BLOOD BANK INSPECTION CHECKLIST AND REPORT

Date of Inspection: **Names of Inspecting Officers:**	**Name & Address of Blood Bank:** **Fax No.** **Tel. No.** **E mail:**
LEVEL State Capital - S Medical College - M District - D Taluk - T	Constitution of the firm (Name of Director/ Partners / Proprietors etc.)
CONTROL Central Govt. - C Public Sector State Govt. - S Undertaking - PSU Public Chari-- Private table Trust - CT Commercial - PC Private Voluntary Hospital - PH Organisation - V	**Medical Officer In charge** Licensed: (Y/N) **License No.** Valid up to: Grant:
TECHNICAL STAFF Medical Officer : Registered Nurse : Blood Bank Technician : Technical Supervisor : Social Workers : Attendants : Others :	Applied for Grant / Licensed for **1. Whole Human Blood IP** **2. Preparation of Blood Components**: a. Packed Red Cells IP b. Washed Cells c. Fresh Frozen Plasma BP d. Pooled Plasma e. Single Donor Plasma f. Platelets Rich Plasma g. Platelets Rich Conc. h. Granulocyte Conc. i. Cryoprecipitate

WORK LOAD FOR PAST TWO YEARS

COLLECTION	**200**	**200**	**DISPOSITION**	**200**	**200**
Voluntary			Used in their Hospital		
Replacement			Issued Outside		
Total			Discarded		
			Total		
Frequency of Reporting			Details of Discarded Blood		
Monthly	M		HBsAg +		
Quarterly	Q		HIV +		
Half Yearly	H		HCV +		
Annually	A		VDRL +		
Reported To:			Date Expired		
			Insufficient Volume		
			Haemolysed		

ROUTINE TECHNIQUES USED FOR TESTS

Cell Grouping		**Serum Grouping**		**Rh (D) Grouping**					
Slide	D	Slide	D	Slide			D	Albumin-	A
Tile	I	Tile	I	Modified tube			M	Enzyme-	Z
Tube	B	Tube	B	Du test for Confirmation of D –ve			Du	Combs-	C
				Performed on all case? (Y/N)					
Cross Matching				HBsAg		HCV		HIV Testing	
Slide	-D	Albumin	-A	Elisa	-E	Elisa	-P	Elisa	-E
Tile	-B	Enzyme	-Z	Rapid	-R	Rapid	-R	W.Blot	-W
Saline	-S	Coombs	-C	Others	-O	Others	-O	Rapid	-R
								Others	-O
Unexpected antibodies									

GENERAL EQUIPMENTS AND INSTRUMENTS

DETAILS OF EQUIPMENTS/INSTRUMENTS	OBSERVATIONS	REMARKS
1. Refrigerators for storing separately tested and untested blood	Yes/No	
For tested Blood a) Capacity: b) Make:	Yes/No	
For Untested Blood a) Capacity: b) Make :	Yes/No	
Whether Thermograph provided Whether Alarm device provided Whether digital dial Thermometer provided	Yes/No Yes/No Yes/No	
2. Weighing device for blood containers	Yes/No	
3. Autoclave with temperature and pressure indicator	Yes/No	
4. Stand by generator	Yes/No	

LABORATORY EQUIPMENTS

DETAILS OF LABORATORY EQUIPMENTS	OBSERVATIONS	REMARKS
1. Refrigerator for kits & reagent storage a) Capacity : b) Make: Whether digital dial thermometer provided	Yes/No Yes/No	
2. Compond microscope with low & high power objectives	Yes/No	
3. Centrifuge – Table Model	Yes/No	
4. Water bath between 37°C to 56°C	Yes/No	
5 Rh. Viewing box in case of slide technique	Yes/No	
6. Incubator with thermostatic control	Yes/No	
7. Mechanical shakers for serological tests for syphilis	Yes/No	
8. Hand lens	Yes/No	
9. Serological graduated pipettes of various sizes	Yes/No	
10. Pipettes (Pasteur)	Yes/No	
11. Glass slides	Yes/No	
12. Test tubes of various sizes/micrometer plates (U or V type)	Yes/No	
13. Precipitating tubes 6 x 50mm of different sizes & glass beakers of different sizes	Yes/No	
14. Test tubes rack	Yes/No	
15. Interval timer	Yes/No	
16. Equipment & materials for cleaning glassware's	Yes/No	
17. Insulated containers for transporting blood between 2°C to 10°C	Yes/No	
18. Wash bottles	Yes/No	
19. Filter papers	Yes/No	
20. Dielectric tube sealer	Yes/No	
21. Plain and EDTA vials	Yes/No	
22. Chemical balance	Yes/No	
23. Elisa reader with printer, washer and micropipettes	Yes/No	
24. Colorimeter for hemoglobin determination	Yes/No	
25. Blood Agitator cum Weighing device	Yes/No	

