Blood Safety Program, Health Care and Diagnostic Division
Department of Medical Services
Ministry of Health
Thimphu, Bhutan

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NATIONAL GUIDELINES ON SCREENING DONATED BLOOD FOR TTIs

VERSION 1

2013

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World Health Organization

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FOREWORD

The transfusion of blood is a complex process consisting of a series of steps starting from blood donor selection to administration of blood to the patient. It involves different departments, different categories of health personnel and clinical areas, therefore, posing high possibility for errors to take place. Blood is a biological product and blood transfusions risk transmitting infections from donor to the recipient. These risks and errors can have serious or some even life-threatening consequences on either blood donor or patient if proper preventive measures are not taken.

It has been observed that variations exist in the process by which donated blood is tested or screened from one laboratory to another in the country. Establishment and implementation of a national quality system which includes quality management, standards, quality assurance, documentation, guidelines, standard operating procedures, regular monitoring and evaluation and traceability in transfusion chain is thus very essential.

Keeping this in view, this guideline "The National Guidelines for Blood Transfusion Services" has been designed to provide useful basic information and recommendations for all stakeholders in the process of blood transfusion.

I urge all health care providers to refer and follow the guidelines to ensure 100% quality-assured blood screening and transfusion which shall ultimately lead to the timely provision of safe blood and blood components for transfusion to all needy in the country.

(DR. UGEN DOPHU)
Director General

ACKNOWLEDGMENT

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CHAPTER 1

1.1 Introduction

Blood transfusion is a life–saving intervention that has an essential role in the total patient management within health care systems. The provision of safe and efficacious blood and blood components involves a number of steps, from the selection of blood donors, appropriate blood collection procedure, processing and testing of blood units, compatibility tests on the patient's sample, issue and its administration to the patient, often termed as 'transfusion chain'. There is a risk of error in each step in this "transfusion chain" that can have serious implications to the recipients of blood and blood products, particularly the transmission of blood borne infections.

Screening for transfusion-transmissible infections (TTIs) to exclude all blood donations at risk of transmitting infections from donors to recipients is a critical process ensuring that transfusions are as safe as possible. Effective screening for evidence of the presence of the most common and dangerous TTIs can reduce the risk of transmission to very low levels.

The screening of all donated blood for transfusion-transmissible infectious agents prior to release for clinical use is a fundamental activity for any blood transfusion service. The development of a reliable and effective blood screening component of the blood transfusion service is therefore a key strategy for the provision of safe blood supply.

The needs assessment study of twenty seven blood banks in the country conducted in December 2010-January 2011 under the WHO/OFID project 'Prevention of HIV/AIDS and Hepatitis in Bhutan' identified that though almost 100% of donated blood units are being screened for the four TTIs, namely HIV, Hepatitis B and C and Syphilis, significant variations in the blood screening process, procedures and laboratory practices exist.

Therefore concerted efforts are being made to establish efficient systems to ensure that all donated blood is correctly screened for specific TTIs and that only non-reactive blood and blood components are released for clinical use.

1.2 National Blood Policy advocates:

- Adequate, timely and easily accessible supply of safe and quality blood and blood products through the establishment of a nationally co-ordinated blood transfusion service with adequate resources for its day to day functions.
- The collection of blood only from voluntary non-remunerated donors.
- Testing on donated blood for infectious agents and blood group serology in quality assured manner.
- Blood transfusions advised and carried out under the supervision of a registered medical practitioner or other suitably qualified and authorized health care professional.
- An effective national regulatory mechanism for oversight of the operations of the blood service.

1.3 Aim and objectives of national guidelines for TTI testing

The aim of the national guidelines is to contribute in establishing an effective national blood screening component of blood transfusion service which ensures that all donated blood units are screened in a quality assured manner.

The guidelines provide technical advice and information on:

a. Basic elements for blood screening
b. TTIs to be screened for all blood donations
c. Selection and evaluation of assays
d. Appropriate screening strategies and algorithms
e. Management of screen reactive blood donors

f. Confirmation of screen reactivity

g. Quality in TTI testing

The requirements and algorithms provided in this document are specific to the screening of donated blood for TTIs and are not designed for diagnostic testing for these infections.

1.4 Scope and target audience

This document can be used as a reference material by different stakeholders namely:

- Policy makers responsible for health, finance, education and quality that directly and indirectly influence blood safety.
- National blood safety program personnel.
- Medical laboratory technicians, technologists in the blood transfusion service, clinical and reference laboratories.
- Laboratory specialists, quality officers, teaching personnel and auditors.

1.5 Consultative process

Spearheaded by the blood safety program, Health Care and Diagnostic Division, Department of Medical Services, Ministry of Health, the guidelines were developed by a technical core group (TCG) comprising of representatives from National Blood Center, Clinical Laboratory, Public Health Laboratory, Laboratory Quality Management team and Drugs, Vaccine and Equipment Division (DVED).

WHO publications namely recommendations on 'Screening Donated Blood for TTTs'-2010, 'Screening for HIV and Other Infectious Agents' and 'Safe Blood and Blood Products' were used as core reference materials. The other reference sources have been mentioned in the later portion of this document.

The document was discussed, reviewed, and revised through a consultative process with wider participation from regional and

district blood bank personnel, representatives from HIV/AIDS Program, Drug Regulatory Authority of Bhutan, Bhutan Medical and Health Council and Quality Assurance and Standardization Division, MoH and WHO technical experts.

1.6 Review time frame

This document shall remain valid and for use by all blood banks in the country responsible for screening blood units.

A process of review shall be initiated by the blood safety program preferable after five years or as and when deemed necessary.

CHAPTER 2

National standards on blood screening for TTIs necessitates:

2.1 Establishment of an effective and well organized national blood screening component in the Blood Transfusion Service.

2.2 Availability of resources-human, financial and basic infrastructure necessary for quality-assured testing.

2.3 Authorized laboratory personnel for testing.

2.4 Mandatory screening of all donated blood units for HIV, Hepatitis B, Hepatitis C, and Syphilis. Use of screen non-reactive blood and blood products for transfusion purpose.

Malaria testing be mandatory in the endemic areas only.

2.5 TTI testing for minimum recommended screening markers. Additional markers of infections that are potential screening targets be introduced as and when deemed essential and necessary.

2.6 Confirmation of all HIV and hepatitis screen reactive blood donors by the National Reference laboratory.

CHAPTER 3

3.1 National screening strategy

Laboratory testing of donated blood is the step that determines whether or not a donation is non-reactive for specific markers of infection and is therefore safe to release for clinical use. The national screening strategy thus developed shall provide the laboratory personnel the required information on how tests are to be used and interpreted and the outcomes of screening process with regard to whether a blood unit can be released and used for transfusion purpose or discarded.

Since the objective is safeguarding the blood supply, the assays selected are highly sensitive, so that all donated blood units yielding reactive or indeterminate test results be considered as 'probably infected' and not transfused to patients. This strategy is meant for testing the blood donations, and must not be used for notifying donors.

