LICENCE CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE TESTING SERVICES IN TRANSFUSION MEDICINE

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1. These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service ("**CLS**") and provide, or intend to provide, as part of that service, testing services in transfusion medicine ("**TM Testing**") (such persons referred to as "**Licensees**").

1.2. These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Service Licensees providing or intending to provide Transfusion Medicine' issued on 10 August 2022.

1.3. For avoidance of doubt, the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.4. For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, and codes of practice made thereunder.

1.5. A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's CLS licence;
(b) shortening the term of the Licensee's CLS licence;
(c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
(d) a direction requiring the Licensee to pay a financial penalty.

1.6. For the purpose of these LCs,

(a) "blood" means (i) whole human blood or (ii) any human blood component that is derived from human plasma, red blood cells, white blood cells

and/or platelets. A list of blood component descriptions is set out in **Annex A**; and

(b) "blood product" means any therapeutic product that is derived from human blood or plasma.

2 Premises and Equipment

2.1 The Licensee shall ensure that the floorings and laboratory benches in its approved permanent premises used in its provision of TM Testing ("**Premises**") are constructed of materials that permit cleaning and disinfection, and are non-absorbent (e.g. non-permeable materials for laboratory furniture).

2.2 The Licensee shall ensure that safety facilities and equipment used in its provision of TM Testing, including but not limited to emergency showers and eye wash, are adequate, accessible, in working order and regularly maintained in its Premises.

2.3 The Licensee shall ensure that its Premises and equipment for the storage and transport of blood and pre-transfusion testing specimen are appropriate and adequate for blood transfusion.

2.4 The Licensee shall ensure that all equipment used in its provision of TM Testing (including but not limited to refrigerators, freezers, platelet incubators or agitators, plasma thawers or water-baths, immunohaematology test systems and centrifuges) are qualified as fit for its purpose[1].

2.5 The Licensee shall ensure that the functionality and performance of all its analytical test instruments used in its provision of TM Testing are verified:

(a) prior to their use in its tests or after any major maintenance, major servicing or relocation; and

(b) to meet the manufacturer's specifications, after having been installed in accordance with the manufacturer's specifications.

2.6 The Licensee shall ensure that for all of its analytical testing instruments and equipment used in its provision of TM Testing:

(a) the appropriate maintenance and functional checks are performed in accordance with the manufacturers' specifications;

(b) equipment failures are investigated and resolved prior to resumption of the use of that equipment; and

(c) there is adequate documentation of all equipment calibration, maintenance, repairs and troubleshoots.

[1] For example, domestic-type refrigerators cannot be used for the storage of blood.

2.7 The Licensee shall ensure that it has:

(a) adequate storage equipment to ensure that reagents and pre-transfusion testing specimens are physically segregated from blood and blood products, and that the storage areas for such reagents and pre-transfusion testing specimens in its Premises are properly organised and clearly labelled;

(b) adequate storage equipment to ensure that crossmatched blood is physically segregated from un-crossmatched blood, and that the storage areas for such crossmatched blood and un-crossmatched blood in its Premises are properly organised and clearly labelled; and

(c) adequate storage equipment to ensure that autologous blood is physically segregated from blood for allogenic transfusion, and that the storage areas for such autologous blood and blood for allogenic transfusion in its Premises are properly organised and clearly labelled.

2.8 The Licensee shall ensure that all of the storage equipment used in its provision of TM Testing is appropriate and adequate for the maintenance of the stability, safety and quality of all blood and blood products.

2.9 The Licensee shall ensure that all blood storage equipment is monitored continuously, or at least once every 4 hours ("**monitoring interval**"), to ensure that temperature is maintained consistently throughout the blood storage equipment. The Licensee shall also keep a record of the temperatures of the blood storage equipment at each monitoring interval.

2.10 The Licensee shall ensure that all of its blood storage equipment is equipped with an alarm system that:

(a) is monitored continuously;

(b) is set to trigger an auditory or visual alarm if the temperature of the blood storage equipment falls outside of the acceptable limit;

(c) is checked at a frequency that is in accordance with the manufacturer's specifications, or at least quarterly, if not specified by the manufacturer; and

(d) will continue to function in the event of power failure.

2.11 The Licensee shall ensure that its Premises has emergency power supply for all of its blood storage equipment or backup blood storage equipment to maintain the integrity of blood.

2.12 The Licensee shall ensure that the shipping containers used by it for transportation of blood shall be of sturdy construction and validated to maintain the appropriate temperatures of the blood and blood products for the following period:

(a) transportation from a licensee who is licensed to provide a blood banking service under the HCSA ("**Licensed Blood Banking Service(s)**") or supplier to the Licensee's refrigerators and/or freezers for the storage of blood and blood products; and
(b) transportation from the Licensee's Premises to the time of administering blood transfusion.

Refrigerators and/or Freezers

2.13 The Licensee shall ensure that all refrigerators used by it for storage of blood contain a fan-cooled cabinet, and that the fan of the fan-cooled cabinet continues to operate when all doors of the refrigerator are closed.

2.14 The Licensee shall ensure that there is no freezing compartment in any blood storage refrigerator used by it.

2.15 The Licensee shall ensure that the interiors of the refrigerators and freezers used by it are clean and adequately insulated.

2.16 The Licensee shall ensure that clear written instructions are available and readily accessible for its personnel to follow in the event of power failure or other disruption of its freezers and refrigerators.

2.17 The Licensee shall retain the temperature records of its freezers and refrigerators (referred to in paragraph 2.9 above) as part of its blood storage facility records for at least 5 years.

3 Reagents and Materials

3.1 The Licensee shall ensure that there are effective measures to quarantine and prevent any inadvertent use of test reagents and critical materials in its provision of TM Testing where:
(a) the reagents and/or critical materials have been received by the Licensee or any of its personnel from the supplier but are not released from quarantine;
(b) the Licensee or any of its personnel have been notified of any issues with the reagents and/or critical materials which may affect their potency, sterility, quality or performance; and/or
(c) suboptimal quality or performance of the reagents and/or critical materials is suspected.

3.2 The Licensee shall ensure that there are appropriate checks on any reagents and critical materials received by the Licensee or any of its personnel from the supplier, and that such checks are done in accordance with its established

criteria for acceptance in respect of its provision of TM Testing prior to the release of the reagents and critical materials for use. The Licensee shall also ensure that its personnel who have received and checked the reagents and/or critical materials are identifiable and traceable.

4 Blood Inventory Management

4.1 The Licensee shall ensure that it implements an inventory system for the receipt, quarantine, storage and release of blood and blood products for transfusion.

4.2 The Licensee shall ensure that there are adequate and effective measures to quarantine and prevent inadvertent use of blood and blood products which are:

(a) received from Licensed Blood Banking Service(s) or supplier(s) until such blood and/or blood products are released from quarantine;
(b) returned unused to its Premises after such blood and/or blood products have been released for transfusion; and
(c) where it or any of its personnel has been notified of issues which may affect the safety of such blood and/or blood products.

4.3 The Licensee shall ensure that it or any of its personnel only accepts blood from:
(a) Licensed Blood Banking Service(s); and
(b) other licensees under the HCSA which have been licensed to provide CLS and are approved under section 11D of the HCSA to provide TM Testing,
and ensure that:
(c) physical inspections are conducted on the accurate labelling, shipping conditions, abnormal appearance[2] of blood, the integrity of the blood bag, ports or seals, and the expiry date of blood accepted by it; and
(d) any blood accepted by it is handled in accordance with its CLS's established processes.

4.4 The Licensee shall ensure that (a) the donor unit ABO and (b) Rhesus (Rh) negative blood group are verified by its personnel for red cell components prior to their release from quarantine.

4.5 The Licensee shall ensure that its personnel do not accept any blood and/or blood products into its blood inventory after the blood and/or blood products have been released for transfusion, unless the blood and/or blood products (as applicable) satisfy all of the following requirements:
(a) the blood and/or blood products do not have an abnormal appearance[3];
(b) the integrity of the blood bag, ports or seals is intact; and

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2 Abnormal appearances include haemolysis and clots.
3 See footnote 2.

(c) the blood and/or blood products (as applicable) have been maintained at the appropriate storage conditions for the duration of release for transfusion.

4.6 The Licensee shall ensure that the blood and blood products received by it or any of its personnel are not released for transfusion after their expiry dates or shelf-life, whichever is earlier.

4.7 The Licensee shall ensure that autologous and directed donation blood handled by it or any of its personnel is only released for (a) the patient from whom that blood is collected or (b) the patient who is directed to receive that blood.

5 Laboratory Practices

5.1 The Licensee shall ensure that its standard operating procedures related to the provision of TM Testing ("**SOPs**") are properly documented, and are made available and readily accessible to all of its personnel.

5.2 The Licensee shall ensure that the SOPs are approved by its Clinical Governance Officer (as appointed under section 24(2) of the HCSA) ("**CGO**") or any other suitably qualified personnel designated by the CGO prior to their implementation and are reviewed regularly and updated periodically as required in its quality management system.

5.3 The Licensee shall ensure that there are clear and effective processes for the storage of all of its specimens used in its provision of TM Testing to prevent unauthorised access and use.

5.4 The Licensee shall ensure that the specimen retention and storage conditions are defined in its SOPs for each type of specimen tested by its CLS.

5.5 The Licensee shall ensure that there is no mix-up of specimens in its provision of TM Testing.

5.6 The Licensee shall ensure that effective measures are implemented to prevent transcriptional or typographical errors in any documentation created or produced by its CLS in relation to its provision of TM Testing.

5.7 The Licensee shall ensure that there are effective measures to ensure the safety and quality of the blood for the recipients of the blood via transfusion.

Specimen Acceptance and Rejection

5.8 The Licensee shall implement effective precautionary measures, including those set out under paragraphs 5.9 and 5.10, to minimise pre-transfusion testing specimen misidentification and mis-transfusions.

5.9 The Licensee shall ensure that the patient's identification on the pre-transfusion testing request and specimen is verified before the pre-transfusion testing is performed. The Licensee shall identify and resolve any discrepancy in the patient's identification and/or the specimen prior to the conduct of any pre-transfusion testing by its CLS.

5.10 The Licensee shall ensure that any pre-transfusion testing specimen handled in its provision of TM Testing is traceable to the person who had collected the specimen.

Pre-transfusion Testing for Patients

5.11 The Licensee shall ensure that a patient's ABO and Rh(D) blood group is determined based on the pre-transfusion specimens accepted by it, and that forward and reverse blood grouping shall be performed on all pre-transfusion specimens, except in the case of neonates where only forward blood grouping is required.

5.12 The Licensee shall ensure that pre-transfusion testing specimens are screened by its CLS for potentially clinically-significant red cell antibodies. Where the specimen is screened positive for clinically-significant red cell antibodies, the Licensee shall ensure that the clinically-significant red cell antibodies are identified.

5.13 The Licensee shall ensure that the patient's blood group, clinically-significant red cell antibodies, transfusion and transfusion reactions, and special transfusion instructions, are reviewed against the patient's historical records, where available.

5.14 In the case where the patient's historical record is unavailable, the Licensee shall ensure that its CLS confirms the patient's ABO blood group prior to transfusion by:

(a) conducting a repeat test of the patient's ABO and Rh blood grouping on the same pre-transfusion specimen, which shall be done by an independent personnel from its CLS who did not perform the initial tests referred to in paragraphs 5.11 and 5.12 above; or

(b) conducting an ABO and Rh blood grouping on a second pre-transfusion specimen.

5.15 The Licensee shall ensure that its CLS does not release any blood for transfusion based solely on the patient's historical records. In the event that its CLS does not have sufficient time to complete the pre-transfusion testing referred to in paragraphs 5.12 and 5.13 above, but has ensured (a) that a patient's ABO and Rh(D) blood group is determined based on the pre-transfusion specimens accepted by the CLS personnel in accordance with paragraph 5.11 above and (b) that its CLS personnel confirms the patient's ABO blood group prior to transfusion in paragraph 5.14 above, the Licensee's CLS shall be allowed to release ABO blood group-specific red cell components.

5.16 The Licensee shall ensure that all discrepancies in relation to the patient's blood group are resolved prior to release of blood for transfusion.

5.17 The Licensee shall ensure that it implements effective measures in its provision of TM Testing to minimise the risks of transcription errors for the documentation and reporting of any patient blood group.

Selection of Blood for Transfusion

5.18 The Licensee shall establish a process for the selection of red cell component for purposes such as:

(a) routine blood transfusion;

(b) life-threatening situations warranting the release of blood prior to the completion of pre-transfusion testing, of which the process established shall minimally include:
  (i) the use of emergency group O red cell component and ABO blood grouping-specific un-crossmatched blood;
  (ii) the use of Group O Rh negative red cells as the emergency blood option for women of childbearing age (*i.e.* 50 years old or younger) of Indian, Caucasian, Middle Eastern and African ethnicity;
  (iii) procedures for the release of blood prior to the completion of pre-transfusion testing made by a qualified medical practitioner where these procedures shall be approved by its CGO of the Transfusion Medicine laboratory discipline; and
  (iv) timely notification to the qualified medical practitioner attending to that patient, should any blood be tested to be incompatible upon completion of pre-transfusion testing;

(c) the release of Rh-positive red cell component and platelets to Rh-negative patients in life-threatening situations, inventory shortages and other exceptional circumstances, of which the process established shall

minimally include an approval from (i) its CGO, (ii) the CGO of a Licensed Blood Banking Service or (iii) a qualified medical practitioner authorised by any of the CGOs stated in paragraphs 5.18(c)(i) and 5.18(c)(ii); and

(d) special circumstances where no compatible red cell components are available.

5.19 The Licensee shall ensure that its CLS only releases ABO-compatible blood for transfusion, except where the circumstances in paragraph 5.18(c) are met, in which case, its CLS is allowed to release Rh-positive red cell component in accordance with the process set out in that paragraph.

5.20 The Licensee shall ensure that its CLS determines the donor blood-patient compatibility using serological crossmatch prior to the release of red cell components for allogenic transfusion except under life-threatening situations.

5.21 The Licensee shall ensure that its CLS performs the serologic crossmatch on a patient specimen for which pre-transfusion testing results remain valid:

(a) up to 3 days from collection of the specimen if the patient (i) has been transfused with any blood in the last 3 months, or (ii) is pregnant in the last 3 months;

(b) up to 7 days from collection of the specimen if the patient (i) has not been transfused with any blood in the last 3 months, or (ii) is not pregnant in the last 3 months; and

(c) up to 3 months for pre-transfusion testing performed prior to an elective surgery, if the patient (i) has not been transfused with any blood in the last 3 months, or (ii) is not pregnant in the last 3 months.

For avoidance of doubt, the day of the collection of the specimen from the patient shall be regarded as Day 0.

5.22 In the case of an electronic crossmatch, the Licensee shall ensure that there are rules built into its CLS's laboratory information system to alert its CLS's personnel of ABO blood incompatibility between the donor unit and patient.

5.23 The Licensee shall ensure that there are measures implemented in its provision of TM Testing to prevent mix-up of blood at the time of release for transfusions.

Post-transfusion Specimen Retention

5.24 The Licensee shall ensure that all pre-transfusion testing specimens and, in the case of any transfusion involving red cell component, at least one segment of integral donor tubing are retained by its CLS for at least seven days after the transfusion for investigation in the event of transfusion reactions or transfusion-related errors.

6 Storage and Transport of Blood

6.1 The Licensee may provide blood and blood components to:

(a) a licensee which has been licensed under the HCSA to provide any of the following licensable healthcare services:
  (i) an acute hospital service;
  (ii) an ambulatory surgical centre service ("**ACS Licensee**"), except for ACS Licensees which only perform ophthalmology procedures that have a low risk of surgical blood loss on patients who are assessed not to require peri-operative blood transfusion[4];
  (iii) a CLS ("**CLS Licensee**"), and which is approved to provide TM Testing under section 11D of the HCSA;
  (iv) a community hospital service, and which is approved to provide a blood transfusion service under section 11D of the HCSA; or
  (v) an outpatient medical service, and which is approved to provide a blood transfusion service under section 11D of the HCSA; and

(b) a person licensed under the Private Hospitals and Medical Clinics Act 1980 to use any premises as a private hospital that is a nursing home, and which is approved under Regulation 18 of the Private Hospitals and Medical Clinics Regulations to perform 'blood and blood product collection, processing, storage, distribution and transfusion services (including autologous blood transfusion)'.

6.2 The Licensee shall ensure that:

(a) each unit of blood is inspected for expiration dates and appearance (such as haemolysis in plasma or discolouration of red cell mass) immediately before issuing or packing the blood unit for transport; and
(b) any units of blood with abnormal appearance[5] shall be quarantined and returned to its CLS.

6.3 The Licensee shall ensure that there are written policies on the transport and storage of blood, which are updated and based on the current and latest

[4] See regulation 38(2) of the Healthcare Services (Ambulatory Surgical Centre Service) Regulations 2023
[5] See footnote 2.

scientific knowledge. The Licensee shall ensure that the written policies are in line with, and incorporate the requirements in **Annex B**.

6.4 Where applicable, the Licensee shall ensure that the cold chain is maintained throughout the transportation of blood from the Licensee's storage location to the applicable licensees stipulated in paragraph 6.1 above.

6.5 The Licensee shall ensure that the temperature of the blood units is checked upon receipt from a Licensed Blood Banking Service or any CLS Licensees which are approved to provide TM Testing under section 11D of the HCSA.

6.6 Upon receipt of any blood unit from a Licensed Blood Banking Service or any CLS Licensees which are approved to provide TM Testing under section 11D of the HCSA, the Licensee shall ensure that such blood units are not left in the insulated transport container, and that such blood units are stored in a properly monitored refrigerator or freezer immediately.

7 Investigation and Escalation of Issues

7.1 The Licensee shall ensure that any suspected transfusion reactions, near-miss incidents [6] or transfusion-related incidents are promptly escalated to the relevant personnel, and investigations are initiated in order to facilitate the continuing care of patients.

7.2 The Licensee shall ensure that it implements a process to investigate transfusion reactions and transfusion-related laboratory errors and that causal factors for transfusion-related laboratory errors are promptly identified and appropriate corrective and preventive measures are taken in a timely manner.

7.3 The Licensee shall ensure that there is an established process for notifications to a Licensed Blood Banking Service or its supplier where blood and/or blood products are suspected to be the cause of adverse reactions.

8 Records

8.1 The Licensee shall ensure that transfusion and any other records related to its provision of TM Testing:

(a) are retained by it for a reasonable period and in accordance with its policies on the retention period for such records; and

[6] An example of a "near-miss incident" is where a Licensee's CLS has issued blood with the wrong blood group for transfusion to a patient, even if the patient was not eventually transfused with that blood.

(b) shall include details of:

(i) equipment maintenance, servicing, repair and preventive maintenance, including:

a. temperature monitoring;

b. alarm testing;

c. validation of insulated boxes; and

d. calibration of a reference standard;

(ii) blood, blood component and blood product inventory;

(iii) patients' group and crossmatch results, and transfusion records;

(iv) disposition of blood, blood components and blood products; and

(v) investigation of transfusion reactions and transfusion-related laboratory errors.

