QUALITY CONTROL IN BLOOD BANK

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Quality Assurance

- It is the sum total of the organized arrangements with the objective of ensuring that products will be of the quality required for their intended use.

- It includes retrospective review and analysis of operational performance data to determine that the overall process is in a state of control and to detect shift or trends that require attention.

Quality Control

- Testing routinely performed tests/activities on materials and equipments to check their proper function

- The monitoring system that checks the effectiveness of existing process/steps by testing the quality of final products

Quality System Essentials (QSEs)

1. Organization and leadership
2. Facilities work environment and safety
3. Human resources
4. Customer focus
5. Suppliers and material management
6. Equipment management
7. Process management
8. Documents and records
9. Information management
10. Management of non conforming events
11. Monitoring and assessment
12. Process improvement

Types

- Internal Quality control
- External Quality Control

Internal Control

- The internal quality control can be maintained by going through a complete checklist of items or test daily to make sure that all systems are being monitored and in control.
- Immediate decisions can be taken to accept or reject results / products.

External Quality Control

- External quality control is a way to compare the performance of a laboratory with reference to other laboratories
- External Quality Assurance also know as ‘proficiency testing’ or External Quality control

Quality in Blood Transfusion Services

In blood transfusion service, the primary goal of quality is 'transfusion of safe unit of blood.'

The quality system deals with all aspects to ensure that the product or 'safe unit of blood' is as safe as possible.

Objectives of Quality in Blood Bank

- To ensure availability of a sufficient supply of blood, blood components of high quality with maximum efficacy and minimum risk to both donors and patients.

- To determine problems in the whole transfusion chain and solve it to achieve the goal .

Quality Management System in Blood Bank

In a blood transfusion center, it means that a management system should exist to look into provision of a safe unit of blood and if any errors are identified, these should be corrected.

Steps involving Quality Control in Blood Bank

- Donor selection and Blood collection
- Serology Laboratory
- Transfusion transmitted Infection
- Component preparation
- Cross-match & Antibody screening
- Storage , issue and transportation

Need for Quality

A failure in the quality of blood collected or screening of donated blood unit can be very serious and may result in fatal consequences.

1. Failure to identify the patient correctly
2. Wrong sample labeling
3. Mix-up of results amongst different patients
4. Failure to detect presence of an abnormality in the patient's sample
5. Issue of unscreened blood due to clerical or technical errors

Quality Control for Reagents

The primary objective of a reagent quality control is to ensure that reagent is functioning as expected.

Quality Control for Reagents

Reagent requirements

- All reagents should be clearly labeled with batch number, expiry date and storage temp;
- Instructions for use should be in-form of SOP's with training.
- All reagents and kit should be used according to the manufacturer's instructions.
- FIFO shall be maintained

Quality Control for Reagents

- Use of positive & negative controls should be done with each batch to show that reagents are potent and specific.
- All reagents must be carefully stored at recommended temp.
- Reagents to be kept at 4-6^{o}C should never be frozen and are stored according to manufacturer's instructions only
- Supply, storage and transportation of kits and reagents should be strictly standardized & manufacturer's instructions should be followed with ensured continuous power supply and periodic temperature monitoring.

Log of Reagents

- Reagent records should include:
  - The name of each reagent with
    - Lot number
    - Batch number
    - Expiry date
    - Name of manufacturer
    - Date of receipt and put in use
  - Grade and strength of reactions at time of receipt (Kit verification).

Frequency of Quality Control of Reagent

Reagents	Frequency of testing along with Controls
Anti human serum	Each day of use
Blood grouping serum	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Enzymes	Each run
Normal saline (LISS and BPS)	Each day of use
Bovine albumin	Each day of use

Quality Control of Reagent Red Blood Cells

Parameters	Quality Requirement	Frequency of Control
Appearance	No haemolysis or turbidity in supernatant by visual inspections	Each day
Reactivity and specificity	Positive reactions with known sera against red blood cells antigens	Each day

Quality Control of ABO Reagent (Anti-A, Anti-B and Anti-AB)

Parameters	Quality Requirement	Frequency of Control
Appearance	No turbidity, precipitate, particles or gel formation by visual inspection	Each day
Specificity	Positive reaction with red cells having corresponding antigen(s); and no reaction with negative control	Daily and of each new lot/batch
Avidity	Macroscopic agglutination with 50% red cells suspension in homologous serum/normal saline using the slide test; 10 seconds for anti-A, anti-B and anti-AB with A_1 and/or B cells at R.T; 20 seconds with A_2 and A_2B cells.	Daily and of each new lot/batch
Reactivity	No immune haemolysis, rouleaux formation or Prozone	Each new lot/batch.
Potency	Undiluted serum should give +++reactions in saline tube test using a 3% red cells suspensions at R.T., titre should be 256 for anti-A, anti-B, and anti-AB with A_1 and/or B cells, 64 with A_2 and A_2B cells.	Each new lot/batch.