If a blood donor is to be notified of a positive test result, confirmatory testing strategy for diagnosis must be applied. In such a situation, referral of the donor for voluntary counseling and testing services for confirmation of the TTI status is recommended. This applies to HIV and hepatitis B and C infections.

3.2 Mandatory TTIs for screening of all donated blood units are:

- Human Immunodeficiency Virus (HIV)
- Hepatitis B (HBV)
- Hepatitis C (HCV)
- Syphilis
- Malaria in endemic districts

The above infections may cause chronic diseases with possible serious consequences to recipients of transfusion. These risks

can be minimized if the screening is performed in an effective, uniform and consistent quality-assured manner.

3.3 National blood screening markers

All blood donations shall be screened for specific serological marker(s) for each mandatory TTI. Table 1 shows the minimum required screening targets.

Table 1: TTIs and Serological Markers

Mandatory TTIs	Serological Markers
Human Immunodeficiency Virus	Antibodies to HIV Type 1 and 2
Hepatitis B	Hepatitis B surface antigen (HBsAg)
Hepatitis C	Anti-HCV antibody
Syphilis	Anti-treponemal antibody
Malaria (only in endemic districts)	Malaria antigen to all four species (plasmodium vivax, falciparum, malariae and ovale)

CHAPTER 4

4.1 Screening assays

Laboratories having ELISA facility shall perform blood screening using ELISA assays.

Laboratories not having this facility shall perform blood screening using Rapid assays.

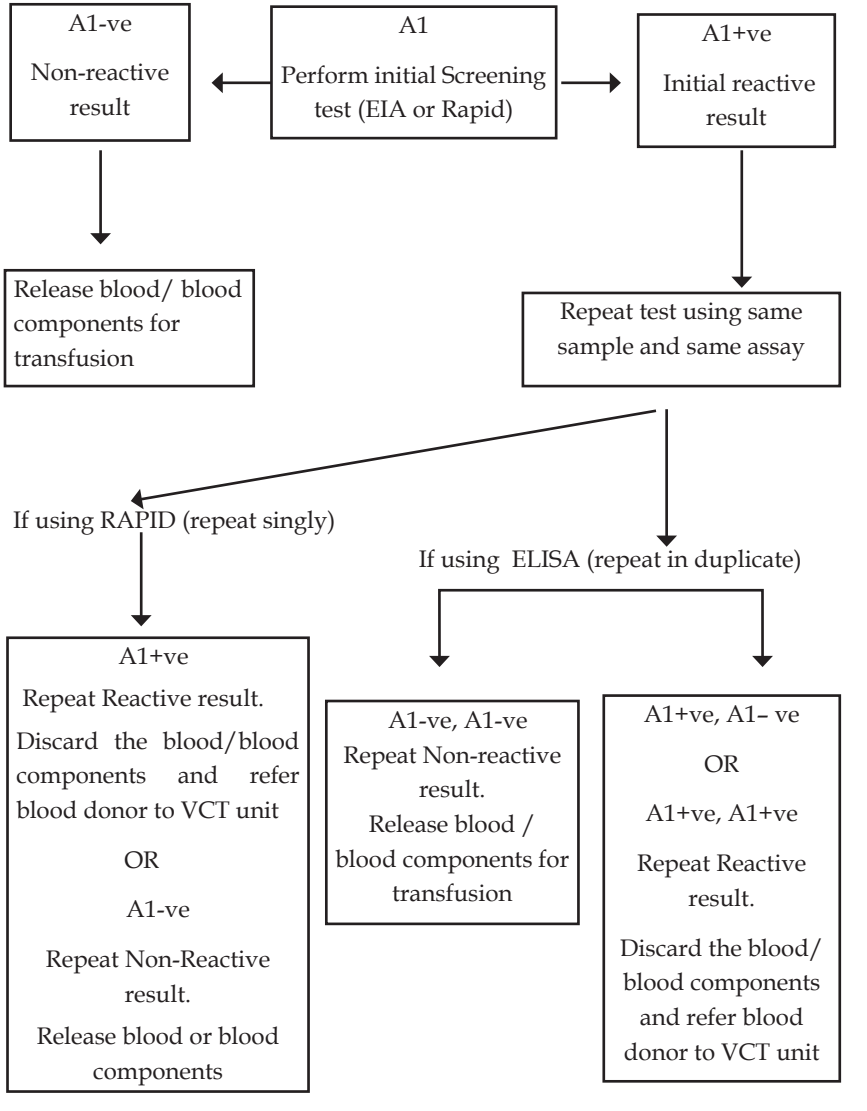
Table 2: Key factors for TTI test assay specifications

TTIs	Screening Markers	Assay	Principle	Sensitivity	Specificity
HIV	Anti-HIV(1,2 ,O)	ELISA	Sandwich (third generation EIA)	≥99.5%	>99.8%
	Anti-HIV(1,2 ,O)	Rapid	Immuno-chromatography	≥99.5%	>99.8%
HBV	HBsAg	ELISA	Sandwich EIA	≥99.5%	>99.8%
	HBsAg	Rapid	Immuno-chromatography	≥99.5%	>99.5%
HCV	Anti-HCV	ELISA	Sandwich EIA	≥99.5%	>99.8%
	Anti-HCV	Rapid	Immuno-chromatography	≥99.5%	>99.8%
Syphilis	Antibody to Treponema Pallidum	TPHA	Haemagglutination	≥99.7%	>99.6%
	Antibody to lipoidal antigen	Rapid Plasma Reagin	Precipitation		
Malaria	Malaria antigens	Rapid	Double antibody sandwich assay	Detect 150 paracites/ ul	Monoclonal Anti-Pan specific pLDH IgG antibody

4.2 National screening algorithm

The following algorithm shall be used for screening HIV, HBV and HCV infections by all blood transfusion centers.

Figure 1:



4.3 Recording test results

In order to record test data adequately, a result/record sheet with the following information shall be maintained for each TTI.

Table 3: TTI assay record sheet

Blood Unit No.	Assay name	Assay lot no.	Initial Result	Repeat Test (R or NR)	Repeat Test Result	Accept/ Discard unit	Tested by/ Date	Checked by/Date

R: Required

NR: Not Required

CHAPTER 5

5.1 Managing blood donors

The management of blood donors is an essential part of the activities of every blood transfusion service. Donors are the source of blood and blood components that are processed and released for clinical use. Therefore, they should be managed in a way that ensures high standards of care and assurance.

5.1.1 Pre-donation counseling

Individual pre-donation counseling shall be provided to all individuals willing to donate blood, be it at fixed or at mobile blood donation sites. It shall be provided by trained and authorized staff in a private and confidential manner.

It should include:-

a. Basic information on high risk behaviors and mode of transmission of infections like HIV and hepatitis.

b. Signs and symptoms of HIV/AIDS, hepatitis and other sexual transmitted infections.

c. Personal risk assessment and importance of self exclusion or self deferral by the unsuitable donor.

d. Basic information on the mandatory TTI tests carried out on all donated blood.

e. Confidentiality of test results.

f. Obtaining an informed consent.

