NATIONAL BLOOD SERVICE (GHANA)



NATIONAL STRATEGY FOR SCREENING OF DONATED BLOOD AND IMMUNOHAEMATOLOGICAL TESTING

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ABBREVIATIONS AND ACRONYMS

Agglutination
Clumping together of red cells.

Antibody
A protective protein produced by the immune response of an individual to stimulation by a foreign protein.It recognizes antigen on foreign red cells and may cause in vivo agglutination and subsequent haemolysis.

Antigen
Any substance recognized as foreign by the body, which stimulates the immune system to mount a response against it.

Anti-Human Globulin Reagent (AHG)
A blood grouping reagent that reacts specifically with human globulin.

Anti-Human Globulin Test
A test using anti-human globulin reagent to detect the presence of human globulin (antibodies) on sensitized red cells.

Apheresis
The process by which one or more blood components are selectively obtained from a donor by withdrawing whole blood,separating it by centrifugation or filtration into its components and returning those not required to the donor.

Blood Bank
Laboratory within a hospital that stores, distributes, and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including immunohaematological tests.

Blood Cold Chain
The storage and transportation of blood and blood components at the appropriate temperatures and conditions from the point of collection to the point of use (from vein to vein).

Blood Component
Blood components are prepared manually from a whole blood collection or may be produced through an automated collection system called apheresis for red blood cells, plasma and platelets.

Blood Donors
A person who donates whole blood and plasma or cellular components.

Blood Centre
A facility that performs one or more of the following activities: donor mobilization, donor screening, blood collection, processing of blood into components, storage, selection, and issuing of blood and blood components. May also perform extended immunohaematological test for recipients.

Compatibility Testing
A set of procedures required to be performed before blood can be issued as being safe for transfusion.

Cross-matching
A term used when testing the patient's serum against the donor red cells before transfusion.

Direct Anti-Human Globulin Test (DAT)
A test used for detecting the presence of human globulin (antibodies) on the surface of red cells.

Document
Written or electronically generated information and work instructions. Examples of documents include quality manuals, policies, procedures, and forms.

Donor Deferral
The non-acceptance of a potential blood donor to donate blood or blood components, either temporarily or permanently, based on general health, medical condition or the risk of exposure to pathogens.

Equipment
A durable item, instrument, or device used in a process or procedure for the preparation or delivery of services.

Haemolysin
An antibody that combines with complement causing it to destroy (lyse) the red cells carrying its specific antigen.

HBV
Hepatitis B Virus

HCV
Hepatitis C Virus

HIV
Human Immunodeficiency Virus

Indirect Anti-Human Globulin Test (IAT)
A test that uses antihuman globulin (AHG) to detect in vitro sensitization of red cells in patient serum or plasma. The AHG act as a bridge to facilitate the binding of patient's IgG antibody if present and facilitate macroscopic agglutination. IgG antibodies present in the patient's serum or plasma are considered clinically significant. It is commonly referred to as the Coombs test.

Issue
The release of blood and blood component for clinical use or transfusion.

Label
An inscription affixed to a unit of blood, blood component, sample or form for identification. The inscription may have information that is required or selected to accompany the unit of blood, blood component, sample or form, which may include content, identification, storage requirements, expiry date, cautionary statements, or indications for use.

Markers of Infection
The detectable agents of infection, including the body's own response to the infectious agent, appearing in the bloodstream during or following an infection.

Nucleic Acid
A complex organic compound found in living cells that consists of chains of nucleotides. There are two types: deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), which make up the cells' genetic information.

National Blood Policy
A statement of intent by the ministry responsible for health that defines the organizational, financial and legal measures at the national level that will be taken to ensure the quality, safety, availability and accessibility of blood and blood components and their safe and appropriate use.

Procedure
A series of tasks performed according to instructions.

Quality
Characteristics of a unit of blood, blood component or sample, critical material, or service that bear on its ability to meet requirements.

Quality Assurance
The creation and operation of standards, programmes and effective management systems to ensure quality. The overall range of activities and systems that provide confidence within the organization that all quality requirements are met.

Quality Control
Retrospective tests or other measures that must be completed with satisfactory results before proceeding further in a given process, and that demonstrates compliance with certain defined limits and specification

Quality Systems
The organization's structure, responsibilities, policies, procedures and resources established by the organization to achieve quality.

Reagent
A chemical substance used to perform an analytical procedure.

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.

Serum Grouping Test
A test to detect ABO antibodies in serum or plasma.

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

Traceability
The ability to trace each individual unit of blood or blood component derived from it, from the donor to its final destination, whether this is a patient, a manufacturer of therapeutic products or disposal, and vice versa.

Transfusion Transmissible Infections (TTI)
An infection that is capable of giving rise to a disease or condition caused by a virus, bacterium, fungus, parasite, agent of transmissible spongiform encephalopathy or other unidentified micro-organism that may be transmitted by transfusion of blood or blood components.

Washed cells
A process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed. The centrifugation, decanting, replacing process may be repeated several times.

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FOREWORD

Blood transfusion is a life-saving intervention that plays an essential role in patient management within health care systems. The global burden of disease due to unsafe blood transfusion can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a nationally-coordinated blood transfusion services
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood including screening for transfusion transmissible infection, blood grouping and compatibility testing
- Reduction in unnecessary transfusion through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

Screening of donated blood for transfusion transmissible infections including HIV, Hepatitis B, Hepatitis C, Treponema pallidum (syphilis) as well as testing for blood groups and compatibility is required to ensure blood safety.

The development of this National Strategy on screening of donated blood and immunohaematological testing is to ensure screening of donated blood for transfusion-transmissible infections, blood group determination and compatibility testing is a core component of national blood safety programme.

Screening for transfusion-transmissible infections (TTIs) to exclude blood donations at risk of transmitting infection from donors to recipients is a critical part of the process of ensuring that transfusion is as safe as possible. Effective screening strategy can reduce the risk of transmission of TTI to very low levels. Blood transfusion facilities should therefore establish efficient systems to ensure that all donated blood is screened in a quality-assured manner for the mandatory TTIs and that only non-reactive blood and blood components are released for clinical use.

The recommendations contained in this National Strategy together with the algorithms have therefore been developed to guide and support all blood collection and testing facilities as well as hospital blood banks to establish appropriate, effective and reliable blood-screening and immunohaematological testing plan in the facilities. This book contains key recommendations for screening of donated blood for TTI, blood grouping and compatibility testing in addition to recommendations and algorithms for the performance of these tests.

It also describes the principles and methods for these tests as well as recommended assays that should be implemented by all facilities. Blood collection, processing,

testing facilities and hospital blood banks must therefore ensure that these recommendations are implemented. The successful implementation of this National Testing strategy by facilities will improve patient safety through reducing the risk of Transfusion Transmissible Infections (TTIs) and complications from adverse transfusion reactions.

Hon Kwaku Agyeman Manu

Minister of Health

INTRODUCTION

It is estimated that up to 5% of blood and blood components such as Concentrated Red Cell (CRC), Fresh Frozen Plasma (FFP), Cryoprecipitate and Platelet Concentrate (PC) may be infective for one agent or the other. These agents may be viral {e.g. Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Cytomegalovirus}, bacterial or protozoan. Testing of blood and blood components should be conducted in accordance with a nationally approved testing strategy, and internationally accepted standards.