EQUIPMENT FOR COMPONENT PREPARATION

DETAILS OF EQUIPMENTS	OBSERVATIONS	REMARKS
1. LAF Bench	Yes / No	
2. Refrigerated Centrifuge	Yes / No	
3. Plasma Expresser	Yes / No	
4. Clipper and Clips and / or dielectric sealer	Yes / No	
5. Weighing device	Yes / No	
6. Dry rubber balancing material	Yes / No	
7. Artery forceps, Scissors	Yes / No	
8. Refrigerators a. Capacity: b. Make Whether Thermograph provided? Whether Alarm device provided? Whether digital dial thermometer provided?	Yes / No Yes / No Yes / No Yes / No	
9. Platelet agitator with incubator	Yes / No	
10. Deep freezer (-30º C to -40º C)	Yes / No	
11. Deep freezer (-75 C to -80 C)	Yes / No	
12. Refrigerated water bath for plasma thawing	Yes / No	
13. Appropriate insulated blood bag containers for transport purposes	Yes / No	
14. Air conditioner for the preparation room	Yes / No	
15. Storage equipments for Granulocyte Conc. (20 C to 24 C)	Yes / No	
16. Blood bags used for component separation	Single/Double/Triple	
17. Specify additive solution used for RBC preservation		

CENTRAL DRUGS STANDARD CONTROL ORGANISATION
FORMAT OF INSPECTION REPORT FOR WHB & COMPONENTS

Name & Address of Blood Bank: **Inspecting Officers:**

Licence No: Date of Inspection :

A. GENETAL:

1. Location and surroundings: (Brief description to be given)

Is away from open sewage, drain, public
Lavatory and other unhygienic surroundings?

2. Building:

Is construction suitable for maintaining hygienic conditions?
Is entry of insects, flies and rodents avoided by proper mesh?
Is lighted and ventilated?
Are walls, floors and ceilings are smooth and washable?

3. Health, Clothing and Sanitation of Staff:

Are employees free from contagious / infectious diseases?
Are employees provided with clean overall, headgears, foot wears and gloves?
Are adequate and clean hand washing and toilet facilities available?

B. ACCOMODATION FOR BLOOD BANK OPERATIONS:

	ROOM	DIMENSIONS (in Mtrs.)	AREA (Sq. Mtrs.)
1.	Registration & Medical Examination . . .		
2.	Blood collection (A/C)		
3.	Laboratory for blood group serology (A/C).. . .		
4.	Laboratory for blood transmissible diseases (A/C) . .		
5.	Sterilization- cum – washing		
6.	Refreshment-cum-rest room (A/C)		
7.	Stores/Records room		
8.	Blood components room (A/C)		
9.	Total Area for Operations:		

C. PERSONNEL:

Are the following whole time technical staff provided

a) Medical officer's name: Qualification: Experience: (as regular service at (Name of BB)

b) Registered Nurse: Qualification: Reg.No: Nursing Council

c) Blood Bank Technicians: Qualification: Institute: Experience

d) Technical Supervisor (Components) Qualifications: Experience:

e) Record of change of Competent Technical Staff with dates:

f) The changes of Competent Technical Staff reported vide their letter No. Dt

D. MAINTENANCE:

1. Privacy for medical examination of donor Yes/No
2. Blood collection area excluded from other activities to avoid risk of contamination Yes/No
3. Separates storage facility for untested blood/component Yes/No
4. Quarantine facility for units awaiting retest Yes/No
5. Is adequate quarantine facility provided for rejected units/ materials awaiting disposal Yes/No
6. Storage of finished products prior to distribution or issue Yes/No
7. Premises area maintained hygienically to prevent contamination Yes/No
8. Blood / components found unsuitable for use and other Biomedical wastes (Management and Handling) Rules 1998. Yes/No

