Blood bag: Saline Dextrose Distilled water Ringer Lactate

4. **Reaction Details** (Please tick)

   Type of Reaction: Immediate Delayed
   Reaction: Mild Moderate Sever

5. **Signs and Symptoms** (Please tick)

Fever	Nausea/Vomiting	Hemoglobinuria	Oozing (Puncture mark)
Rash	Tachycardia	Jaundice	Pain at effusion site
Chills/ Rigors	Hypotension	Pallor/Cyanosis	Other (Describe)

Please Record:

Vitals	Pre- Transfusion	Post - Transfusion	Present
Temperature			
Blood Pressur			
Respiration Rate			
Pulse			

1. **Please complete form and forward with appropriate blood specimens and Blood Unit (IV tubing with sealed at both ends) send request to Blood Bank**

2. **Take Blood from opposite arm to transfusion**

Type of Vial		Number	Sample Received in Blood Bank	
Red Top Vial	-	**One**	**Yes**	**No**
EDTA Vial(Lavender Top)	-	**Two**	**Yes**	**No**
Blood culture Bottle	-	**One**	**Yes**	**No**
Urine sample	-	**Two**	**Yes**	**No**

(Urine sample: At a time of Transfusion Reaction & after 4 hrs Post Transfusion)

Reviewing Doctor:

Name: _____ Tel. No / Mobile No _____

Signature: _____ Date: _____

Annexure I

XYZ Blood Bank

Component Preparation

SN	Unit ID	Type of bag	Pilot tube no	Red cells	FFP	RDP	Cryo	CPP	Remarks

XYZ Blood Bank

Quality Control of Whole Blood and Packed Red Cells

S.No	Date	Bag Details	Donor No	Date of Collection	Date of Expiry	Appearance	Vol	Hct	Culture

Signature of Technician _____ **Signature of MO**

XYZ Blood Bank

SUMMARY REPORT OF QUALITY CONTROL IN BLOOD & BLOOD COMPONENTS
(Monthly)

Date:

Total Units Collected	Whole Blood		Packed Red Cells		Fresh Frozen Plasma		Random Donor Platelet		RDP sent for Culture
	No. of Components	QC Performed	No. of Components	QC Performed	No. of Components	QC Performed	No. of Components	QC Performed	QC Performed
1 % of Total Units									

Comment:

1% QC performed on total number of units collected all are within acceptable range. No corrective action is required.

Documentation:

Blood Bank QC Register for Blood / Blood Components

QC Performed By:	Verified By:	Checked By:	Authorized By:
Technical Manager	Quality Manager	Medical Office	Head of Department

XYZ Blood Bank

Pre donation information

Please read these points before Donating Blood

1. Transfusion Transmitted Disease are prone to happen in person with risk behavior in sexual pattern like multiple partner, unprotected sex or intravenous drug etc. Please do not donate Blood if you have to any risk behavior
2. The test done on your donated Blood are follows:

   HBs Ag

   Anti HIV

   Anti HCV

   VDRL

   Malaria Parasite
3. These tests are also done free of cost at ICTC Centre if you are looking to get the test done. Please contact Department of Microbiology,
4. All the test result s are kept highly confidential.
5. You need to answer these or self exclude yourself in view to help patient and yourself.

XYZ Blood Bank

New Lot Verification Register

Name of the reagent changed:

Department:

Date	Parameter	Lot No	Result with old reagent	Lot No.	Result with new reagent	Acceptable Variation in %	Observed Variation in %	Verified by

Sign of HOD/QM

Note:

New lot verification is applied to reagents both testing kits and QC material.

It is done by analyzing two Patient samples, one low value and one high value with the old and new reagent. Variations observed should not be more than 10%.

Annexure J

XYZ Blood Bank

TTI Testing worksheet

Date of testing	_____
Name of firm	_____
Lot No	_____
Kit expiry	_____
OD of cut off	_____
Gray area OD	_____

Reactive samples _____Validity criteria ----------

Sample of gray area _____

Plan of ELISA microplate

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Remarks: Test Valid? Yes / No

XYZ Blood Bank

ANALYZER WASTE DISCARD LOG

Month/Year:

DATE	Cell vounter	CLIA	ELISA Washer	TTILAB 300	TECH.SIGN
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

Annexure K

XYZ Blood Bank **BB/QS/FM/00**

XYZ Blood Bank

CLINICIAN FEED BACK FORM

We thank you for using our Blood Bank services. Your suggestion and feedback is very valuable to us. Please help us to serve you better by sparing a few minutes of your time to fill out this form.