Annex A

LIST OF BLOOD COMPONENT DESCRIPTIONS

Cryoprecipitated Antihemophilic Factor
The cold insoluble portion of plasma processed from Fresh Plasma.

Cryoprecipitated Antihemophilic Factor, Pooled
Two or more units of Cryoprecipitated Antihemophilic Factor combined into one bag. The total volume will be indicated on the label. To assist in the pooling process, 0.9% sodium chloride (USP) may be added.

Fresh Frozen Plasma
Plasma separated from the blood of an individual donor and placed at -18°C or colder within 6 to 8 hours of collection from the donor, depending upon the anticoagulant or collection device.

Granulocytes Pheresis (also known as Apheresis Granulocytes)
A suspension of granulocytes in plasma prepared by cytapheresis.

Granulocytes/Platelets Pheresis (also known as Apheresis Granulocytes / Platelets)
A suspension of granulocytes in plasma prepared by cytapheresis, with the concurrent collection of platelets.

Irradiated Blood Components
Blood or blood component that has been exposed to gamma irradiation to prevent proliferation of T lymphocytes, and includes but is not limited to the following:
Granulocytes Pheresis, Irradiated
Granulocytes/Platelets Pheresis, Irradiated
Platelets, Irradiated
Platelets Pooled, Irradiated
Platelets Pheresis, Irradiated
Platelets Pheresis, Leukocytes Reduced, Irradiated
Red Blood Cells, Irradiated
Red Blood Cells Leukocytes Reduced, Irradiated
Red Blood Cells Pheresis, Irradiated
Whole Blood, Irradiated

Liquid Plasma
Plasma separated from the blood of an individual donor and not frozen.

Plasma Cryoprecipitate Reduced
Fresh Frozen Plasma from which cryoprecipitate has been removed.

Plasma for Manufacture (also known as Recovered Plasma)
Plasma for use in manufacturing and prepared from allogeneic donations. Plasma selected for manufacture that has been collected from Whole Blood or apheresis plasma collected for transfusion that has expired (non-commercial plasma derived products).

Plasma Frozen Within 24 Hours of Collection (also known as Frozen Plasma)
Plasma separated from whole blood or apheresis collection, and placed at -18°C or colder within 24 hours of the collection.

Platelets
A suspension of platelets in plasma prepared by centrifugation of Whole Blood.

Platelets Pooled
Two or more units of platelets that have been combined into one bag.

Platelets Leukocytes Reduced
Platelets Leukocytes Reduced are prepared by a method known to reduce the leukocyte number to $< 8.3 \times 10^5$ in at least 95% of the components sampled.

Platelets Leukocytes Reduced Pooled
A suspension of platelets in plasma that has been leukocyte reduced. The leukocyte reduction process can take place either before or after the pooling process.

Platelets Pheresis
A suspension of platelets in plasma prepared by cytapheresis. Whole Blood undergoes centrifugation in a cell separator, with the return to the donor of components not collected.

Platelets Pheresis Leukocytes Reduced
Platelets collected by apheresis that are prepared by a method known to reduce the residual leukocyte number to $<5 \times 10^6$ in 95% of the components sampled.

Red Blood Cells
Red cells concentrated by the removal of most of the plasma from sedimented or centrifuged Whole Blood.

Red Blood Cells Deglycerolized
Red blood cells to which glycerol has been added (e.g. as a cryoprotective agent) and subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Frozen
Red Blood Cells that have been stored in the frozen state at optimal temperatures in the presence of a cryoprotective agent.

Red Blood Cells Leukocytes Reduced
Red Blood Cells prepared by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to $< 5 \times 10^6$.

Red Blood Cells Low Volume
When 300-404 mL of Whole Blood is collected into an anticoagulant volume calculated for 450 +/- 45 mL or 333-449 ml of Whole Blood is collected into an anticoagulant volume calculated for 500 +/- 50 ml of Whole Blood.