E. EQUIPMENTS:

Whether the cleanliness & maintenance of all equipments adequate Yes/No

Whether equipment calibration/standardization carried out at the following frequencies:

EQUPMENT	PERFORMANCE	FREQUENCY OF CALIBARATION	OBSERVATIONS
1. Temperature recorder	Compare against thermometer	Daily	
2. Refrigerated centrifuge	Observe speed & temperature	Each day of use	
3. Hematocrit centrifuge	Speed	Standardize before initial use, after repair or adjustments & annually.	
4. General Lab. Centrifuge	Speed	Tachometer. Every 6 months	
5. Automated Blood typing	Observe with controls for correct results	Each day of use	
6. Hemoglobinometer	Standardize against cyanomethomoglobine	Each day of use	
7. Refractometer or Urinometer	Standardize against distilled water	Each day of use	
8. Blood container weighing device	Standardize against Known weight	Each day of use	
9. Water bath	Observe temp.	Each day of use	
10.Rh view box	Observe temp.	Each day of use	
11.Autoclave			
12. Serologic Rotator	Compare with controls		
13. Laboratory Thermometer		Before initial use	
14. Electronic Thermometer		Monthly	
15.Blood agitator		Each day of use.	

F. REAGENTS AND SUPPLIES:

a) Are all reagents and supplies stored at proper temperature in a safe and hygienic place and in a proper manner? Yes/No

b) Are all reagents and supplies used within their expiry date? Yes/No

c) Are samples of the following reagents tested to assess their quality?

REAGENTS AND SOLUTIONS	FREQUENCY OF TESTING ALONG WITH CONTROLS	OBSERVATION
1. Anti-human serum	Each day of use	
2. Blood grouping serums	Each day of use	
3. Lectin	Each day of use	
4. Antibody screening and reverse grouping cells	Each day of use	
5. Hepatitis test reagents	Each day of use	
6. Syphilis serology reagents	Each day of use	
7. Enzymes	Each day of use	
8. HIV I and II reagents	Each day of use	
9. Normal Saline	Each day of use	
10. Bovine albumin	Each day of use	

G. GOOD MANUFACTURING PRACTICES (GMPs) STANDARD OPERATING PRACTICES (SOPs)

1. Is written standard operating procedures maintained Yes/No

Does the SOPs include the following?

a) Criteria to determine donor suitability Yes/No
b) Methods of performing donor qualifying test Yes/No
c) Methods of relating the product to the donor Yes/No
d) Blood collection procedure with precautions to accurately measure the qty. of blood collected Yes/No
e) Methods of component preparation Yes/No
f) Tests performed on blood & blood products during processing Yes/No
g) Pre-transfusion testing Yes/No
h) Procedures of managing adverse reactions Yes/No
i) Storage temp. and methods of controlling storage temp. Yes/No
j) Expiry date of all final products Yes/No
k) Criteria for accepting returned blood Yes/No
l) Quality control procedure for supplies and reagents Yes/No
m) Schedules and procedures for equipment maintenance and calibration Yes/No
n) Labeling procedures Yes/No
o) Procedures for plasma/platelet/ leucophersis Yes/No
p) Procedures for preparing recovered plasma Yes/No
q) Procedures for review of records Yes/No

H. CRITERIA FOR BLOOD DONATION:

Whether disposable needles or lancets are used for specimen collection: Yes/No

1. Do they have a proper donor registration card? Yes/No

Whether the following examination is carried out in each donor before phlebotomy and recorded.

a. Age (18 to 60) :
b. Weight (not less than 45 kgs) :
c. Temperature and pulse :
d. Blood pressure :
e. Heamoglobin (not less than 12.5g) – indicate the test methods :
f. Respiratory diseases :
g. Skin diseases at the site of phlebotomy :
h. Past medical history of TTD. :
i. Precautionary observation to avoid professional donor :

2. Does the donor card specify the following conditions for deferment of blood donation along with the period of deferment?