1. Was the Blood Product required available in the blood bank?
   Yes / No

2. Was it issued within the time limit explained?
   Yes / No

3. Was the blood / blood product received in good condition?
   Yes / No

4. Were sufficient ice packs issued along with the blood?
   Yes / No

5. Were instruction given to you regarding transport of platelets? (For Platelet issues only)
   Yes / No

6. Were the department staff Polite and courteous?
   Yes / No

7. Did you receive satisfactory answers to your question?
   Yes / No

8. How was the overall quality of service received? Excellent / Good / Unsatisfactory

9. Your suggestions and comments to improve our service:

_____

Doctor/ Nursing Staff Name: _____ Signature: _____

Date: _____ Tel No:

Follow up Action :……

Signature of Q. Manager

XYZ Blood bank
Quality
Indicators Sheet

Quality Indicator	Jan	Feb	Mar	Apr	May	Jun
1 Volume of Work						
2 No. of Complaints -						
Donors / Patients						
[complaint register]						
3 Clinicians Satisfaction Level						
4 Turn-around-time - Urgent						
5 Donor deferral 6 Adverse Reaction rate 7 Discard rate 8 TTI Reactive rate						

Sig Q Manager

Annexure L
Self-assessment Quality checklist

Clause No	Clause	Implemented (Yes /No)	Documented (Yes/No)	Remark (If any)
1.	**ORGANISATION AND MANAGEMENT**			
1.1	**Legal identity**			
1.1.1	The blood bankhas a valid license from regulatory authorities, as applicable or Has applied for renewal of the license in time.			
1.1.2	The organization under which the blood bank functions is legally identifiable.			
1.2	**Responsibility**			
1.2.1	An organization chart (organogram) is defined and displayed			
	The organization chart of the blood has linkage with the parent organization (If hospital based blood bank)			
1.2.2	The blood bank has a quality manager empowered by the head of the institution to deploy the quality management system.			
1.2.3	The top management is well aware of regulations , standards and laws			
1.2.4	Job responsibilities are clearly defined and documented for all the staff working in the blood bank			
1.3	**Ethics in blood bank**			
1.3.1	The blood bank personnel are bound by the ethical code of their respective profession			
1.3.2	Ethics in blood bank is defined and incorporatedin the quality manual.			
1.3.3	The blood bank is not engaged in practices restricted by law and upholds the reputation of the profession.			
1.3.4	Ethics underpin all the procedures and processes carried out in blood bank			
1.4	**Quality Management System**			
1.4.1	The responsibilities for the design, implementation, maintenance and improvement of the quality management system are well defined			
1.4.2	The quality policy and objectives of the quality management system : are defined are issued under the authority of the Director/ In-			

	charge of blood bank are documented in a quality manual.			
1.4.3	The quality manual of the blood bank includes and describes the quality management system covering all the aspects of standards The structure of the documentation used in the quality management system. references to the supporting procedures including technical procedures.			
1.4.4	All personnel are trained and retrained in the quality management system with appropriate in-house training			
1.4.5	The quality manual is kept up to date under the authority of an individual responsible for maintaining quality management system.			
1.4.6	For implementation and maintenance of quality management system, the management has appointed quality manager and deputy.			
1.4.7	For supervision and maintenance of technical operations, the management has appointed technical manager and deputy.			
1.4.8	Roles and responsibilities of technical manager and the quality manager are defined to oversee compliance with the requirement of the quality management system.			
1.4.9	The blood bank has defined emergency operation policies and procedures to respond to the effects of internal and external disaster.			
1.5	**Policies, processes and procedures**			
1.5.1	Quality and operational policies, processes, and procedures have been developed and implemented to ensure that the requirements of the standards are satisfied.			