Quality Acceptable of Rh Anti-sera (Anti-D)

Parameter	Quality requirement	Frequency of control
Appearance	No turbidity, precipitation, particles or gel formation by visual inspection	Each day
Specificity	Positive reaction with R_1r cells / Known D Positive cells	Each day and each new lot/batch. And no reaction with rr cells.
Avidity	Visible agglutination with 40% red cells suspension in homologous serum using the slide test.	Each day and each new lot/batch
Reactivity	No immune haemolysis, rouleaux formation or prozone phenomenon.	Each new lot/batch
Potency	Undiluted serum gives +++ reactions in designated test for each serum and a titre 32-64 for anti-D.	Each new lot/batch

Acceptable Titre and Avidity of ABO Reagents

Anti-sera	Type of the reagent	Type of red cells (2 -3% cells suspension)	Titre	Avidity Time	Intensity
Anti-A	Polyclonal Monoclonal	A_1 A_2 A_2B O B A_1 A_2 A_2B O B	1:256 1:128 1:64 - - 1:256 1:128 1:64 - -	10-12 sec 15-18 sec 15-18 sec - - 3.4 sec 5-6 sec 5-6 sec - -	+++ ++ To +++ ++ - - +++ ++ To +++ ++++ - -
Anti-B	Polyclonal Monoclonal	B A_1B O A_1 B A_1B O A_1	1:256 1:128 - - 1:256 1:128 - -	10-12 sec 12-15 sec - - 3-4 sec 5-6 sec - -	+++ ++ - - ++++ +++ - -
Anti-AB	Polyclonal Monoclonal	A_1 B A_2 O A_1 B A_2 O	1:256 1:256 1:64 - 1:256 1:256 1:128 -	10-12 sec 10-12 sec 15-18 sec - 3-4 sec 3-4 sec 5-6 sec -	+++ +++ ++ To +++ - ++++ ++++ +++ -

Acceptable Quality of Anti-globulin (Gel / Beads) Reagent

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual in inspection.	Each day
Reactivity and Specificity	No prozone phenomenon No haemolysis or agglutination of unsensitized red cells Agglutination of red cells sensitised with anti-D serum containing not more than 0.2 mg/ml antibody activity	Each lot Each day Each day and each new lot/batch.

Transfusion Transmitted Infection testing Done in Blood Bank

- HBs Ag
- HIV 1 & 2
- HCV
- Syphilis
- Malaria Parasite

Frequency of Transfusion Transmitted disease

Reagents	**Frequency of testing along with controls**
Hepatitis B Antigen	Each run
HIV 1 & 2 Antibody	Each run
Hepatitis C Virus	Each run
Syphilis serology reagents	Each run
Malaria Test	Each run

Assuring quality of examination procedure

- The daily QC values shall be documented on Levey Jennings curve and CV % from monthly QC data must be calculated.

Flow chart should be made to manage “Out of control situation”

- If a reagent produces results outside the limits set by the manufacturer or Blood Bank, the deficiency should be reported to the Quality Manager.
- Search for recent events that could have caused changes
- Examine environmental condition
- Follow manufactures troubleshooting guide
- Refer to manufacturer of equipment, reagents or QC/Calibrator vendor.

Quality Control in Blood/ Blood Components

Frequency of Testing

1% of component shall be tested for Quality Control out of which 75% shall match the acceptable ranges as per National guidelines set by Govt. of India(DGHS).

QC of blood/blood component preparation

1. Whole blood:

- Frequency of control: 1% of all units with minimum of 4 units per month
- Storage :- 2ºC to 6 ºC, for CPDA-1 the storage time is 35 days, CPD & CD2D – 22days.

Parameter	Quantity Requirement	Frequency of Control
Volume	350/450 ml ± 10%	1% of all units
Anticoagulants	49/63 ml	All units
PCV (Hct)	30 to 40%	4 units per month
HBsAg	Negative by ELISA	All units
Anti-HCV	Negative by ELISA	All units
Anti-HIV ½	Negative by ELISA	All units
Syphilis	Negative by Screening test	All units
Sterility	By culture	Periodically (1% of all units)

Calculation for Total Volume of Whole Blood taken in 450 ml of Bag

Volume of Whole Blood: 450 ml ± 10% OR 472 gms. ± 10%

Calculate the volume from the formula given below:

$$\text{Volume (ml)} = \frac{\text{Weight of the Bag with Blood (gms)} - \text{Weight of the empty Bag (with Anticoagulant)}}{1.05}$$