Pre-donation information can be provided to a group of potential donors and should include the following information.

Table 4: Pre-donation information

- Basic information about blood science
- Importance of voluntary blood donation
- General information about blood donation process and pre and post-donation care
- Importance of honest answers during the donor interview procedure
- HIV transmission and HIV risk reduction

All potential blood donors shall be offered information, education and communication (IEC) materials that have been developed and made available to all blood centers for further reading by blood donors to re-inforce key points covered in the pre-donation counseling procedure.

5.1.2 Post-test counseling: It is recommended that all blood donors are provided with post-test counseling by trained staff.

A. Screen non-reactive donors:

Donors, who test non-reactive to all TTIs, shall be encouraged to donate blood regularly and lead low-risk lifestyles.

B. Screen reactive donors:

Whenever a screening test is reactive to anti-HIV, anti-HCV or/ and HBsAg, initial counseling to the blood donor shall include:

- ✓ Screening test results of his/her donation.
- ✓ Explanation to the donor on the non-specific reactivity detected by highly sensitive screening assays to ensure blood safety to the recipients.

- ✓ Information on the discard of the reactive unit and the deferral advice on future blood donation.
- ✓ Referral to a Voluntary Counseling and Testing (VCT) center for further counseling and information and consenting for confirmatory testing.

CHAPTER 6

6.1 Quality in TTI testing

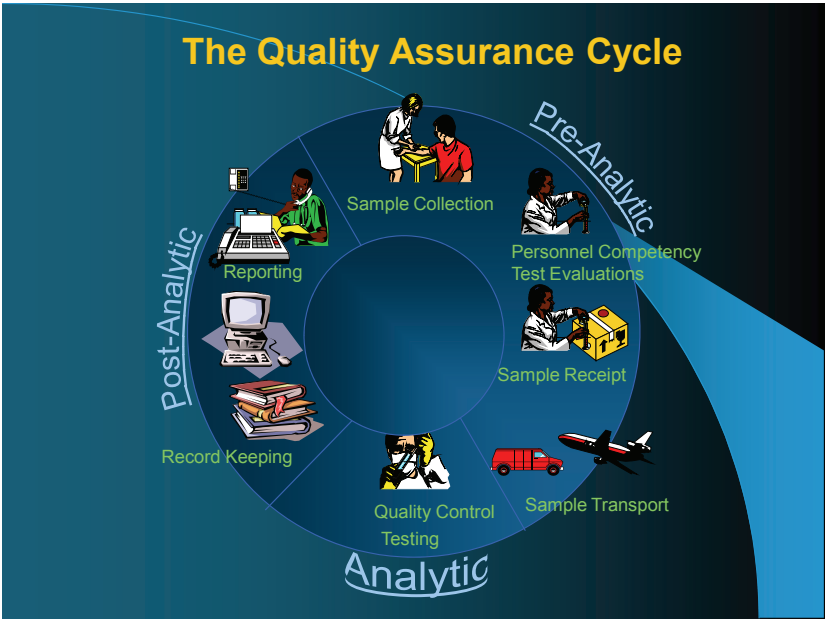
Blood transfusion can be a possible route of transmission of infections to the recipients. Therefore quality in TTI testing is essential to prevent this transmission, make best utilization of donation and reduce unnecessary wastage of this limited resource.

TTI testing is dependent on number of factors that need to be controlled for which principles of Quality Assurance (QA) must be applied by all blood transfusion centers irrespective of what assays are used or how many tests are done.

6.2 Quality Assurance is a set of activities undertaken that ultimately guarantees:

- Appropriate tests are performed on the correct samples.
- Reliable assays are used.
- Accurate and reliable results are obtained consistently.
- Screened blood and blood components are available in the blood inventory.
- Only screen non-reactive blood and blood components are released for transfusion.
- Health of blood donors, recipients and staff is safe-guarded.

Figure 2:



6.3 Factors essential for assuring quality in TTI testing:-

6.3.1 Quality of the specimen used for testing:

- Ensure correct labeling of specimen.
- Specimens that are heamolysed, grossly contaminated or lipemic may cause false positive results, especially when ELISA is used. Hence perform adequate centrifugation of samples.
- Preservative such as Sodium azide when added to prevent contamination of specimens can affect ELISA results as it inactivates some conjugates like peroxidase.

6.3.2 Quality of test kits and reagents used:

- Quality of kits and reagents used in TTI testing is one of the most crucial determinants of quality.

- National standard specifications and criteria developed for assessment, selection and validation of test kits shall be followed.
- Test kits shall be evaluated by Public Health laboratory for sensitivity, specificity and ease of performance and ones with highest sensitivity shall be preferred since the aim is to prevent infection in the recipient.
- All test kits used shall be within date of expiry and shall be stored at required temperatures.
- Interchanging of reagents between kits and lots shall be avoided unless clearly specified by the manufacturer.

6.3.3 Type of Controls used while testing

To ensure reproducibility and reliability of test results, the assay performance shall be checked. This shall be done using:

6.3.3.1 Internal Controls

- These are set of 'Positive' and 'Negative' controls which are built into each test device, ELISA or Rapid assay.
- They shall be used with each test run and data recorded and analyzed for trends for any corrective action necessitated.
- If the internal controls do not produce the expected result, the test shall be considered invalid and must be repeated.

6.3.3.2 External Controls

- These are known 'Borderline Positive' and 'Negative' samples that shall be either prepared in-house or by STI/TTI unit, Central laboratory, JDW, NRH Thimphu and dispatched to all centers especially ones with ELISA facility.
- They provide valuable information on the integrity of the test system, kits, and reagents and also on the performance of the staff.

- External Controls shall be used daily with each ELISA test run and blood banks using rapid assays shall run at-least when:
    - a new test kit is received.
    - kit with new lot number is received.
    - changes in storage temperatures of kits.
    - new staff is performing the test.
- Use of Levy-Jennings chart by TTI laboratories using ELISA screening assays is highly recommended as it is an invaluable tool to validate the ELISA results on any given day. It helps in monitoring control values on a run-by-run basis.