Abortions	6 months	
History of blood transfusion	6 months	
Surgery	12 months	
Typhoid	12 months after recovery	
History of malaria and duly treated	3 months (endemic) 3 years (non-endemic area)	
Tattoo	6 months	
Breast feeding	12months after delivery	
Immunization	15 days	
Rabies vaccination	1 year	
History of hepatitis	12 months	
Immunoglobulin	12 months	

Does the donor card specify the following conditions for rejection of blood donation

Cancer	Heart disease
Abnormal bleeding tendencies	Unexplained weight loss
Diabetes controlled on insulin	Hepatitis B infection
Chronic nephritis	Sign & symptoms suggestive of AIDS
Liver disease	Tuberculosis
Polycythemia Vera	Asthma
Epilepsy	Leprosy
Schizophrenia	Endocrine disorders

I. a) COLLECTION OF BLOOD :

1. Preparation of phlebotomy site :
2. Type of Anticoagulant used :
3. Amount of Anticoagulant used :
4. Amount of blood collected :
5. Blood collected in bags/ bottles :
6. Whether smaller blood bags are used for pediatric purposes? :
7. Whether manufacture's test report available for the batch of CPDA solution used :
8. Whether proper mixing of blood and Anticoagulant done during collection? :
9. Whether disposable needles and sets are used? :
10. If a second puncture is required is a new disposable set used? :
11. How are the sample tubes labeled? :
12. Whether emergency drug kit available as per Sec I (5) of Schedule F? :

b) STORAGE:

1. Blood storage refrigerators available :
   i) Make: Capacity :
   ii) Make: Capacity :
2. Whether recorded thermographs preserved with dates? :
3. Do they check alarm system off & on when temperature deviation or failure of power supply? :
4. How do they transport the blood?
   a. To hospital wards :
   b. To outside hospital/ blood bank :
5. Do they reuse the returned bottle of blood? :
   If yes give details

6. Storing of blood components Temperature Duration / Expiry period
   a. FFP
   b. CRP
   c. PLATELETS
   d. RED CELL CONC

7. Whether donor & patient's blood samples preserved for 7 days post transfusion?

J. DONOR BLOOD TESTING:

1. Whether collected blood is tested for sterility as per I.P
2. Frequency/ percentage of sterility testing.
3. Whether Hb estimation is carried out on collected blood as per I.P
4. Method used for ABO Grouping—Slide /Tube/Others (Specify)
5. Grouping done on Cells /Serum/Both
6. Method adopted for preparation of pooled cells.
7. Whether Du test is carried out on D negative blood.
8. Whether test for unexpected antibodies carried out.
9. Do they inform donor of any positive results?
10. Is the donor debarred permanently if he is HbsAg /HIV positive.
11. Do they follow up HbsAg/HIV positive donors?
12. Methods and kits used for testing:

Name of test	KIT Manufacturer	Brand Name
A) VDRL		
B) HbSAg		
C) HIV 1&2		
D) HCV		
E) HBC		

K. a) PATIENTS PRETRANSFUSION TESTS:

1. Is there proper requisition form in use? :
2. Do they test for Auto– agglutinins? :
   If so what is the procedure followed:
3. Do they carry out antibody detection test? :
4. Are the red cells sensitized with IgG :
   Used as controls for AGT? : Slide/ Tube method
5. What method for cross matching
   a. Major /Minor :
   b. Saline / Enzyme / Albumin /AGT :
   c. Do they use AGT for all cases? :
      If not, specify where used?

b) QUALITY CONTROL :

1. Do they have a hospital transfusion committee to review procedures? :
2. Do they carry out personnel proficiency test? :
3. Are the staff encouraged to attend courses / seminars/ conferences? :
4. Whether every batch of reagents procured are tested initially before use. :

c) TRANSFUSION COMPLICATIONS:

1. Does the Lab. Manual describe the tests done in case of HTR? :
2. Do they have transfusion records which accompany the blood bags when issued? :

I. RECORD AND REPORTS:

1. Do they have records of the following activities?

a) Blood donor record :
b) Master records for blood and components :
c) Issue register :
d) Components issue register :
e) Records of blood bags :
f) Register for diagnostic kits and reagents :
g) Copies of cross matching reports issued to Patients :
h) Adverse reaction records :
i) Stock register for all other consumables :

2. How long the records are maintained? :

M. LABELLING:

Whether labels of blood containers comply with Schedule F and I.P :

N. OBSERVATIONS, IRREGULARITIES AND RECOMMENDATIONS: