



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Donor Blood / Blood Components Testing (Immunohematologic and Ttd Testing)		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

- 1.1 To set system and responsibilities of screening donors blood for blood group, unexpected antibodies and blood-born transmitted diseases.
- 1.2 To provide safe blood and blood products to recipients.

2. DEFINITONS:

- 2.1 N/A

3. POLICY:

- 3.1 For the benefit of the transfusion recipient, the donor's blood should be screened for blood group, unexpected antibodies and blood-born transmitted diseases.
- 3.2 All immunohematologic and transfusion transmitted diseases (TTD) testing should be cross-checked by two qualified staff members.

4. PROCEDURE:

4.1 Immunohematological Testing:

- 4.1.1 All blood units are subjected to immunohematological Testing (using samples of blood obtained from the donor during blood/ blood component collection). This includes:
 - 4.1.1.1 Determination of the donor's forward ABO group (RBC grouping).
 - 4.1.1.2 Determination of the donor's reverse ABO group (serum/ plasma grouping).
 - 4.1.1.3 Determination of the donor's Rh-D type.
 - 4.1.1.3.1 This includes test for weak D. In cases of Rh-D negative results.
 - 4.1.1.3.2 Rh phenotyping could be done as per availability.
 - 4.1.1.4 Detection of unexpected antibodies to red cell antigens (antibody screening).
 - 4.1.1.5 Confirmation of agreement between donor's current and historical group/type .
 - 4.1.1.6 All results and confirmation of agreement between donor's current and historical group/ type are documented.
- 4.1.2 All blood units are subjected to confirmation of the ABO/Rh-D grouping using segments from RBC components:
 - 4.1.2.1 Determination of the donor's forward ABO group (RBC grouping).
 - 4.1.2.2 Determination of the donor's Rh-D type.
 - 4.1.2.3 ABO/Rh-D confirmation is performed after initial labelling.
 - 4.1.2.4 All results and confirmation of agreement between donor's current and historical group/ type are documented.
- 4.1.3 Discrepancies are solved before releasing any blood/blood components. This includes:
 - 4.1.3.1 Discrepancies between donor's current and historical group.
 - 4.1.3.2 Discrepancies between donor's groups using blood tubes and bag segments

- 4.1.4 All blood units must be tested for the detection of Unexpected Antibodies to Red Cell Antigens (for Allogeneic Donors) using the withdrawn EDTA sample during donation.
 - 4.1.4.1 If antibody screen is positive, antibody identification should be done to detect the type of the antibody (as per availability).
 - 4.1.4.2 Quarantine all positive antibody screening test donor blood.
- 4.1.5 Detailed procedures for immunohematologic testing will be discussed later.

4.2 Transfusion Transmitted Diseases Testing:

- 4.2.1 There is a written agreement between the MCH blood bank and Hafar Al Batin Central Laboratory And Blood Bank for performing transfusion-transmitted diseases testing.
- 4.2.2 For testing, a sample of blood from each donor is sent to Central Laboratory And Blood Bank after checking.
 - 4.2.2.1 All screening tests are done in the Central Laboratory And Blood Bank (except for malaria as applicable).
- 4.2.3 All blood units must be screened for the transfusion transmitted diseases (TTD) by an MOH approved method like chemiluminescence (using samples of blood obtained from the donor during blood/ blood component collection).
- 4.2.4 All blood units must be screened for the following transfusion transmitted diseases (TTD) markers:
 - 4.2.4.1 HBs Ag
 - 4.2.4.2 Anti-HBc Ab
 - 4.2.4.3 Anti-HBs Ab. for all Anti-HBc Ab Positive samples
 - 4.2.4.4 Anti-HCV Ab
 - 4.2.4.5 Anti HIV I/II Ab
 - 4.2.4.6 Anti-HTLV Ab
 - 4.2.4.7 Nucleic acid Amplification Technology (NAT) for HBV- DNA, HCV- RNA, and HIV RNA
 - 4.2.4.8 Serological test for syphilis.
 - 4.2.4.9 Malaria by rapid immunochromatographic test for malaria Ag (e.g. OptiMal), thick film or any other MOH approved tests.
 - 4.2.4.10 Any other additional or supplemental tests as mandated by relevant health authorities.
- 4.2.5 All blood component units are stored in separate secured proper storage places and are not distributed or issued for transfusion unless all TTD test results are released.
- 4.2.6 Regarding sample repeats or test confirmation, the Central Laboratory And Blood Bank regulations are followed.
- 4.2.7 Specific requirements for HBV:
 - 4.2.7.1 The designated laboratory must, as a minimum, perform specific tests for HBs Ag and determine the anti-HBc status.
 - 4.2.7.2 Samples containing HBs Ag, with or without anti-HBc, indicate infection with HBV. Discard the blood units.
 - 4.2.7.3 Anti-HBs Ab test should be performed to all Anti-HBc Ab positive samples (which are not reactive for HBs Ag and their HBV-DNA NAT test is negative):
 - 4.2.7.3.1 If anti-HBs Ab result is negative or the titre is at a level less than or equal to 100 IU/L, discard blood.
 - 4.2.7.3.2 If anti-HBs Ab are present at a level greater than 100 IU/L (strongly reactive), use blood.
- 4.2.8 Blood unit or any prepared component is discarded in case of:
 - 4.2.8.1 Positive serological/ NAT test result for any of the transfusion transmitted diseases (TTD), on the first screening test, even;
 - 4.2.8.2 Positive antibody screening tests.
- 4.2.9 Blood donors are deferred in the following conditions,
 - 4.2.9.1 Defer permanently all blood donors with positive screening or confirmatory results for HIV I/II, HTLV I/II, HBV and HCV.
 - 4.2.9.2 Defer for three years all blood donors with positive Malaria test from the date of