Maintaining records of all quality control results is essential. Refer to Annex 1 for 'Log for Quality Control results'

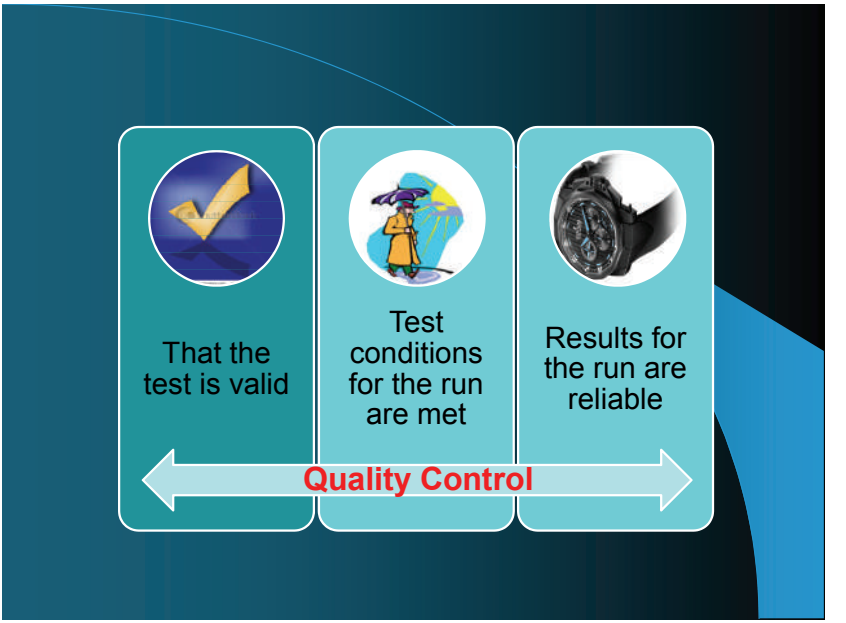
6.3.4 Quality Control & Calibration of equipment

Laboratories using ELISA equipment shall have quality control measures in place. These shall include:

- Procurement of equipment that fulfill national standard specifications.
- Periodic calibration of sensitive equipment such as micropipettes, multichannel pipettes, incubators and shakers.
- Periodic maintenance of ELISA washers, readers and other sensitive equipment. Calibration should be done every six months and results of Optical Density (OD) should be within 10% of expected.
- Cleaning the washer after use to avoid crusting of salt within the metallic pipes of the washer. Rinsing with distilled water is therefore a must for this equipment.
- Periodical checks of the light filters in ELISA readers for moisture and fungal contamination to prevent erroneous OD values. For this silica gel packs can be kept in filter box.

Documentation is the key to proper maintenance. Anything that is not documented can be taken as not done.

Figure 3



6.3.5 Validation of test results

Validation is assuring that a system, process, reagent or equipment is performing the way it is supposed to do through recorded evidence.

Validation tools are:-

- Inclusion of positive & negative controls in every test run.
- For rapid tests, check for a clear internal control spot or line.
- Independent reading of rapid test by 2 different technicians.
- Use of mechanical reader to reduce errors in subjective testing.

6.3.6 Interpretation of results

- Interpretation of results must be done with caution.
- Validation of every test run as discussed above is essential for proper interpretation of results.
- All readings for both quantitative and qualitative tests and calculations should be checked by two individuals and verified by the supervisor or in-charge before release.
- All results must be properly recorded in work sheets. Print outs of results, calculations of cut off values, graphs, etc. should be maintained for documentation purpose.
- Any error detected should be brought to the notice of the concerned staff and corrective measures instituted promptly.

6.3.7 Use of Standard Operating Procedures (SOPs) for TTI testing

SOP is a validated written instruction on how to perform a specific procedure by the staff. A list of SOPs for common tests or procedures in TTI testing has been developed. Refer to Annex 2.

6.3.8 Staff and training

- There shall be sufficient number of staff to perform blood screening on all donated blood units. All staff performing screening of blood for TTIs shall have the basic training in general medical laboratory technology including blood banking curriculum with TTI testing module. Please refer to Annex 3 for 'Training module on TTI testing'.
- For a staff at blood center to be permitted to perform the TTI testing, the quality manager shall assess his or her competency. Once the required competency is demonstrated, he/she shall be authorized to perform this task. Please refer to Annex 4 for 'Competency Assessment Checklist'. The new staff shall also receive 'on the job' or an induction training which shall include organization

and management of the center, job description, line of reporting, good laboratory practice principles, SOPs, work sheets and reporting formats in use.

- Each blood center shall have one staff delegated for quality management with following responsibilities:
    - To establish written policies and procedures in a quality document which shall define 'how' the blood units shall be screened for TTIs and 'who' shall screen them with well defined line of reporting.
    - To monitor and review the quality assurance activities.
    - Establish and maintain system for documentation.
    - Conduct training of staff.

6.3.9 Documentation and records

All blood centers performing TTI testing shall maintain a complete set of documents:

- Standard operating procedures
- Forms, worksheets, records of TTI test results
- Records of TTI testing equipment
- Quality control test results and QC logs
- Inventory records of test reagents and test kits
- Records of blood samples referred to PHL for confirmatory tests
- Competency assessment report of staff

All documents shall be stored for minimum of five years.

6.3.10 Assessment

A. Annual data collection and analysis

The blood safety program shall assess the effectiveness of the screening process and its outcomes through compilation and analysis of an annual data that shall be submitted by all blood center. The following are the key indicators that shall be used to monitor the outcomes.

Table 5: Indicators for TTI screening

Indicator No.	Indicator
1	Number of blood centers using SOPs for TTI testing.
2	Number of staff trained in the use of national guidelines and SOPs on screening of blood for TTIs.
3	Number of blood centers participating in an EQAS for TTIs (NEQAS or IEQAS)
4	Percentage of blood units screened in quality assured manner

B. Monitoring and Supervision

Periodic audits to monitor the core activities of the blood centers shall be conducted by a trained team, using the developed assessment tools. Advice on preventive and corrective measures shall be given as part of continous quality improvement. Please refer to Annex 5 for the questionnaire to be used during the audit.

C. Participation in external quality assessment scheme (EQAS)

All TTI testing blood centers shall participate in atleast one EQAS in TTIs.

D. The national hemovigilance system

This system shall be established whereby all serious adverse events for example TTIs in blood donors and recipients shall be

reported, investigated and monitored.

6.3.11 Error management in TTI testing with ELISA

Types of error	Cause of error	Managing error/ Action needed
Transcription errors	- Mislabeling - Faulty data entry	Staff to be vigilant
Sampling error	- Errors in addition of samples to the plate - Interchanging specimens	To keep a vacant slot in rack
Equipment error	- Lack of equipment maintenance & calibration - Lack of cleaning- Presence of Fungus on filters, - Faulty volumes	-Fixing responsibility among staff & periodic supervision -Periodic cleaning and maintenance -Calibration and QC of equipment
Poor technique	Sudden change of staff / kit used in the BTS	Training of staff and periodic supervision
Management errors	- Lack of periodic training of staff - Lack of updating of SOPs/ manuals	Quality manager to be vigilant and conduct periodic competency assessment of staff

CHAPTER 7

7.1 Role of Public Health Laboratory

The Public Health Laboratory shall serve as the reference laboratory for TTI screening in the country with following roles and responsibilities.

- ❖ Evaluation of TTI test kits
- ❖ Confirmation of screen reactive blood donors
- ❖ Organization of NEQAS for TTIs

7.1.1 Evaluation of TTI test kits

Following process will be in place to screen out unknown/ unevaluated/poor quality test kits available in the market prior to procurement.

1. Provide test kit specifications and criteria to DVED before tenders are floated.
2. Assess performance (detection limit) of test kits on the test kit samples provided by the registered suppliers to DVED and provide feedback to DVED to facilitate the selection of appropriate test kits during the procurement process.
3. Conduct physical inspection and verification to confirm the supplied test kits and batch number. In case of different batch/lot number or more than one batch/lot, test kit performance will be assessed.