The most common cause of fatal transfusion reactions is the administration of ABO incompatible red cells. Therefore, the ABO and the Rh 'D' typing of the donor unit and patient sample is of critical importance. Blood donors and patients who have been previously pregnant or transfused may have red cell alloantibodies in their plasma. These antibodies can cause a shortened red cell survival, or haemolysis in a recipient. It is therefore mandatory for all blood facilities to routinely test for ABO and Rh 'D' blood groups and screen for red cell antibodies in all donated blood units and in all patients requiring blood transfusion.

In accordance with World Health Organization (WHO) recommendations, the National Blood Policy of the Ministry of Health prescribes that all donated blood should be tested for HIV, HBV, HCV and syphilis prior to release for clinical use. Testing for these infectious agents is mandatory for the provision of safe blood supply in Ghana. In special circumstances, additional tests may be performed on donated blood.

The National Strategy for Screening of Donated Blood and immunohaematological testing has been developed with the purpose of standardizing the testing strategies for blood and blood components nationwide. The national policy on blood testing defines the fundamental requirement for the testing of all donated blood prior to transfusion and pre transfusion testing.

Components of the current document were initially developed in 2009 under the "Health Services Rehabilitation Project III (HSRP3), Component 2: Support to Blood Services, Technical Assistance" by members of the working group on Quality, GMP & Laboratory Services.

The current document, which is the first edition of the National Strategy for Screening of Donated Blood and immunohaematological testing, provides a comprehensive guidance on red cell serological testing, microbiological testing for Transfusion Transmissible Infections (TTI), and quality framework and operational issues on testing.

This edition was completed in April 2021.

CHAPTER 1: RED CELL SEROLOGICAL TESTING

1.1 ABO AND RH 'D' TYPING

ABO grouping involves the testing of red cell suspensions of unknown group to determine the presence or absence of A and/or B antigens (cell or forward grouping), and testing the unknown serum/plasma to determine the presence or absence of A and/or B antibodies (serum or reverse grouping).

In forward grouping the unknown red cells are tested against known ABO grouping reagents, to determine the identity of antigens on the red cells, i.e. if an unknown red cell sample is tested against a known anti-A reagent and a positive result (agglutination/haemolysis) is obtained, this indicates the presence of "A" antigen. The forward and reverse grouping results should correlate with the ABO blood group system.

A range of systems, equipment and techniques are available for red cell serological testing. Saline methods are commonly used to perform ABO grouping tests.

Reagent antisera used for ABO and Rh 'D' testing should be standardized. Appropriate controls should be set up with every batch of tests, to confirm that reagent antisera, reagent red cells and all other reactants used such as enzymes or AHG are working as expected. The test results are valid only when the controls give the expected results.

1.1.1 Key Recommendations for ABO and Rh 'D' Typing

1. ABO and Rh 'D' typing should be carried out on all donated blood and patient samples using standard procedures and reagents.
2. For first time donors, two independent ABO and Rh 'D' typing should be performed and the two results must concur.
3. For patients requiring blood transfusion, two independent grouping should be performed on the patients' sample, and the results must concur. Results should be compared with previous results if possible and all anomalies should be investigated and resolved.
4. Donated blood and patient sample should be screened for irregular antibodies.
5. High titre antibody A and B in all blood group O donations should be determined and donations labelled as such

1.1.1 ABO Blood Grouping

Donor and patient red cells should be tested with monoclonal anti-A, anti-B and anti-AB (optional) reagent, which are capable of detecting all subgroups of these red cell glycoproteins. Serum grouping should also be performed by testing the donor plasma or sera with A, B and O reagent red cells.

1.1.2 Rh 'D' Blood Grouping

All donated blood shall be tested for the presence or absence of the Rh 'D' antigen using appropriate monoclonal anti-D reagent that can detect weak D including D^{VI} antigen and all patients' blood shall be tested for the presence or absence of the Rh 'D' antigen using appropriate monoclonal anti-D reagent that cannot detect the D^{VI} antigen.

1.1.2.1 First Time Donors

Two independent testing for ABO and Rh 'D' blood group must be performed for first time donors. The two results must be compared and any anomaly resolved for the donation to be used.

1.1.2.2 Repeat Donors

The ABO and Rh 'D' grouping result for a repeat donor should be compared with the result from the previous donation to check that it correlates. In the case of an anomaly, it should be investigated and anomaly resolved for a donation to be used. If the anomaly cannot be resolved, the donation should not be used.

1.1.3 Method for ABO and Rh 'D' Blood Group Typing

1.1.3.1 Tube Method

Tube testing may be used for forward and reverse grouping of the blood sample. A 3-5% cell suspension (Refer Appendix 1) of the donated blood is used. The cell suspension is added to antisera already dispensed into clean and appropriately labelled glass test tubes. The tubes are then incubated at room temperature after mixing the sample with the antisera (the tubes can be centrifuged for immediate results) for reactions to take place. The tubes are then tapped gently to re suspend the red cell buttons while observing for agglutination and or haemolysis. The reactions of the tests are graded and recorded.

Reverse or serum grouping is performed to confirm the presence of expected naturally occurring antibodies in the serum or plasma. Reagent red cells demonstrating the strongest antigenic makeup for A and B are used.

1.1.4.2 Microplate Method

Microplate is a flat plate with multiple wells used as small tubes. It usually has 96 wells and can be used for blood grouping of both donor and patient samples. A "U" shaped microplate is recommended for blood grouping.

Sample from the donated blood or patient is suspended in 85% saline, and added to already dispensed or coated antisera in the microplate wells. The microplate is then incubated at room temperature after mixing the sample with the antisera (the microplate can be centrifuged for immediate results where a microplate centrifuge is available) for reactions to take place. The microplate is then shaken on a microplate shaker (where available), or by tapping gently to re-suspend un-agglutinated cells. The reactions of the tests are graded and recorded.

1.1.4.3 Microcolumn or Gel Method

In gel testing, antisera or blood grouping reagents are already suspended in a gel medium in columns or cards. Red cell suspensions of donated blood or patient sample are added to the columns and centrifuged for the reactions to occur in the gel if the corresponding antigen is present.

A buffered gel column is used for reverse grouping using plasma or serum and known ABO red cells. Manufacturer's instructions must be adhered to during testing.

1.1.4.4 Automated system

At present, the following automated and semi-automated immuno-haematology platforms are available;

1. column agglutination technology
2. solid phase red cell adherence assay and
3. erythrocyte magnetic technology

Any of these automated systems can be used.

1.1.1 Recommendations for ABO and Rh 'D' Typing on Donated Blood/Patient Sample

1.	ABO and Rh 'D' typing should be carried out on all donated blood and patient samples.
2.	Cell (Forward) and Serum (Reverse) grouping shall be performed on all donated blood/patient samples using standardized reagents.
3.	For first time donors, two independent grouping should be performed. The first on the sample obtained during blood donation and the second from the pilot tubing of the blood unit and the results must concur.
4.	For patients requiring blood transfusion, two independent grouping should be performed on the patients' sample, and the results must concur. Results should be compared with previous results if possible and all anomalies should be investigated and resolved.
5.	All donated blood shall be tested for the presence or absence of the Rh 'D' antigen using appropriate monoclonal anti-D reagent that can detect weak D including D^{VI} antigen.
6.	All Rh 'D' negative donor sample shall be confirmed by the Indirect Antiglobulin Test (IAT). All positive results (agglutination or haemolysis) by IAT is termed Rh 'D' positive and the unit shall be labelled as such.
7.	All patients' blood shall be tested for the presence or absence of the Rh 'D' antigen using appropriate monoclonal anti-D reagent that cannot detect the D^{VI} antigen. Patient's sample typed as weak D is considered Rh 'D'-positive and must be given Rh 'D'-positive blood. All patients typed Rh 'D' -negative must be given Rh 'D'-negative blood.

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Donor Blood Grouping Algorithm



Repeat cell and serum grouping

Discrepancy in ABO results



Perform two(2) independent cell and serum ABO & RhD grouping using polyclonal IgG and IgM Anti D reagent on pilot sample and sample from the tubing of the blood bag

ABO & Rh 'D' positive results



Record patient blood group as ABO & Rh'D' positive in appropriate books and/or computer

Rh 'D' negative results



Label donation unit as ABO Rh 'D' negative

IAT negative results



Confirm Rh 'D' negative by IAT test

IAT positive results



Label donation unit as ABO Rh 'D' positive



Record in appropriate books and/or computer

National Blood Service

Patient Blood Grouping Algorithm



Repeat cell and serum grouping

Discrepancy in ABO results



Perform two(2) independent and serum ABO + Rh 'D' grouping using monocional Anti 'D' Reagent on all samples by tube/micro-plate method

ABO & Rh 'D' positive results



Record patient blood group as ABO & Rh'D' positive in appropriate books and/or computer

Rh 'D' negative results



Record patient blood group as ABO & Rh 'D' negative in appropriate books and/or computer

IAT negative results



Confirm Rh 'D' negative by IAT test

IAT positive results

1.2 SCREENING FOR IRREGULAR ANTIBODIES IN DONATED BLOOD AND PATIENT SAMPLE

Antibody screening is performed to determine whether patient or donor serum/plasma contains irregular (immune or unexpected) red cell antibodies. These irregular antibodies which are present in serum are different from the naturally acquired anti-A or anti-B antibodies which are present in the serum of all healthy adults. However, some irregular antibodies are naturally occurring; others are produced in response to exposure to foreign red cell antigens, commonly through transfusion or pregnancy. Irregular antibodies are therefore more likely to be detected in multi-transfused patients and multiparous women.

In an instance where Indirect Anti-Human Globulin Test (IAT) detects irregular antibody, then it is probably clinically significant and requires further testing to determine its specificity. Reasons for antibody screening include:

1. Clinically significant, irregular antibodies in patients who require blood transfusion should be detected to avoid transfusing red cells with the corresponding antigens which may cause a haemolytic reaction. If clinically significant antibodies are detected, antigen-negative blood may be selected for the crossmatch procedure prior to transfusion.

2. Clinically significant, irregular antibodies in pregnant women may cause haemolytic disease of the fetus and newborn (HDFN). Detecting the irregular antibody enables the clinician to be aware of the situation and treat the patient accordingly.

3. The presence of irregular antibodies in donated blood may complicate transfusions of whole blood or plasma (sometimes referred to as 'minor incompatibility').

4. Irregular antibodies detected in donated blood may be a possible source of blood for preparation of grouping reagents.

1.2.1 Detection of Irregular Antibodies (Antibody Screening)

Antibody screening involves testing the unknown serum/plasma against a set of group O screening reagent cells. These reagent cells are phenotyped red cells that in combination contain most of the antigens necessary to detect clinically significant antibodies. Antibody screening usually requires a set of two or three different screening reagent red cells.

a. Principle

Antibody screening test is performed to detect the presence of unexpected antibodies, especially alloantibodies in the serum to antigens of the non-ABO blood group system such as Duffy, Kell, Kidd, MNS, P, and certain Rh types that are considered clinically significant.

b. Controls

Each of the antibody screening red cells used should be tested using a weak anti-Rh (usually an anti-D and/or anti-c) serum as a positive control and AB serum as a negative control. For anti-globulin tube techniques, IgG coated/sensitized red cells should be used to check all negative test results.

1.2.2 Method for Detecting Irregular Antibodies

1.2.2.1 Tube Method

To screen serum/plasma samples for irregular antibodies, the recommended test tube methods are:

1. Indirect Anti-Globulin Test (IAT)
2. Low Ionic Saline Solution Indirect Anti-Globulin Test (LISS IAT)

1.2.2.2 Automated Method

Screening of serum/plasma samples for irregular antibodies using fully or partially automated method such as column agglutination technology (CAT) or erythro-magnetic technology (EMT) should be done using validated equipment and software .

1.2.3 Identification of Red Cell Antibody (Antibody Identification)

Once red cell antibodies have been detected, they should be identified to determine their clinical significance.

The methods used for the identification should always include the methods by which the antibody was detected during the antibody screening. It is important to use a range of techniques in order to detect antibodies that react optimally in different ways, such as anti-K by saline IAT, and anti-M by saline at room temperature.

Antibody identification should be carried out using a panel of group O cells that have been extensively typed for the presence or absence of antigens that correspond to the known clinically significant antibody specificities. Antibody identification involves testing the unknown serum/plasma against a panel of 9 - 11 reagent red cells.

1.2.4 Recommendation for Screening for Irregular Antibodies in Donated Blood and Patient Sample

1. All donated blood must be screened for irregular red cell antibodies.
2. All antibodies detected should be identified and donations labelled as such.
3. Donations labelled with an identified antibody should only be transfused to patient without the corresponding antigen.
4. All irregular antibodies detected for patients requiring transfusion must be identified.
5. Patients with identified clinically significant irregular antibodies should only be transfused with blood lacking the corresponding antigens (antigen negative blood).
6. All antenatal patients must be screened for red cell irregular antibodies as part of interventions to manage haemolytic disease of the foetus and newborn (HDFN).
7. All antibodies detected in antenatal samples must be identified and titration of the antibodies performed.

1.2.5 Anti-A and/or Anti-B Titre (Haemolysin Potential)

Passively acquired anti-A and /or anti-B antibodies, when group O whole blood is transfused to certain non-group O recipients, may cause morbidity and mortality. Ideally, or for best practice blood of the same group should be transfused. However, this may not always be possible, especially in emergency situations or neonatal exchange transfusion. The risk can be reduced by identifying donations most likely to cause a reaction and labelling those donations for group O use only. Haemolytic transfusion reactions may occur as a result of high levels of IgG anti-A and/or anti-B antibodies in plasma containing products.

Group O whole blood and plasma identified as containing high titre anti-A and anti-B antibodies, by titration, are labelled 'high titre' for transfusion to group O patients only.

1.2.5.1 Anti-A and/or Anti-B Antibody Titration Test

Donated blood may be tested for high titre anti-A and/or anti-B antibodies. High titre antibodies can be detected by using a single dilution (e.g. 1 in 128, in saline). At this dilution, strong alloagglutinins should still be able to agglutinate group A and B reagent red cells.

Group A and B reagent red cells are used for titration as they give the strongest reaction with anti-A or anti-B alloagglutinins.

1.2.5.2 Interpretation

1. Agglutination or haemolysis indicates high titre Anti-A and/or Anti-B antibody.
2. No agglutination indicates low titre Anti-A and/or Anti-B antibody.

1.2.5.3 Recommendations for High Titre Anti-A and/Anti-B Antibody Testing

1. All blood group O donations should be tested for high titre anti-A and anti-B antibodies.
2. All blood group O donations found to have high titre anti-A and/or anti-B antibodies must be labelled as such and should only be given to blood group O patients requiring blood transfusion.

1.2.6 Red Cell Antigen Screening

Selected group O donations may be screened for additional red cell antigens, such as those within the Rh and Kell systems. This may be carried out by using reagents with specificities such as anti-C, anti-c, anti-E, anti-e and anti-K. Results of extended antigen screening should be added to the records, and subsequent donations from the same donor flagged so that the donations can be identified from available stock, and selected if they fit the type required to resolve a compatibility problem. Alternatively, the donors may later be traced to donate blood for patients with such antigens.

1.2.6.1 Recommendations for Extended Red Cell Antigen Screening

1. Red cell typing should be performed on selected blood group O donations for the other blood group systems apart from ABO.
2. These units should be labelled with the typed antigens and transfused to corresponding antibody-negative recipients.

1.3 COMPATIBILITY TESTING

Compatibility or pre-transfusion testing is the final procedure performed to determine suitability of selected donor blood and blood component of appropriate ABO and Rh 'D' type for a patient requiring transfusion. The compatibility testing involves the following processes:

1. Check the records for any previous grouping and/or antibody screening result of the patient.
2. Perform ABO and Rh 'D' typing of donated blood and patient samples.
3. Perform antibody screen test on the patient blood sample, and in the event of a positive screen, this should be followed by antibody identification.

4. Select ABO compatible donor blood for cross-match.
5. Perform cross-match using patient serum or plasma against the donor red cells.
6. Label compatible units and issue blood and blood components for transfusion.

1.3.1 Cross-matching

There are a number of methods for cross-matching.

1.3.1.1 Major/ Routine Cross-matching

Major cross-matching involves testing serum/plasma of the recipient with the red cells of the donor unit. Thus major cross-matching test for antigens of the red cells of the donor against the antibodies in the serum of the intended recipient.

1.3.1.2 Minor Cross-matching

The minor cross-matching is not a substitute for routine cross-matching. This involves testing the red cells of the recipient with the plasma of the donor unit for transfusion. This test is normally performed when investigating adverse transfusion reaction and for plasma transfusion.

1.3.1.3 Electronic Cross-matching

In electronic cross-matching, a validated computer program is used to match the blood groups of intended recipients with blood groups of donor units selected for transfusion.

1.3.1.4 Emergency Cross-matching

In an emergency, when time does not allow for all the tests in the major cross-matching to be performed, it is recommended that an antibody screening is performed in addition to the ABO and Rh 'D' typing of the intended recipient. If the antibody screening is negative, it is not necessary to carry out an indirect anti-globulin test cross-match. Blood can be issued on the basis of the group and screening results, and the results of the immediate spin cross-match.

Only in rare instances should blood be issued without any tests being performed. In an instance where uncross-matched unit has to be issued, a minimum of ABO and Rh 'D' grouping of the intended recipient should be performed and group compatible unit issued. In such circumstances, antibody screening and routine cross-match must be performed in retrospect.

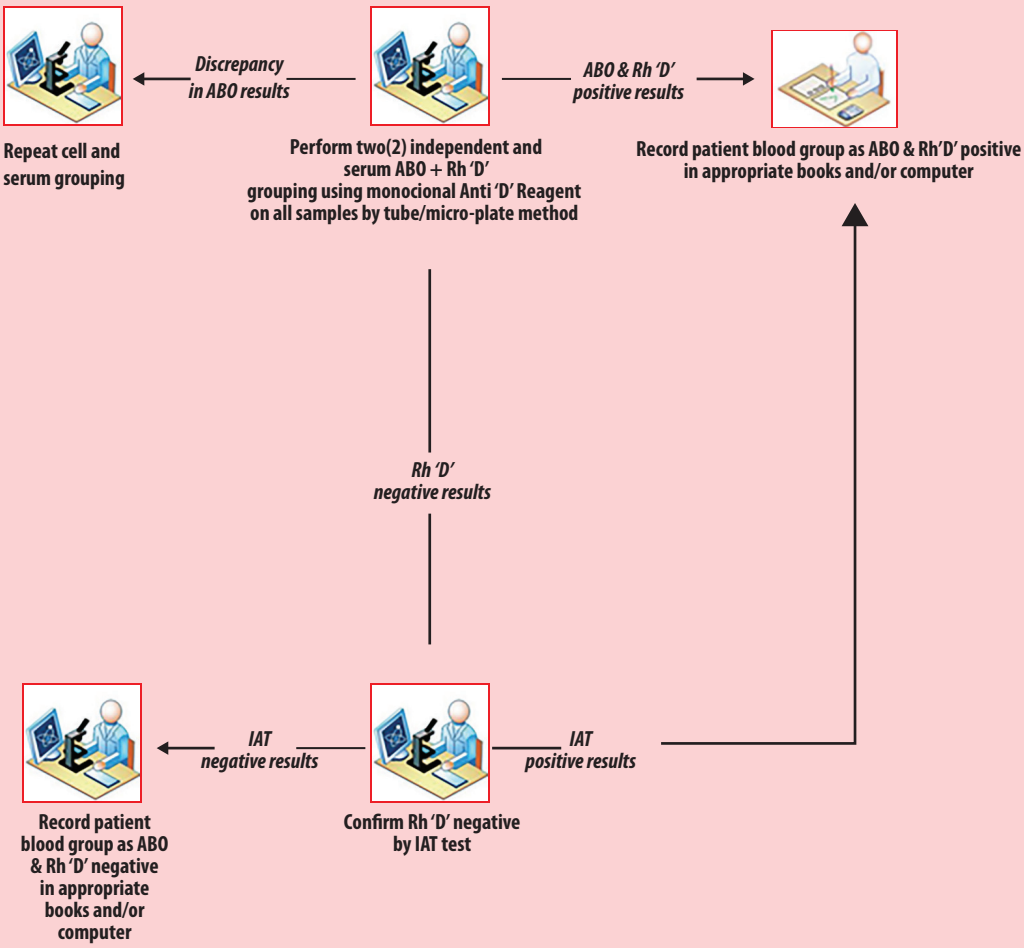
1.3.1.5 Recommendations for Compatibility Testing

1. There should be clear written policies and continuing education on compatibility testing.
2. Laboratories should have in place written protocols, which define the responsibilities of all staff in dealing with urgent requests.
3. Cross-matching should be performed using patient sample collected not more than 3 days in advance of the actual transfusion when the patient has been transfused or pregnant within the preceding 3 months.
4. A pre-transfusion sample should be retained for at least 3 days' post-transfusion, to ensure that repeat ABO grouping of the pre-transfusion sample can be performed in the event of an acute adverse transfusion reaction.
5. ABO and Rh 'D' grouping is the most important serological test performed on pre-transfusion samples and the sensitivity and security of testing systems must not be compromised.
6. The IAT cross-match is the default technique, which should be used.
7. If the patient is known to have formed a red cell alloantibody, each new sample should be fully tested to exclude the presence of further alloantibodies.
8. When one antibody specificity has been identified, it is essential that the presence or absence of additional clinically significant antibodies is established.
9. An IAT cross-match must be used if the patient's plasma contains or has been known to contain, red cell alloantibodies of clinical significance.
10. Where patients cannot be identified by name, the minimum identifiers are gender and a patient unique or hospital number.
11. In instances where the DAT is positive in a patient transfused within the previous month, an eluate made from the patient's red cells should be prepared and tested for the presence of specific alloantibodies.
12. To reduce the risk of interpretation and transcription errors, fully automated systems for electronic cross-matching should be done by trained and competent staff.