* Weight of the empty Bag (with Anticoagulant) of 450 ml = 100 gms

2. Red cell concentrates

- Perform the same assay as for Whole blood
- Storage : 2º-6º C, for 35 days if prepared from WB collected in CPDA-1

The Quality Control of red cell concentrate (Prepared from 450 ml Blood)

Parameter	Quantity Requirement	Frequency of Control
Volume	280 ± 40 ml	1% of all units
PCV (Hct)	70%± 5%	Periodically (1% of all units)

The Quality Control of red cell in preservative sol. (ADSOL/SAGM)

Parameter	Quantity Requirement	Frequency of Control
Volume	350 ± 20 ml	1% of all units
PCV (Hct)	55-65%	Periodically (1% of all units)

3. Platelet concentrates

- Prepared within 6 hours of blood collection
- Must evaluate at least 1% of platelets monthly for platelet count, pH and plasma volume
- Platelets should be selected from each centrifuge in use
- Storage : 20º-24ºC

Parameter Quality	Requirements	Frequency of control
Volume	50-70 ml	All units
Platelets count	$\geq 5.5 \times 10^{10}$	4 units per month/ 1% of all units (whichever is more)
pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	0.5 ml	4 units per month/ 1% of all units (whichever is more)
WBC contamination	$5.5 \times 10^7 - 5 \times 10^8$	4 units per month/ 1% of all units (whichever is more)

4. Quality of Platelet concentrate by Apheresis

Parameter	Quality requirement
Volume	>200 ml
Platelets count	$\geq$ 3.0 – 7.0 x 10^{11}
pH	> 6.0 (at the end of permissible storage period)
Residual leucocytes	< 5.0 x 10^{6}
Red cells	Traces to 0.5 ml

5. Fresh Frozen Plasma

- frozen within 6 hours of blood collection using –80°C deep freezers or blast freezers
- Stored at –30°C
- Date of expiry one year

Parameter	Quality control	Frequency of control
Volume	200–220 Plasma	4 units per month/ 1% of all units (whichever is more)
Stable coagulation factors	200 units of each factor	4 units per month
Factor VIII	0.7 units/ml	4 units per month
Fibrinogen	200–400 mg	4 units per month

6. Cryoprecipitate

Parameter	Quality control	Frequency of control
Volume	10–20 ml	1% of all units
Factor VIII	80–120 units	1% of all units
Fibrinogen	150–250 mg	1% of all units

Labeling

- Unique identification number
- ABO and Rh type
- Date of collection and expiry
- TTI screening sticker
- Volume of component

Storage

Refrigerators

- External ambient temperature
- Range: 2 to 6°C
- Continuous monitor temperature chart to record ‘fluctuations’ -
- THERMOGRAPHS: Changed weekly & preserve records
- ➢ Bacterial cultures
- ➢ Audible and visual alarm signal
- ➢ Digital temperature display

Deep freezers

- **Temperature recording :** Range: -35°C to -40°C
- **Cooling down time:** A full load of plasma packs at +25°C takes a max. of 5 hrs for all the packs to reach below -5°C and 30 hrs to below -20°C

Platelet agitator

- All PCs to be stored only in agitators: continuous gentle flat bedded –

  5 days
- Interruption compromises the viability
- Temperature monitoring
- **"Swirling"** to be checked before issue
- Regular Quality Control of RDPs and AP-PCs

External Quality Assurance (EQA)

- Proficiency Testing Programme is designed to evaluate the overall performance and accuracy engaged in blood banking testing.
- Determine the performance of Individual Blood banks for specific tests or measurement and to monitor Blood Banks continual performance and improvement.
- To provide additional confidence to Blood Bank / Laboratory clients.
- It is a blind testing

External Quality Assurance

- The internal QC should be complemented by regular external quality assurance e.g. participation in a proficiency testing programme

- Proficiency programme test, coded “normal” and “problem” blood samples are distributed from national or regional reference laboratory to the participants usually 2x to 4x a year.