7.1.2 Confirmation of all screen-reactive blood donors

All screen reactive blood donors for HIV, HBV and HCV shall be referred to VCT center in their respective hospital. The counselors shall provide VCT services and collect blood samples for confirmatory testing by PHL. This shall be done in a coded manner. Each VCT center in co-ordination with its respective blood center shall dispatch the processed samples using 'Sample

dispatch and confirmatory test report form' to PHL (Annex 6).

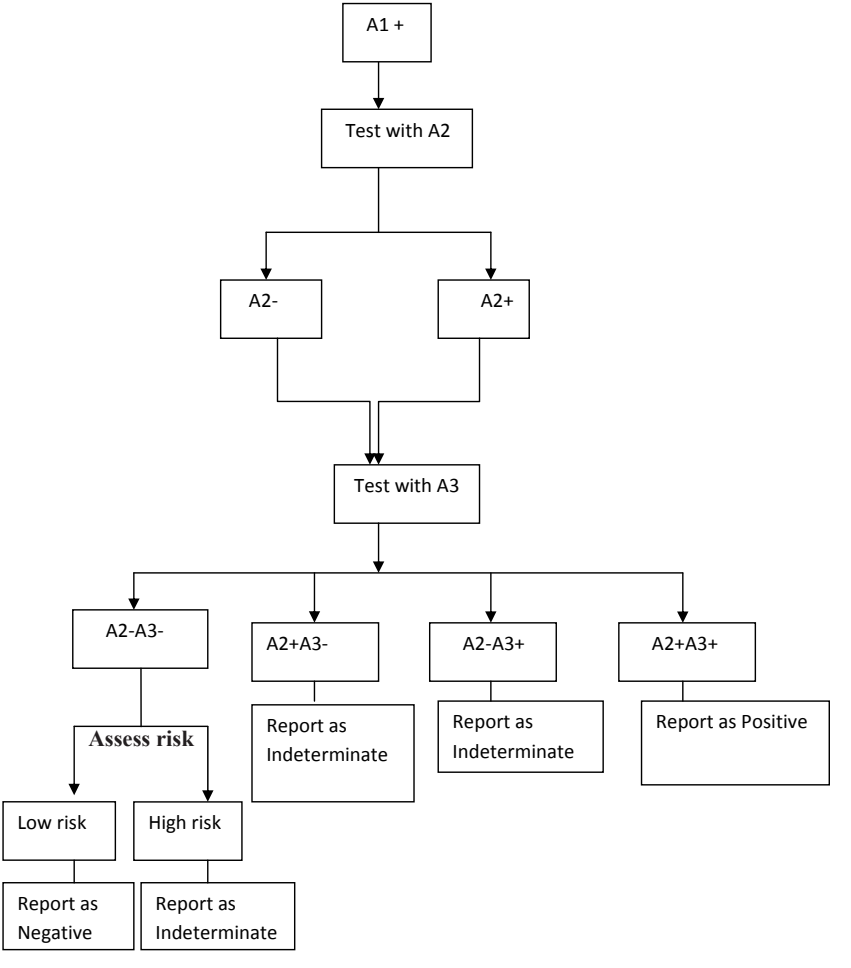
Important points to be remembered by the staff responsible for sample referral are as follows:

Table 6: Sample referral process/conditions

Steps	Requirements	Responsibility
Sample type	Whole blood or anti-coagulated blood	VCT staff
Sample processing	Samples shall be separated in a closed system centrifuge to yield approximately 3-5 ml of serum	Referring blood center
Sample transport	Sample shall be sent to the PHL as soon as possible or within 24 - 48 hours in sterile, leak proof, unbreakable containers with proper cold chain maintained at +2°C to +4°C.	Referring blood center
Sample storage	Separated serum/plasma samples can be stored in a refrigerator at +4°C for a week or in a freezer at –20°C or lower temperature for a longer period	Referring blood center
Quality check on sample	The quality of the sample shall be checked for evidence of hemolysis, jaundice or lipemia, and for adequate quantity and packaging.	Referring blood center and PHL

HIV confirmation*:* PHL shall carry out the confirmatory test for HIV using the below algorithm.

Figure 4: Algorithm for HIV confirmation



Note: A1 is the assay used for blood screening against which the donation is reported as 'Screen Reactive'.

A2 and A3 are two different assays with higher specificities than A1 assay. They shall be based on different antigen preparations and/or different test principles.

All individuals with indeterminate result shall be advised to repeat the test after one month.

Hepatitis B confirmation*:* Blood donors tested reactive to Hepatitis B surface antigen shall be confirmed by PHL by supplementary or full hepatitis B serological testing.

Hepatitis C confirmation*:* Blood donors tested reactive to anti-HCV shall be confirmed by second or third line supplementary testing.

Communication channel**:** All the test results shall be informed by PHL to the 'Care and Treatment unit' (CTU) from where the results shall be dispatched to the referring VCT center. The VCT center shall in turn inform the results to the concerned blood center and also carry out the necessary counseling and referrals for the management and care of HIV/HBV/HCV confirmed positive individuals and only counseling for confirmed negative individuals.

7.1.3 Conduct NEQAS for TTIs

PHL shall conduct NEQAS in TTIs (HIV, Hepatitis B & C and syphilis) for all blood centers in the country as per the NEQAS protocol. The frequency of panel proficiency testing will be six monthly and in addition an onsite supervisory visit shall be conducted periodically. PHL shall provide evaluation feedback to individual blood centers after each cycle and prepare an annual performance report (please refer to NEQAS/TTIs guidelines for operation details).

CHAPTER 8

8.1 Procurement and supply process

An effective procurement system can assist in ensuring that the right quality product is purchased at the right price for right use. Maintenance of supplies is critical to ensure that the testing laboratory can continue to function without problems.

Since major challenges faced by all blood centers in last few years were due to issues related to procurement and supplies of required TTI test kits and equipment, it becomes imperative that a mechanism is in place and known to all laboratory staff involved in this process.

8.1.1 Procurement cycle as recommend by Ministry of Health is as follows:

Table 7:

Deadline	Assignment
1st Jan to end March	Preparation of Bill of Quantities
Mid April	Invitation of Tenders/Bills
Mid May	Receipt and opening of tenders
Mid June	Compilation of tenders
Mid July	Evaluation of tenders
Mid August	Selection of bills
Mid Sept	Completion of award / placement of purchase of orders
Mid Dec	Supplies received
Mid Jan	Distribution of supplies completed

8.1.2 Role of laboratory focal person/s at DVED

- He/she shall have the knowledge and expertise in laboratory materials and supplies, their quality, standards, prices, availability, purchasing alternatives etc that enables him/ her to contribute significantly to

the ultimate decision in the purchase of goods during the annual procurement cycle.

- He/she shall work closely with end users and other relevant divisions.
- He/she shall work closely with the laboratory technical team at the JDW,NR Hospital.

8.1.3 Selection of test assays

Those assays that satisfy the assessment criteria and expected performance levels based on the feedback report submitted by PHL to DVED, shall be included on the evaluation list of tenders.