1.3.2 ALGORITHM FOR COMPATIBILITY TESTING

National Blood Service

Patient Blood Grouping Algorithm



1.4 ADDITIONAL TESTING

1.4.1 Sickle Cell Testing

Sickle testing of red cells, to rule out donations heterozygous for HbS, may be required for patients with haemoglobinopathies such as sickle cell SS, SC patients. Donations found to be sickling positive are to be confirmed. Heterozygote HbS positive red cells (e.g. HbAS) are suitable for most adult patients.

1.4.2 Recommendation for Sickle Cell Testing in Donated Blood for Transfusion

1.	Perform sickling (HbS) test on all donations meant for transfusion to patients with haemoglobinopathies such as SS, SC patients.
2.	Donations must be sickling-negative and labelled as such.
3.	The sickling test should be performed at the Hospital Blood Bank.

CHAPTER 2: SCREENING ASSAYS FOR TRANSFUSION TRANSMISSIBLE INFECTIONS

A wide range of infectious agents have been documented as transmissible by blood transfusion. This is particularly important with respect to the collection of blood from donors in the "window period" of an infection.

2.1 SELECTION OF ASSAYS

The National Blood Policy on testing of donated blood states that all units collected must be tested prior to transfusion for HIV, HBV, HCV and syphilis, and any other transfusion transmissible microbial agents that may be thought to be relevant by the National Blood Service.

The World Health Organization (WHO) recommends mandatory testing of all donated blood for HIV I&II, HBV, HCV and syphilis prior to release for clinical use. Testing for these infections is mandatory for the provision of safe blood supply in Ghana. In special circumstances such as an outbreak of other transfusion transmissible agents that may compromise the safety of the blood supply, additional tests may be performed on donated blood.

Various types of assay have been developed for use in blood screening. The assays most commonly in use are designed to detect antibodies, antigens or the nucleic acid of the infectious agent. However, not all assays are suitable in all situations and each assay has its limitations, which need to be understood and taken into consideration when selecting assays. Appropriate evaluation is required in selecting the type of assay for each TTI, based on critical assay characteristics, such as sensitivity and specificity, as well as cost and ease of use.

The main types of assay used for blood screening are:

1. Immunoassays (IAs):
    - Enzyme immunoassays (EIAs)
    - Chemiluminescent immunoassays (CLIAs)
    - Haemagglutination (HA)/particle agglutination (PA) assays
    - Rapid/simple single-use assays (rapid tests)

2. Nucleic acid amplification technology (NAT) assays.

2.2 TESTING ASSAYS

Screening of blood is an effective protective barrier against disease transmission in blood transfusion. Two main kinds of screening assays are available to detect infectious disease markers in donated blood: Immunoassay and Nucleic Acid Testing.

2.2.1 Immunoassays

Immunoassays are biochemical assays that measures the concentration of proteins, antibodies or antigens that a body produces as a result of infection. Immunoassays employ different labels to allow for the detection of antigens, antibodies or a combination of the two at low concentration with high specificity.

2.2.2 Simple Rapid Assays

This assay consists of antigen or antibody conjugated to colloidal chromogen immobilized on a porous or semi porous membrane.

a. Principle of Simple Rapid Assays

The principle is based on immunochromatography where upon addition of appropriate sample to the test kits, the sample flows along the immobilized membrane. As the sample moves along the membrane, specific antigen or antibody binds to their corresponding antibody or antigen to form immune complexes. The immune complexes form a visible spot/dot/line at a defined position on the membrane due to the colloidal chromogen build up at the site.

b. Characteristics of Simple Rapid Assays

1. Simple rapid assays give a qualitative result within a short turnaround time.
2. The assay comes in simple-to-use formats and require no additional reagents except those supplied in the test kit.
3. Rapid/simple single-use assays are discrete, individual, disposable assays i.e. they are used once and discarded.

c. Limitations of Simple Rapid Assays

1. The reading of the results is based on the subjective evaluation.
2. No evidence of the original test results can be kept.

2.2.3 Enzyme Immunoassay (EIA)

Enzyme Immunoassay (EIA) uses solid phase and an enzyme to detect immune complexes. Depending on the antigen-antibody combination, the assay is called an indirect, sandwich or competitive EIA.

a. Principle of Enzyme Immunoassay

The enzyme is linked to a secondary antigen or antibody and converts a substrate to a color change. This color is quantified by a spectrophotometer and interpreted as a measure of the amount of the immune complexes present in the sample. EIA results are measured as optical density of the immune complex formed. A cut-off may be determined and any optical density equal or greater than the cut-off is reported as reactive.

b. Characteristics of Enzyme Immunoassay

1. EIA is characterized with high sensitivity and specificity
2. EIA involves simple operation procedure.
3. They are most appropriate for screening large numbers of sample.
4. EIA shortens the window period of detection.

c. Limitations of Enzyme Immunoassay

1. Cross reactivity or false positives can occur due to enzymatic activity in the blood sample.
2. Readouts (measurement of optical densities) must be obtained in a short time since the detection is based on enzyme/substrate reactions.

2.2.4 Chemiluminescent Immunoassay (CLIA)

Chemiluminescent Immunoassay is an enzyme-catalyzed reaction where there is a chemical generation of light at a certain wavelength. This light is measured by spectrophotometer and is interpreted as a measure of the amount of immune complexes present.

a. Principle of Chemiluminescent Immunoassay

Luminol is a very common chemiluminescent substrate used for detection of horseradish peroxidase (HRP). HRP catalyzes the decomposition of luminol in the presence of peroxide to produce an excited state intermediate. Flashes of visible light (maximum at 425nm) is emitted on decay of the singlet intermediate. On enzymatic cleavage of the phosphate group, the intermediate compound becomes destabilized and decomposes via an intermediate anion.

b. Characteristics of Chemiluminescent Immunoassay

1. CLIAs have high specificity because there is absence of interfering emissions.
2. CLIAs have improved sensitivity and allow for multiplexed detection.
3. CLIAs allow for compatibility with other immunoassay protocols.
4. CLIAs have reduced incubation time and low consumption of reagents.

c. Limitations of Chemiluminescent Immunoassay

1. CLIAs are mostly closed analytical systems and do not allow for integration with other instruments.
2. The cost involved in testing by CLIA is high because it requires a significant investment in equipment and reagent.

2.2.5 Particle Agglutination Test

The particle agglutination assay, mainly antibody assays, use a range of particles including red cells and inert particles such as gelatin and latex to detect proteins, antigens and antibodies the body produces in response to infections. The basic principle of haemagglutination and particle agglutination assays are the same irrespective of the type of particles used.

a. Principle of Particle Agglutination Test

Particle agglutination assays detect the presence of specific antibody or antigen in a test sample through the agglutination of particles coated with the complementary specific antigen or antibody respectively.

b. Characteristics of Particle Agglutination Test

1. Particle agglutination test does not involve enzymes, substrate or washing of wells.
2. It does not require any special equipment for washing and incubation.
3. The result of particle agglutination test is read visually.
4. Particle agglutination test is suitable for screening large numbers of blood samples.

c. Limitations of Particle Agglutination Test

1. Results of particle agglutination is dependent on the subjective evaluation.
2. No evidence of the particle agglutination test results can be kept.

2.2.6 Nucleic Acid Amplification Testing (NAT)

Nucleic Acid Amplification Technology testing should only be considered when there is an efficient and effective screening programme based on antigen/antibody testing in place.

NAT detects the presence of viral nucleic acid; Deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA), in donated samples. The presence of specific nucleic acid indicates the presence of the viral particle and that the donation is likely to be infectious. NAT may differ according to required equipment and infrastructure, pre-amplification sample processing, reaction temperature, turnaround time, ease of use, limit of detection and cost. All tests involve broadly the same principle.

a. Principle of Nucleic Acid Amplification Technology

Nucleic acid is extracted from a blood sample followed by amplification at optimal temperatures. Detection of amplified nucleic acid is then determined by any of the under-listed means, followed by comparison with known titrated controls;

- Visually on an agarose gel illuminated under ultraviolet light.
- Examining reaction tubes in a turbidimeter.
- Incorporation of fluorescent labels in the reaction allowing continuous real time monitoring of Nucleic Acid production during amplification.

b. Characteristics of Nucleic Acid Amplification Technology

1. NAT can either be performed on individual donations (ID NAT) or pooled donations (Pooled NAT) to detect the nucleic acid of the infectious agent.
2. NAT targets individual nucleic acids.
3. NAT screening assays are presented as single or multiplex.
4. Multiplex NAT screening assays can detect DNA or RNA from multiple agents simultaneously.

c. Limitations of Nucleic Acid Amplification Technology

1. NAT is complex and requires technical expertise.
2. NAT requires a dedicated infrastructure, equipment and consumable.
3. NAT requires a significant investment in equipment, assay and training.

CHAPTER 3:
SCREENING FOR TRANSFUSION TRANSMISSIBLE INFECTIOUS AGENTS

Screening for mandatory transfusion transmissible infectious (TTI) agents is recommended for the provision of safe blood. The four mandatory TTIs, per the National Blood Policy, are:

- Human immunodeficiency virus (HIV)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Treponema pallidum (Syphilis).

All donated blood should be screened for at least one suitable serological marker for each of these four infectious agents. Screening for additional markers of the mandatory infectious agents or other transfusion-transmissible infectious agents could be considered, depending on the risk, logistics and level of resources available. Importantly, screening of donated blood should be performed in a quality assured manner.

Key Recommendation for TTI Testing

1. All blood and blood components should be screened for infectious agents prior to their release for clinical use or further processing into components. Only blood and blood components from donations that are non-reactive in all screening tests for all defined markers should be released for clinical or manufacturing use.
2. Screening of all donated blood should be mandatory for the following infectious agents using the following markers as the minimum;
    - HIV-1 & HIV-2: screening for either a combination of HIV antigen and HIV antigen-antibody.
    - Hepatitis B: Screening for the Hepatitis B Surface Antigen
    - Hepatitis C: Screening for either a combination of HCV antigen-antibody or HCV antibodies
    - Syphilis: Screening for specific Treponema pallidum antibodies.
3. Adequate resources (materials and logistics) should be made available for the consistent and reliable screening of donated blood for TTIs.
4. A sufficient number of qualified and trained staff should be available to implement the blood screening programme.

5. A national system for evaluation, selection and validation for all assays used for blood screening should be in place.
6. Specific indicators of performance of all assays should be designated and monitored continuously to assure the reliability of results.
7. All test for TTIs should be performed in a quality-assured manner incorporating Quality systems (including standards, training, documentation and assessment).
8. Only blood facilities licensed as "Class III" by the Food and Drugs Authority (FDA) are mandated to test donated blood for TTIs.
9. A quarantine system should be in place for the physical segregation of all unscreened donations and their blood components until all required tests are completed. All reactive units should be removed from the quarantine stock and stored separately and secured until they are disposed of safely in accordance with appropriate disposal protocols.
10. Systems should be in place to maintain the confidentiality of test results.
11. Confirmatory testing of reactive donations should be undertaken for donor notification, counselling and referral for treatment, deferral or recall for future donation and look back on previous donations.

3.1 INFECTIOUS AGENTS

3.1.1 Human Immunodeficiency Virus (HIV)

The human immunodeficiency virus (HIV) is a retrovirus and an enveloped RNA virus. It is found in blood and other body fluids and transmissible by the parenteral route. Infectivity estimates for the transfusion of infected blood and blood components are much higher (around 95%) than for other modes of HIV transmission.

A number of different groups and subtypes (clades) have been identified with some significant antigenic differences. HIV-1 and HIV-2 are the two major distinct virus types with significant cross-reactivity between them. HIV-1 is now endemic in many parts of the world. HIV-1 group M is responsible for more than 99% of the infections worldwide, whereas the prevalence of HIV-2 is mainly restricted to countries in West Africa and India. Additionally, a few infections with HIV group O and group N have been observed in Africa.

The appearance of antibody marks the onset and persistence of infection, but not immunity.

3.1.1.1 Screening for HIV

The methods used to identify the presence of HIV employ the following screening targets;

- Serological markers:
  - anti-HIV-1, including group O, + anti-HIV-2
  - HIV p24 antigen (p24 Ag)
- Viral nucleic acid: HIV RNA can be detected in pooled or individual samples.

3.1.1.2 Recommendations

1. Screening of HIV should be performed using a highly sensitive and specific EIA or CLIA for the detection of HIV antigen (p24) and antibody (anti-HIV-1 + anti-HIV-2) on all donated blood.
2. In emergency situations in which blood and blood components are needed urgently but are not readily available, screening using a highly sensitive and specific anti-HIV-1 + anti-HIV-2 rapid assay may be performed to enable blood to be released for use. However, the blood should be retested as soon as possible using recommendation 1 above. Any discrepant results should be investigated further and corrective action taken, including communicating with the prescriber.

3.1.2 Hepatitis B Virus

Hepatitis B virus (HBV) is an enveloped DNA virus belonging to the hepadnavirus group. HBV may be found in blood and other body fluids and is transmissible by the parenteral route. The virus replicates in the hepatocytes.

3.1.2.1 Screening for HBV

The methods used to identify the presence of HBV employ the following screening targets:

- Serological markers:
  - Hepatitis B surface antigen (HBsAg)
  - Hepatitis B core antibody (anti-HBc)
- Viral nucleic acid: HBV DNA can be detected in pooled or individual samples.

3.1.2.2 Recommendations

1. Screening of HBV should be performed using a highly sensitive and specific HBsAg immunoassay by EIA or CLIA.
2. In emergency situations in which blood and blood components are needed urgently but are not readily available, screening using a highly sensitive and specific HBsAg rapid assay may be performed to enable blood to be released for use. However, the blood should be retested as soon as possible using recommendation 1 above. Any discrepant results should be investigated further and corrective action taken, including communicating with the prescriber.
3. Screening for anti-HBc is not recommended as a routine. The need to screen for anti-HBc should be based on the residual risk of HBV transmission.

3.1.3 Hepatitis C virus

Hepatitis C virus (HCV) is an enveloped RNA virus belonging to the flavivirus group. HCV may be found in blood and other body fluids and is transmissible by the parenteral route. The virus replicates in the hepatocytes.

3.1.3.1 Screening for HCV

The methods used to identify the presence of HCV employ the following screening targets:

- Serological markers:
  - HCV antibody
  - HCV antigen
- Viral nucleic acid: HCV RNA.
  - HCV RNA can be detected in pooled or individual samples.

3.1.3.2 Recommendations

1. Screening of HCV should be performed using a highly sensitive and specific HCV antibody immunoassay or a combination of HCV antigen-antibody immunoassay by EIA or CLIA.
2. In emergency situations in which blood and blood components are needed urgently but are not readily available, screening using a highly sensitive and specific anti- HCV rapid assay may be performed to enable blood to be released for use. However, the blood should be retested as soon as possible using recommendation 1 above. Any discrepant results should be investigated further and corrective action taken, including communicating with the prescriber.

3.1.4 Syphilis

Syphilis is caused by the bacterium Treponema pallidum. Syphilis may be found in blood and other body fluids and is transmissible by the parenteral route.
The treponemes are relatively fragile, in particular being heat-sensitive; storage below +20°C for more than 72 hours results in irreparable damage to the organism such that it is no longer infectious. However, there still remains a risk of transmission through the transfusion of blood and blood components stored below +20°C.
Blood components stored at higher temperatures (above +20°C), such as platelet concentrates, or those not stored at lower temperatures for any length of time, such as blood collected and used within 48 hours, present a significantly higher risk of transmitting syphilis.

3.1.4.1 Screening for Syphilis

The methods used to identify the presence of syphilis employ the following screening targets:

- Non-specific, non-treponemal markers: antibody to lipoidal antigen (reagin)
- Specific treponemal antibodies.

3.1.4.2 Recommendations

1. Screening should be performed using a highly sensitive and specific test for treponemal antibodies: either TPHA or enzyme immunoassay.
2. In emergency situations in which blood and blood components are needed urgently but are not readily available, screening using a highly sensitive and specific syphilis rapid assay may be performed to enable blood to be released for use. However, the blood should be retested as soon as possible using recommendation 1 above. Any discrepant results should be investigated further and corrective action taken, including communicating with the prescriber.

3.2 CONFIRMATORY TESTING FOR TTIs

Confirmatory testing is performed to confirm the infectious status of donors based on the repeat reactive screening tests. This allows for donor notification, counselling, deferral and referral.

3.2.1 Interpretation and Use of Confirmatory Results

Donations that are repeat reactive may be confirmed as negative, inconclusive or positive.

a. Confirmed Negative

A donor showing repeat reactive results on screening and negative results on confirmatory testing is considered confirmed negative. The donor should be counselled and temporarily deferred. The donor can be accepted for future donations when screened non-reactive. All such donations must be discarded appropriately.

b. Inconclusive Results

A donor showing initial reactive results on screening and non-reactive results on repeat tests with a positive result on confirmatory testing is considered inconclusive. The donor should be counselled, deferred for blood donation and followed-up for further investigations. All such donations must be discarded appropriately.

c. Confirmed Positive

A donor showing repeat reactive results on screening and positive results on confirmatory testing is considered confirmed positive. The donor should be counselled and permanently deferred and referred for appropriate medical care. All such donations must be discarded appropriately.

3.3 MANAGEMENT OF BLOOD DONORS

The management of blood donors is an essential part of the activities of every blood centre and blood screening facility. Donors should be managed in a way that ensures high standards of care and assures them of the concern of the blood centre--- and the facility for their health and well-being.

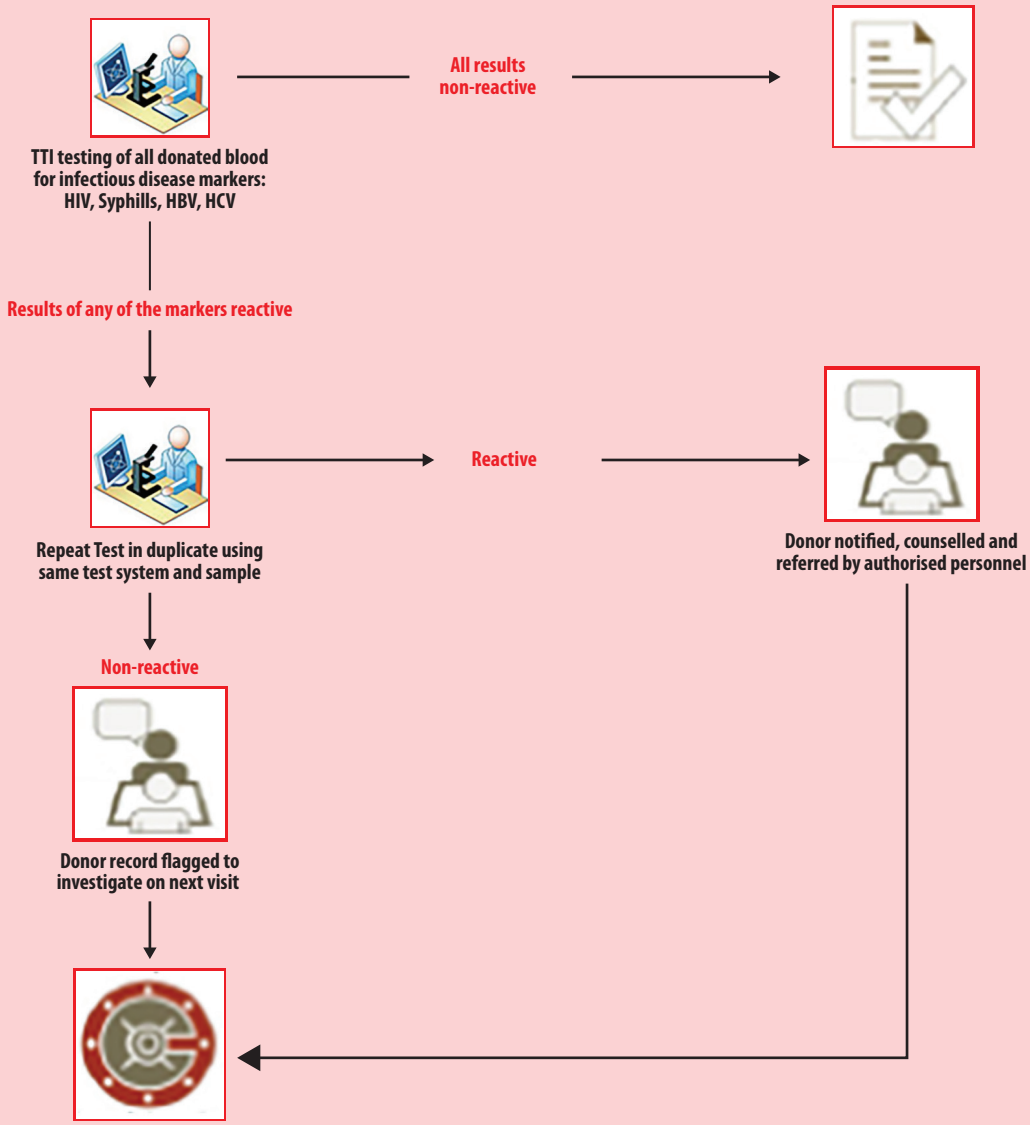
3.3.1 Key Recommendations

1. All screening facilities should follow the recommended testing strategy on confirmation of initial reactive results.
2. Donors who test negative for TTIs should be encouraged to donate regularly and continue to live safe and healthy lifestyles.
3. All donors with initial and inconclusive TTI results should be notified, counselled and deferred appropriately.
4. All donors with confirmed positive TTI results, should be notified, counselled, deferred and referred for further management.

3.4 ALGORITHM FOR TTI TESTING

National Blood Service

TTI Testing Algorithm



National Blood Service

TTI Confirmatory Testing Algorithm



TTI testing of all donated blood for infectious disease markers: HIV, Syphills, HBV, HCV

All results non-reactive



Difussion article for clinical use

Results of any of the markers reactive



Repeat Test in duplicate using same test system and sample

Non-Reactive



Donor record flagged to investigate on next visit

Reactive



Perform confirmatory testing using another test system and sample from blood bag

Non-Reactive



Donor record flagged to investigate on next visit

Reactive

Notify donor, counsel, refer and defer donor

CHAPTER 4: QUALITY

Quality systems are crucial for the overall effectiveness of all aspects of screening of donated blood and assuring quality, safety and efficacy of all blood and blood component. It is the responsibility of the Blood Service as well as all facilities screening donated blood and performing compatibility testing to implement these quality recommendations.

4.1 PREMISE

1. All premises should be constructed and maintained in a way that suits the activities flow to be carried out.

4.2 PROCEDURE

1. The recommended tests must be performed on the correct samples using qualified test reagents and kits.
2. Tests must be performed, controlled and documented in accordance with standardized procedures to ensure consistency.
3. Blood and blood components can only be released for transfusion when all the required mandatory and additional laboratory tests have been completed, documented and approved by the appropriate person.
4. Only screened non-reactive blood and blood components for all mandatory test shall be released for blood transfusion.
5. Screening laboratory should participate in external quality assessment (EQA).
6. All activities in screening laboratories should be reviewed on a regular basis through self-inspection and internal and external audits.

1.3 PERSONNEL

1. All staff must be given appropriate training and assessed to be competent to perform the test.
2. Staff should be assessed on a regular basis on their knowledge of policies and their competency in the performance of procedures.
3. Training and competency assessment records should be maintained for each member of staff.

1.4 EQUIPMENT

1. All equipment should be qualified, calibrated and validated before use.
2. All equipment should be regularly maintained and serviced on schedule with necessary documentation and records.
3. All equipment must be operated by trained staff in accordance with manufacturers' instructions.

1.5 DOCUMENTATION

1. A complete set of appropriate documents, including the quality policy, quality manual and standard operating procedures, forms and datasheets should be developed and kept up-to-date.
2. All processes carried out by the blood facility should be documented and the records kept for traceability purposes. The records should include but not limited to donor records, test results, quality control results, details of test kits and patient records.
3. All documents should be maintained and retained according to the National Blood Service document management system to ensure confidentiality of records, safe storage, retrieval, archival and disposal of documents to ensure traceability of records.

Appendices 1

NATIONAL BLOOD SERVICE
STANDARD OPERATING PROCEDURE
Preparation of Red Cell Suspensions

1. SCOPE AND APPLICATION

A 3-5% red cell suspension is used for the following tube examination procedures:

I. ABO and Rh 'D' typing
II. Direct antiglobulin test and auto control
III. Donor unit compatibility (cross match)
IV. Red cell phenotyping

For best results, red cell suspensions should be used for testing on the day of preparation.

2. PRINCIPLE

A red cell suspension is a common reagent used for many serologic procedures. Red cell suspensions provide the appropriate serum to cell ratio to allow for grading and interpretation of tests results.

3. RESPONSIBILITY

Biomedical Scientist

Technical Officer

4. MATERIALS REQUIRED

i. Test tubes
ii. Test Tube Racks
iii. Pasteur Pipettes
iv. 85% Normal saline
v. Serological centrifuge

5. SPECIMEN

The preferred specimen is an EDTA tube of venous blood anticoagulated blood or clotted blood samples

6. QUALITY CONTROL

i. Visually compare the 3-5% red cell suspension to commercially prepared red cell suspension to ensure the appropriate strength has been achieved.

ii. Mix the red cell suspension immediately before performing the serological procedure.

iii. Visually inspect on each day of use for turbidity, discoloration or any signs of bacterial contamination.

iv. Daily Quality Control should consist of known positive and negative red cells

7. PROCEDURE

Preparing a 3-5% Red Cell Suspension

1. Label a tube with the patient identifier or donor unit number.
2. Add approximately 3-5 drops of blood from the patient or donor sample and add to the test tube. For donor tubing segments, cut open the segment and squeeze 1-2 drops of blood into the test tube.
3. NOTE: Since antibody-coated RBCs are heavier than uncoated cells and settle to the bottom of the sample the contents should be mixed well before blood is removed. If a clotted specimen is used, blood should be removed from the bottom of the clot for the same reason.
4. Fill the test tube approximately 3/4 full with saline by positioning the tip of the wash bottle directly over the tube and squeezing it. This will mix the blood and the saline, increasing the efficiency of washing.
5. Centrifuge the tube for the appropriate time calibrated for cell washing.
6. Remove the test tube and decant the supernatant saline.
7. Shake the cells loose from the bottom of the tube.
8. Add approximately 40 drops of saline necessary to prepare 3- 5% suspension.
9. Mix to re-suspend.
10. Mix the red cell suspension immediately before performing the serological procedure.

Preparing washed 3-5% Red Cell Suspension

1. Label a tube with the patient identifier or donor unit number.
2. Add 2 drops of whole blood or 1 drop of packed cells into a labelled test tube.
3. Fill test tube ¾ full with saline to re-suspend the cells. Avoid contamination of tubes when dispensing saline into several tubes.

4. Centrifuge the tube to obtain clear supernatant and a defined red cell button.
5. Decant the supernatant.
6. Following the removal of supernatant, gently re-suspend the red cell button.
7. If more than one wash, is required repeat steps 3 through 5.
8. After the last wash, gently re-suspend the red cells with saline to a 3-5% red cell suspension.
9. Adjust to a 3-5% suspension by adding saline or centrifuging to removing saline.
10. Mix the red cell suspension immediately before performing the serological procedure.

Preparation of a Standard Cell Suspension

A standard may be prepared as in the table below for use as a comparison.

Final Concentration	2%	3%	4%	5%
RBC volume, mL	Final volume, diluted with 85% saline, in mL			
0.1	5	3.3	2.5	2
1.0	50	33	25	20

NATIONAL BLOOD SERVICE (GHANA)