Parameters / test covered under EQA

1. HBsAg
2. Anti- HIV 1&2
3. Anti- HCV
4. Syphilis (VDRL)
5. Malarial Parasite
6. NAT (HBV/ HCV/ HIV-1, HIV-2, HIV-O & HIV-M)
7. Hemoglobin
8. Blood Group
9. Cross-match
10. Antibody Screening & Identification
11. Factor VIII
12. Fibrinogen
13. Sterility Testing
14. APTT

BEQAS
Blood Bank External Quality Assessment Scheme
Cycle No: 31

Participant Name:

Participant Code No.:

Month: March 2019

Samples # 01, 02, 03, 04 & 05- Serum Specimens													
S. No.	Parameter	Methodology / Equipment Used	Cut off Value	Sample No.01		Sample No.02		Sample No.03		Sample No.04		Sample No.05	
				OD	Result	OD	Result	OD	Result	OD	Result	OD	Result
A.	HBsAg												
B.	Anti-HIV 1&2												
C.	Anti-HCV												
D.	Syphilis												

Samples # 06 & 07- Whole Blood				
S. No.	Parameter	Methodology/ Equipment Used	Sample No.06	Sample No.07
E.	Malaria Parasite			
F.	Hemoglobin (gm/dl)			

Sample No-08 (Patient)	
G. Direct Anti-globulin Test (DAT) (Sample No. 08)	Positive / Negative

H. ABO Rh (D) Grouping & Typing Technique Used (Sample No. 08)								
Scoring System (Tick Appropriately)	ABO Rh (D) Grouping & Typing							
0 - 4+	Slide	Title	Tube	Column (Gel)	Column (Bead)	Micro Plate	Other Specify	
Patient Identification	Cell (Forward) Typing			Plasma (Reverse) Group		ABO & Rh (D) Result		
	Circle as appropriate			Circle as appropriate				
	Anti A	Anti B	Anti AB*	Anti D	A_1 Cells	B Cells	O Cells	
As a Patient (Sample No: 08) *(5% Red Cells Suspension & Plasma)	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	
	1+	1+	1+	1+	1+	1+	1+	
	2+	2+	2+	2+	2+	2+	2+	
	3+	3+	3+	3+	3+	3+	3+	
	4+	4+	4+	4+	4+	4+	4+	

BEQAS
Blood Bank External Quality Assessment Scheme
Cycle No: 31

Participant Code No.:

I. ABO Rh (D) Grouping & Typing Technique Used (Samples No. 09, 10 & 11)

Scoring System (Tick Appropriately)	ABO Rh (D) Grouping & Typing						
0 - 4+	Slide	Title	Tube	Column (Gel)	Column (Bead)	Micro Plate	Other Specify

Patient Identification	**Cell (Forward) Typing**				**Plasma (Reverse) Group**			**ABO & Rh (D) Result**
	Circle as appropriate				**Circle as appropriate**			
	Anti A	**Anti B**	**Anti AB***	**Anti D**	**A_1 Cells**	**B Cells**	**O Cells**	
As a Donor Unit No-1 (Sample No: 09) *(5% Red Cells Suspension & Plasma)	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	
	1+	1+	1+	1+	1+	1+	1+	
	2+	2+	2+	2+	2+	2+	2+	
	3+	3+	3+	3+	3+	3+	3+	
	4+	4+	4+	4+	4+	4+	4+	
As a Donor Unit No-2 (Sample No: 10) *(5% Red Cells Suspension & Plasma)	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	
	1+	1+	1+	1+	1+	1+	1+	
	2+	2+	2+	2+	2+	2+	2+	
	3+	3+	3+	3+	3+	3+	3+	
	4+	4+	4+	4+	4+	4+	4+	
As a Donor Unit No-3 (Sample No: 11) *(5% Red Cells Suspension & Plasma)	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	Neg.	
	1+	1+	1+	1+	1+	1+	1+	
	2+	2+	2+	2+	2+	2+	2+	
	3+	3+	3+	3+	3+	3+	3+	
	4+	4+	4+	4+	4+	4+	4+	

Method Used (Circle)	Tube	Column	Other**		
J. Compatibility Testing (Samples No. 12, 13 & 14)					
		Scoring System (circle)		0 - 4+	
	Saline	With Additive LISS/ Others**			**Would you transfuse this unit? (Circle)**
Sample No of Donor & Recipient	Room Temperature	Room Temperature	37^0C	IAHG	
Sample No. (Donor) – 09 **Sample No. (Recipient) - 12**	Neg.	Neg.	Neg.	Neg.	**YES NO**
	1+	1+	1+	1+	
	2+	2+	2+	2+	
	3+	3+	3+	3+	
	4+	4+	4+	4+	
Sample No. (Donor) – 10 **Sample No. (Recipient) - 13**	Neg.	Neg.	Neg.	Neg.	**YES NO**
	1+	1+	1+	1+	
	2+	2+	2+	2+	
	3+	3+	3+	3+	
	4+	4+	4+	4+	
Sample No. (Donor) – 11 **Sample No. (Recipient) - 14**	Neg.	Neg.	Neg.	Neg.	**YES NO**
	1+	1+	1+	1+	
	2+	2+	2+	2+	
	3+	3+	3+	3+	
	4+	4+	4+	4+	
**Specify Other Additive				*** Other Method	

THANK YOU