Table 8: The procurement steps shall be as follows:

Activity	Responsibility
Define specification of the items for procurement	NBTS , Clinical laboratory, PHL & QASD jointly
Information and floating of tender to potential, registered suppliers	DVED
Technical evaluation in accordance with set protocols and assessment criteria and feedback submission to DVED	PHL
Technical review of qualified tenders and short list the potential suppliers	Jointly NBTS, Clinical laboratory, EMTD; facilitated by DVED
Selection done based on financial and convenience criteria from the qualified list	Selection Committee of MoH
Notification of the Award and signing of contract with the supplier	DVED
Issue of 'Purchase Order'	DVED

8.1.4 Quality testing of procured supplies

This shall be carried out by the technical team from QASD, PHL and Microbiology unit of National Clinical Laboratory. It shall involve accepting or rejecting the newly delivered goods based on criteria for quality inspection and laboratory testing of batch samples.

If 10% of the randomly selected samples are declared sub-standard, then the whole batch is rejected and returned to the supplier.

8.1.5 Receiving and testing of procured supplies

Once the supplies are accepted by the above mentioned team then:-

- DVED shall be responsible for:
  - receiving and dispatching the supplies to all laboratories.
  - informing the laboratories to accept supplies formally and in a well documented manner.
  - handling product complaints from the receiver (e.g. transportation problems)

- End-users shall be responsible for :
  - receiving the supplies formally and in a well documented manner.
  - quantifying them against the indent prepared.
  - reviewing manufacturer's instructions, recommendations, storage requirements.
  - co-ordinating with Bio-Medical Engineering Division (BMED) for the equipment installation and development of maintenance plan.
  - conducting quality checks on the new test kits.

8.2 Inventory management of supplies

8.2.1 Guidelines for calculating the actual usage of test kits

In order to quantify the annual test kits requirement, the staff must take the following factors into account:

- ✓ The expected number of donations/blood units to test in a specified period of time.
- ✓ The number of repeat testing on 'Initial Reactive' samples (you may refer to your last year's data to get an approximate figure). For ELISA it shall be tested in duplicate and for rapid it shall be tested singly.
- ✓ The number of external quality control and EQAS samples that the blood center shall test in one year.
- ✓ Approximate additional number in case of assay failures
- ✓ Available stocks and the length of remaining shelf-life of the kits.

National standard specifications developed for each test assay shall be strictly followed while preparing the annual indent list.

8.2.2 Stock control

To ensure that sufficient quantities of supplies are available at all times and services are not interrupted, an efficient stock control system shall be in operation. All involved in testing blood units play an important role, but responsibility can be taken by the quality manager.

Maintaining a stock card can greatly help in stock control process:

The following information can be included:

a. Name of the item
b. Lot number for each item
c. Monthly utilization of each item
d. Minimum stock levels required to allow delivery time of atleast three months when reordering DVED for supplies
e. Order unit or pack size if required
f. Storage conditions

CHAPTER 9

9.1 Regulation of blood and blood products

Human blood and blood products due to their therapeutic nature is declared by the Bhutan Medicines Board as medicinal products and shall be regulated and controlled under the Medicines Act of the Kingdom of Bhutan 2003.

9.1.1 Purpose

The regulation shall ensure the manufacture, distribution or delivery of safe quality blood and blood products through appropriate control of premises, facilities, equipments, processes and standards.

9.1.2 Scope

This regulation shall cover all the premises and activities related to collection, preparation, storage, dispatch, quality control and quality assurance of blood and blood products.

9.1.3 Regulatory checks shall include but not limited to:

- Testing of the donated blood units according to the written procedure.
- Screening tests for infections:
  -HIV 1 /2
  -Hepatitis B
  -Hepatitis C
  -Syphilis
  -Malaria
- Blood grouping and Immuno-hematological tests
- Verification of TTI results on all blood donations.
- Competency assessment reports of the staff handling/ processing blood units at all blood centers.

ANNEXURE

Annex 1

'Log for Quality Control results'

Date Time of QC	Test Kit Lot#	Test Kit Exp. Date	Control Kit Lot #	Control kit Exp. Date	Negative Control Result	**Positive Control Result**	**Results Acceptable? Yes /No**	**Performed by**	**Reviewed by and Date**

Corrective Action taken (use reverse side of page)

Date	Action Taken	Initials	Reviewed by and Date

Annex 2

'List of SOPs for TTI testing'

1. Anti -HIV antibody- ELISA assay
2. Anti -HCV antibody -ELISA assay
3. Hepatitis B surface antigen- ELISA assay
4. Treponema Pallidum Heemagglutinaton Assay
5. Anti -HIV antibody-Rapid assay
6. Anti -HCV antibody-Rapid assay
7. Hepatitis B surface antigen-Rapid assay
8. RPR testing
9. Malaria testing
10. SOP on the reception, handling and checking the quality of specimen
11. SOP on reporting TTI results
12. SOP on preparation of external quality controls
13. SOP on performing checks with external quality controls
14. SOP on use of Levy-Jennings control chart

Annex 3

'Training module on TTI testing'

Training module for TTI testing under blood bank curriculum for pre-service training of Medical Laboratory Technicians (MLT) shall be as follows:

Module – Blood banking TTI testing

Teaching aim and objectives:

1. Impart knowledge on basic Microbiology and immunology of transfusion transmitted infections.
2. Develop practical skills in testing all TTIs in the blood center setting.

Teaching Approach:

1. Lectures audio-visual presentations
2. Hands on practice

Core topics for lectures:

A. General introduction

1. Introduction to immunology
2. Normal microbial flora
3. Common infective agents, sources and methods of transmission through blood transfusion

B. Immunity

4. Types and mechanisms of immunity
5. Organs and cells of immune system
6. Immune response of the body

C. Basic concept of antigen and antibody

7. Familiarization of terminology of antigen, epitope, and haptens
8. Structure and types of immmunoglobulins

9. Basic antigen-antibody reactions

D. Serodiagnosis

10. Test principles of different tests
11. Titre
12. Principle of techniques used for diagnosis like, heamagglutination, neutralization, complement fixation, labeled solid phase assays and ELISA ASSAY.
13. Collection, preservation and transport of specimens for immunology.
14. Basic knowledge of the disease diagnosed by immunological techniques and diagnostic procedure (HIV, HBsAg, HCV and Syphillis).
15. Basic principles of newer techniques like, PCR and Western Blot.

E. Safety issues

1. Laboratory safety
2. Waste disposal
3. Post exposure prophylaxis

Hands-on training

1. To develop SOPs
2. Selection of reagents / test kits and developing specifications
3. Daily machine maintenance
4. Quality control
5. Sample handling, testing and preservation
6. Communication of test results
7. Documentations (both hard and soft copy)

Learning Outcomes:

Should be well versed with-

- Basic principles of the tests
- Sampling of immunological samples
- Techniques of pipetting
- Preparation and testing of all TTIs by Rapid and ELISA methods
- Documentation of reports
- Carrying out daily QC activities including Levy-Jennings Control charts

Annex 4

'Competency Assessment Checklist'

Name of the trainee: _____Name of test procedure: _____

Instructions: *Fill in dates when the trainee observes or performs each objective or procedural step, as applicable. Put a bar and your initial against it whenever a task is performed. Enter as N/A for not applicable task.*
The trainee should inform the supervisor when he/she feels the objective/ procedure has been mastered or when a deadline has been set.