Red Blood Cells Pheresis
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis.

Red Blood Cells Pheresis Leukocytes Reduced
Red Blood Cells in anticoagulant or in anticoagulant and storage solution that have been prepared by automated cytapheresis that have been leukocyte reduced by a method known to retain at least 85% of the original red cells and to reduce the leukocyte number in the final component to $< 5 \times 10^6$.

Red Blood Cells Rejuvenated
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above.

Red Blood Cells Rejuvenated Deglycerolized
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above, subjected to a cryoprotective agent and stored frozen at optimal temperatures. The cryoprotective agent is subsequently removed by washing with successively lower concentrations of sodium chloride (USP).

Red Blood Cells Rejuvenated Frozen
Red Blood Cells that have had 2,3-diphosphoglycerate and adenosine triphosphate restored to normal levels or above and then subsequently exposed to a cryoprotective agent and stored at optimal temperatures in a frozen state.

Red Blood Cells Washed
Red Blood Cells remaining after washing with a volume of compatible solution using a method known to remove almost all of the plasma. Depending on the method used, the preparation may contain variable quantities of leukocytes and platelets from the original unit.

Thawed Plasma
Thawed plasma prepared from Fresh Frozen Plasma or Plasma Frozen Within 24 Hours of Collection, that has been thawed and stored for up to 5 days.

Thawed Plasma Cryoprecipitate Reduced
Thawed plasma prepared from Plasma Cryoprecipitate Reduced.

Whole Blood
Whole Blood is collected in an anticoagulant or preservative solution and is not further processed. This product shall not be used as a source of platelets or labile coagulation factors.

Annex B

REQUIREMENTS FOR THE STORAGE AND TRANSPORT OF BLOOD

The Licensee shall ensure that its CLS comply with all of the following requirements in its provision of TM Testing:

Types of blood	**Requirements for storage of the type of blood**	**Requirements for transport of blood**
Whole Blood and Red Blood Cell Components	• Whole Blood and Red Blood Cell components shall be stored between 1°C and 6°C. • Blood shall be stored in a blood bank refrigerator which has been specially designed for the purpose. This includes blood that is kept in sites outside the blood bank, such as surgical or obstetric units. • Blood units shall be arranged so that the oldest blood is easily at hand and is used first.	• Whole Blood and all liquid Red Blood Cell components must be transported in sturdy, well-insulated containers with refrigerants that will ensure maintenance of a temperature of 1°C to 10°C. • Refrigerants used shall be adequate and appropriate to maintain temperature throughout the period of transportation and up to the time of administering transfusion. The recommended refrigerants are wet ice in leak-proof containers and chemical coolant pouches.
Fresh Frozen Plasma, Frozen Plasma and Cryoprecipitate	• Fresh Frozen Plasma, Frozen Plasma and Cryoprecipitate shall be stored at the temperature of -18°C or lower. • Stocks shall be rotated so that the oldest product is used first.	• Thawed Plasma must be transported in sturdy, well-insulated containers with refrigerant that will ensure maintenance of a temperature of 1°C to 10°C.

	• Fresh Frozen Plasma and Frozen Plasma which are thawed and used for the correction of labile coagulation factor deficiencies shall be transfused immediately. Thawed units of Fresh Frozen Plasma and Frozen Plasma shall not be re-frozen. • Fresh Frozen Plasma and Frozen Plasma shall be thawed between 30 and 37°C and stored at 1 to 6°C for up to 24 hours. • Reconstituted cryoprecipitate shall be stored at room temperature until transfusion, and shall be administered within 6 hours of thawing and 4 hours of pooling. Thawed units shall not be re-frozen.	
Platelets	• Platelet concentrates shall be stored at 20°C to 24°C. • Continuous gentle agitation is required. • If the hermetic seal of any bag containing platelets is broken, the platelets must be transfused within 4 hours.	• Platelets shall be maintained at temperatures of 20°C to 24°C during shipment. Well-insulated containers without added ice are sufficient.