1.5.2	All policies, processes and procedures have been approved by Director/ In-charge of the blood bank			
2.0 ACCOMMODATION AND ENVIRONMENT				
2.1	**Space allocation**			
2.1.1	**Location and surroundings** The blood bank is Located in a hygienic place Has good infrastructure and adequate workplace for efficient operations. Designed as such to minimize the risk of injury and occupational illness			
	Signagesfor fire and non-fire hazards within the facility are displayed and also for restricted entry to controlled areas.			
Accommodation of blood bank				
2.1.2	The blood bank hasadequate area for the scope of services as per regulatory requirements.			
Processing of blood component from whole blood by a blood bank				
2.1.3	Blood bank has adequate area for preparing blood components commensurate with the quantum of work to maintain quality of blood components			
Plasmapheresis, Plateletpheresis and Leucapheresis				
2.1.4	A minimum additional air conditioned area as per regulatory requirements is provided for apheresis in the blood bank			
Blood donation camp				
2.1.5	Requirements are fulfilled / complied withfor holding blood donation camps			
2.1.6	There is effective separation between adjacent sections of the blood bank where incompatible activities are performed to prevent cross-contamination.			
2.1.7	Access of those areas is controlled where quality of examinations can be affected and where samples,reagents and equipment arekept.			

2.1.8	Adequate storage space and conditions are provided to ensure the continuing integrity of samples, documents, files, manuals, equipment, reagents, blood bank/ blood centre supplies, records and results.			
2.1.9	Work areas are clean and well maintained (good housekeeping). Storage including transportation and disposal of dangerous material are according to regulatory requirements. Special procedures and training for personnel is given to meet these requirements.			
2.1.10	Adequate back up facility for maintaining electrical supply round the clock.is available			
2.2	**Environment Control**			
	The blood bankhas documented policy and process to minimize and respond to environmentally related risks to the health and safety of employees (including immunization), donors, volunteers, patient/ recipients and visitors. Suitable environment and equipment are available to maintain safe environment.			
2.3	**Biological, Chemical and Radiation Safety**			
	The blood bank Has a policy and procedure for monitoring adherence to biological, chemical and radiation safety standards and regulations Monitors, controls and records environmental conditions, as required by relevant specifications or where they may influence the procedures and quality of the results Monitors sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels as appropriate to the technical activities concerned.			
2.4	**Internal Communication Systems**			
	Effective Communication systems within the blood bankare present for efficient transfer of information			

	appropriate to size and complexity of the facility			
3.0	**PERSONNEL**			
3.1	**Personnel Requirement**			
	The blood bankhas aprocess for employment of an adequate number of individuals qualified by education, training and/ or experience as per applicable regulations.			
3.2	**Qualification**			
	The blood bankhas adequate and appropriately qualified officials as Director/In-charge/Medical officer Technician(s) Registered Nurse(s) ' Technical Supervisor(s) Counselor			
3.3	**Job description/ responsibilities**			
3.3.1	Job descriptions are Defined as appropriate to qualifications for each job position. Documented and Communicated			
3.3.2	Personnel performassigned activities on the basis of appropriate qualification, education, training and/ or experience.			
3.4	**Responsibilities of Medical Director/ In-charge/ Medical Officer blood bank, Technical Manager and Quality Manager**			
3.4.1	The responsibilities of Director/In-charge/Medical Officer Technical Manger Quality Manager is defined ,Documented and communicated			
3.5	**Training**			
3.5.1	The blood bank has a procedure for training and it includes Training of all personnel specific to the tasks they			

	perform and also to quality assurance and quality management systems. Personnel adequately trained initially and continually for the tasks undertaken and relevant to their needs. Continuing education program available to staff at all levels. Training to prevent and report adverse incidents and/or contain the effects of the incident			
3.6	**Competence**			
	Thereis a policy and procedure for competency evaluation of each person to perform assigned tasks			
3.7	**Personnel health**			
	The blood bank has policies and procedures for personnel healthincluding Pre-employment medical examinations Regular health check ups Monitoring occupational health hazards			
3.8	**Personnel records**			
	Blood bank has a policy to maintain records of the personal information, relevant educational and professional qualification, training and experience, and competence of all personnel including Immunization status records of all staffs are easily available			
3.9	**Confidentiality of information**			
	Policy to maintain confidentiality of information regarding donor/ patient/ recipient is present.			
	Health records of staff arekept confidential and in a safe place.			
4.0	**EQUIPMENT**			
4.1	**Equipment requirement**			
	The Blood bank has the requisite equipment as per blood bank scope of activities/services and documented			