Sl. No	Objective/Procedural Step	Process, date of assessment and number of times.			Trainer's initial and date
		Ob	Ps	Pi	
1	Collect blood sample using proper blood collection technique				
2	Disposal of lancets and other biohazard waste appropriately as per the good infection control practice				
3	Read test procedure (SOPs/Manuals)				
4	Determine if requirements for acceptable testing environment are met (e.g.,temperature, lighting, level work space)				
5	Label test sample and the test device and other appropriate paperwork				
6	Load test device, add reagents, time test, and read result correctly				
7	Practice test with negative and positive external quality control samples				
8	Read and record results on report form and log sheet				

9	Record internal and external quality control results in appropriate QC log				
10	Evaluate a new test kit and record results in QC log				
11	Post test counseling provided to the blood donor				
12	Referring and managing of the blood samples/donors for confirmatory testing				
13	Documentation of all test processes				

Final certification by Head of center: Name/designation/
Signature:_____Date of certification:_____

Requirement for the competency certification

Observation **(Ob):** 03 times

Performance under supervision **(Ps):** 03 times; Perform independently without error **(Pi):** 03 times

Annex 5

'Questionnaire for auditing TTI screening process'

Name of the blood center: _____

Supervisor's name: _____

Reporting period: _____

1. Indicate the assay used for TTI screening and the number used

TTIs	Assay used (Please tick)					
	Simple/Rapid Test		ELISA		Other, specify	
	Used	No.	Used	No.	Used	No.
HIV I/II						
Hepatitis B						
Hepatitis C						
Syphilis						
Others, specify						

2. Does the blood bank have an algorithm for TTI testing?

Yes ☐ No ☐

2.1 If yes, please provide a copy of the algorithm.

3. Are internal quality control (IQC) samples used in each run in order to validate the test run? If yes, please provide a copy of the QC log.

Yes ☐ No ☐

4. What is the total number of donations testing in the reporting period? _____

5. Please indicate the number of donations that were reactive in the screening test.

TTIs markers	Screening test reactive	
	No of initial reactive (IR)	Number of repeat reactive (RR)
HIV I/II antibodies		
Hepatitis B Surface antigen		
Hepatitis C antibody		
Treponemal pallidum antibodies		

6 Are HIV, HBV and HCV screen reactive results confirmed by PHL? Yes ☐ No ☐

If yes, please indicate the number of the confirmatory positive results in the reporting period.

TTI	No. of Reactive samples sent to PHL	Confirmed Positive Result	
		Number	%
HIV 1/2			
HBV			
HCV			

7. Does the blood center keep records of TTI test results, by type of donations?

Yes ☐ No ☐

7.1 If yes, please complete the following table

TTI Markers	Donation from Voluntary non-remunerated blood donors			Donations from Family/ Replacement blood donors		
	No. of blood units collected	No. of units tested	No. of units with 'RR' results	No. of blood units collected	No. of units tested	No. of units with 'RR' results
HIV 1/2 antibodies						
HBsAg						
Hepatitis C antibodies						
Treponeman pallidum antibodies						
Others, specify						

8. Was blood ever issued without screening for the transfusion transmissible infections during the reporting period?

Yes ☐ No ☐

8.1 If yes, please complete the following table

	Reasons (Tick as appropriate)			Number of units issued unscreened
TTI not screened	Test kits/ reagents not available	Emergency Transfusion	Any other reason specify	
HIV 1/2				
Hepatitis B				
Hepatitis C				
Syphilis				

9. Does the blood centre store frozen samples of donor serum or plasma?

Yes ☐ No ☐

9.1 Are these used for look-back studies?

Yes ☐ No ☐

10. Are test kits/reagents and donor samples stored in temperature-monitored equipment?

	Yes	No
[1]Test kits/ Regents	☐	☐
[2] Donor samples	☐	☐

11. Does the blood centre participate in an external quality assessment scheme (EQAS) for TTI testing?

Yes ☐ No ☐

11.1 If yes, in which area and at which level does the blood center participate in EQAS? Please tick:

Level	HIV	HBV	HCV	Syphilis	Malaria
International					
Regional					
National					
Any other					

11.2 The blood center to produce the EQAS reports to the supervisor.

Annex 6

'SAMPLE DISPATCH AND CONFIRMATORY TEST REPORT FORM'

Public Health Laboratory

Department of Public Health

TO BE FILLED BY REFERRING LABORATORY

Laboratory information

Name of Laboratory personnel:

Hospital address:

SAMPLE INFORMATION

Sample ID No : _____

Date of collection:_____/_____/____ ate of dispatch:_____/_____/___

BLOOD SCREENING TEST DETAILS

Test result**:**_____ Tested on: _____/_____/____

Screening Assay used(Rapid /ELISA/Others specify):_____

Assay name:_____ Manufacturer's name:_____

Lot no.:_____ Expiry date: _____

Analyzed by (Name & signature):_____

CONFIRMATORY TEST (s)

Request for : *(Please tick)* HIV Hepatitis B Hepatitis C

Name ,designation, address of the person el to whom result should be informed: _____

FOR PHL USE ONLY

Date received:
_____/____/_____
Received by: _____
Sample ID: _____
Tested on: _____/_____/____

Condition of sample upon receiving:
□ Good
□Notgood,specify:_____
_____

Test Assay(s) used	Test kit used	Lot no.	Expiry date	Test result
1) _____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Final interpretation: _____

Analyzed by (name & signature): _____

Verified by: _____

Date of dispatch of report form: _____/_____/_____

Sent by: _____ Sent to: _____(name and address)

GLOSSARY

Audit: Systematic, independent and documented examination to determine whether activities comply with a planned and agreed quality system.

Alogorithm: Document that defines the actual testing process. It includes clear statements on:

- Definition of screen non-reactive and decision points for the release of screen non-reactive donations
- Whether initially screen reactive tests should be repeated
- Fate of screen reactive donations
- Subsequent action to be taken with screen reactive donors

Blood: Human blood drawn from a donor and mixed with anti-coagulant.

Blood center: A facility or centre that performs all the following functions:

- Recruiting blood donors
- Screening and selecting blood donors
- Blood collection
- Testing, and processing of blood units
- Transportation, receiving, and storage of blood units
- Pre-transfusion tests on patients blood samples
- Issue of blood or blood components for clinical transfusion

Blood storage center: A center that is involved in the following functions only:

- Receiving and storing screened blood and blood components from another authorized blood transfusion center
- Performing compatibility tests
- Blood issue for transfusion

Blood component: Any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma). It is not intended to capture plasma derived products.

Blood collection: A procedure whereby a single donation of blood is collected in an anticoagulant solution.

Blood donor: A person who gives whole blood or one of its components.

Blood product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma derived products.

Calibrate: To set measurement of equipment against a known standard.

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance, or other undesirable situation in order to prevent recurrence.

Competence: Ability of an individual to perform a specific task according to procedure.

Compliance: Meeting required standards.

Conformance: Fulfillment of requirements as defined by standards.

Consistency: Doing the same thing time after time, which makes the outcome more predictable and reduces variations in products and processes.

Cross–reactivity: When an antibody recognizes not only its corresponding specific antigen, but also other antigens that may have certain similarities.

Critical: Capable of affecting quality.

Document (noun): Written or electronically generated information involved in providing a product or service. Examples are policies, standards, standard operating procedures, work instructions, reports and records.

Document (verb): To capture information for use in documents through writing or electronic media.

Expiry: The last day on which blood, component, or tissue is considered suitable for transfusion or transplantation.

Equipment: A durable item, instrument or device used in a process or procedure.

Error: An incident where the quality system has failed.

ELISA/EIA: Enzyme Linked ImmunoSorbent Assay

Evaluation: The specific selection process to determine the suitability of a procedure or material (e.g. assay, reagent, equipment).

External Quality Assessment: The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories.

External Quality Assessment scheme: A recognized scheme for organizing External Quality Assessment. This can be a local scheme or organized at national, regional or international levels.

Guidelines: Documented recommendations.

Good Laboratory Practice: Means ensuring that laboratory functions are carried out in accordance with requirements and may include planning, performance, monitoring, recording and reporting of laboratory functions.

Good Manufacturing Practice: Means ensuring that products are consistently produced and controlled in accordance with appropriate standards and regulatory requirements.

Internal Quality Control: Testing that's routinely performed on material and equipment to ensure their proper function.

Issue: To release for clinical use /transfusion.

Infra-structure: System of permanent facilities and equipment of an organization.

Label: An inscription affixed to a unit of blood, component or sample for identification.

Labeling: Information that is required or selected to accompany a unit of blood, component or sample, which may include content, identification, and description of process, storage requirements, expiration date, cautionary, or indication for use.

Maintain: To keep in the current state.

Material: A good or supply item used in manufacturing process. Materials are a type of input product. Reagents are a type of material.

National Blood Transfusion Service: The organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services. The NBTS coordinates all activities concerned with blood donor recruitment and the collection, testing, processing, storage and distribution of blood and blood products, the clinical use of blood and surveillance of adverse transfusion events. Activities shall be carried out within a network of national/regional blood center and blood storage centers together referred to as blood transfusion service.

Organization: An institution, or part thereof that has its own functions and administration.

Policy: A written statement which guides present and future decisions. It determines the future course of action to be established.

Post-donation procedures: All procedures and activities done after blood donation.

Process: A set of related task and activities that accomplishes a work goal**.**

Processing of blood: Any procedure that takes place after the blood is collected.

Process Control: The efforts to standardized and control process in order to produce predictable output.

Procedure: A series of task usually performed by one person according to instructions.

Pre-donation procedure: It includes mandatory process and activity done before proceeding to blood donation.

Pre-qualification of assays: A process designed to ensure that assays meet global/national standards of quality, safety and efficacy. Prequalification consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers.

Preventive action: An action taken to reduce the potential for an error to occur.

Product: A tangible result of a process.

Quality: Characteristics of a unit of blood, component, sample, or service that bear on its ability to meet requirements. Fit for its purpose.

Quality control samples: Well-characterized samples, individual or pooled, that are where possible calibrated against international standards and are diluted in an appropriate matrix.

Quality System: The organizational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Quarantine: To isolate nonconforming blood, component or materials.

Reactions: In reference to a transfusion, a suspected or proven, unexpected response to a blood transfusion, manifested by signs and/or symptoms.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of is biological or chemical activity.

Replacement/family donation: Donation given by an individual who gives blood when it is required by a member of the patient's family or community. This may involve a hidden paid donation

system in which the donor is paid by the patient's family.

Screening algorithm: A sequence of steps in the blood screening process to determine the suitability of each unit of donated blood and its components for clinical or manufacturing use. A blood screening algorithm specifies the actual tests to be used and, based on each test result, directs the user to the next step.

Service: An intangible result of a process or procedure.

Shall: A term used to indicate a requirement.

Supplier: Individual or organization that provides an input material or service.

Standard Operating Procedure: Local written instructions for the performance of a specific procedure in a standardized manner.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (e.g., materials, blood component, and patient blood sample) obtained from a supplier meet specified requirement.

Traceability: The ability to follow all steps of a process or procedure from the beginning to end.

Transfusion Transmissible Infection: An infection that is potentially capable of being transmitted by blood transfusion.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

Validation: Confirmation and provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.

Verification: Evaluating the performance of a system with regard to its effectiveness based on intended use.

Voluntary non-remunerated donation: Donation given by an altruistic donor who gives blood freely and voluntarily without receiving money or any other form of payment.

Voluntary Counseling and Testing: Voluntary HIV counseling and testing is the process by which an individual undergoes counseling enabling him or her to make an informed choice about being tested for HIV. This decision must be entirely the choice of the individual. He/she must be assured about the confidentiality of the procedure.

Whole blood: Blood collected in an anticoagulant solution with or without additives.

ACRONYMS

AIDS	:	Acquired Immunodeficiency Syndrome
BMHC	:	Bhutan Medical and Health Council
CPDA	:	Citrate Phosphate Dextrose Adeninine
DMS	:	Department of Medical Services
DRA	:	Drug Regulatory Authority
DVED	:	Drugs Vaccine and Equipment Division
ELISA	:	Enzyme Linked Immuno-Assay
EQAS	:	External Quality Assessment Scheme
EMTD	:	Essential medicines and technology Division
Hb%	:	Hemoglobin
HBsAg	:	Hepatitis B Surface Antigen
HBV	:	Hepatitis B Virus
HCV	:	Hepatitis C Virus
HIV	:	Human Immunodeficiency Virus
HR	:	Human Resource
IEQAS	:	International External Quality Assessment Scheme
IQC	:	Internal Quality Control
MLT	:	Medical laboratory technician
MoH	:	Ministry of Health
NEQAS	:	National External Quality Assessment Scheme
NBTC	:	National Blood Transfusion Committee
NBTS	:	National Blood Transfusion Service
NBC	:	National Blood Center
OFID	:	OPEC Fund for International Development

PCR	:	Polymerase Chain Reaction
PHL	:	Public Health Laboratory
PRC	:	Packed red cell
PC	:	Platelet Concentrate
QA	:	Quality Assurance
QM	:	Quality manager
QC	:	Quality Control
RBC	:	Regional Blood Centre
RGoB	:	Royal Government of Bhutan
SOP	:	Standard Operative Procedure
TPHA	:	Treponema Pallidum Hemagglutination
TTI	:	Transfusion Transmissible Infections
VBD	:	Voluntary Blood Donation
VCT	:	Voluntary Counseling and Testing
WHO	:	World Health Organization
WB	:	Whole Blood

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