- treatment and cessation of symptoms.
- 4.2.9.3 Defer for one year all blood donors with positive Syphilis test from the date of treatment and cessation of symptoms.
- 4.2.10 All blood component units' storage places should be labelled clearly according its status either Unscreened or Screened.
- 4.2.11 On release of any Non-Reactive blood component units, they should be checked again for TTD test results reports and found non-reactive before release.
- 4.3 Sending Samples And Receiving Results Of TTD:**
- 4.3.1 Policy and procedure of the Central Lab and Blood Bank regarding samples are followed.
- 4.3.2 Samples:
- 4.3.2.1 NAT samples: One EDTA tube sample (about 4 ml), from which plasma is separated and kept in refrigerator. Other specimens may be used according to the kit manufacturer.
- 4.3.2.2 Serology Samples: Plain tube 6 ml or plasma sample from the bag as required.
- 4.3.3 Procedure:
- 4.3.3.1 Sampling is done by phlebotomist, and technician/ specialist of the donor room.
- 4.3.3.2 Technician/ specialist of the component preparation room receives the samples from the donation area. He/ She separates the serum or plasma, keep them in samples' refrigerator (2-8 °C) until transportation to the Central Lab and Blood Bank (and other units as required).
- 4.3.3.3 Head of Lab and Blood Bank or his deputy is responsible for providing the facility for sending samples and forms to the Central Lab and Blood Bank. He has to follow the safety transportation directions.
- 4.3.3.4 Blood bank technician/specialist prepares the request the Central Lab and Blood Bank for TTD and checks the samples.
- 4.3.3.5 The hospital driver receives the samples for TTD testing which are kept in transport container and delivers them to the Central Lab and Blood Bank.
- 4.3.3.6 Staffs of the Central Lab and Blood Bank are responsible for testing all sent samples of blood donors and sending the results in written format by Fax or with the porter. Results also may be sent by E-mail. (They are also responsible for confirmation of positive samples results).
- 4.3.3.7 Supervisor of blood bank or his deputy receives the results from the Central Lab and Blood Bank (or other units as required), and record the results in the donor register. He/ She have to keep the result papers in the specified file.
- 4.3.3.8 Upon request, Supervisor of blood bank or his deputy sends other samples from plasma bags to be tested again to solve any problem about labelling. Melt FFP and get samples from ports or tubes.
- 4.3.3.9 Supervisor of blood bank technicians or his deputy must notify the Preventive medicine department/health authorities with all the confirmed TTD positive test results.
- 4.3.3.10 Malaria testing is done using rapid immune-chromatographic test which could be done in the lab serology unit or in blood bank as per availability. Thick film examination could be used and is done in hematology unit.
- 4.3.3.11 Supervisor of blood bank technicians or his deputy must notify the Preventive medicine department/health authorities with all the confirmed TTD positive test results.
- 4.4 Malaria parasite testing:**
- 4.4.1 It done by rapid immunochromatographic test for malaria Ag (e.g. OptiMal), thick film or any other MOH approved tests.
- 4.4.2 Whole blood and blood components will not be used for transfusion unless the result is negative.
- 4.4.3 Detection of malaria antigen using rapid immune-chromatographic test (e.g. Opti-Mal®):
- 4.4.3.1 Principle:
- 4.4.3.1.1 It is a rapid immune-chromatographic test which uses monoclonal

- antibodies against the metabolic enzymes parasite lactate dehydrogenase (pLDH) of *Plasmodium spp.*
- 4.4.3.1.2 These monoclonal antibodies are lined into two lines in the test, one specific for *Plasmodium falciparum* (Pf) and the other for pan-specific monoclonal antibodies which reacts with all 4 malaria species (P) which infect humans (*P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*).
 - 4.4.3.2 Sample: whole blood.
 - 4.4.3.3 Method:
 - 4.4.3.3.1 Unpack the contents.
 - 4.4.3.3.2 Label the cad with blood donor number.
 - 4.4.3.3.3 Put 1 drop and 4 drops of the buffer in the first (blood) and the second (buffer) wells respectively then wait for one minute.
 - 4.4.3.3.4 Put about 10 ul of the well-mixed whole blood of donor in the first (blood) well, mix, and wait for one minute.
 - 4.4.3.3.5 Put the strip in the first well, and wait for 10 minutes.
 - 4.4.3.3.6 Remove the strip from the first well, put it in the second (buffer) well, and wait for 10 minutes.
 - 4.4.3.3.7 Interpret the results.
 - 4.4.3.4 Result Interpretation:
 - 4.4.3.4.1 For the test to be valid: the control (C) line must be present.
 - 4.4.3.4.2 If no colored lines in the 2 test lines (Pf) and (P), the test is *negative*.
 - 4.4.3.4.3 If one colored line (P); the test is positive for *malaria spp.*
 - 4.4.3.4.4 If both test lines (Pf) and (P) are colored; the test is positive for *P. falciparum*.
 - 4.4.4 Slides staining and examination for malaria parasites:
 - 4.4.4.1 Sample: whole blood
 - 4.4.4.2 Stain preparation (in case of unavailability of ready-to-use stain):
 - 4.4.4.2.1 Add stain and glass beads to bottle.
 - 4.4.4.2.2 Add glycerol and alcohol.
 - 4.4.4.2.3 Shake vigorously and place at 37°C for 24 hours
 - 4.4.4.2.4 With further frequent shaking, remove from the incubator and shake again over 24 hours.
 - 4.4.4.2.5 The stain is then ready for use. Filter small amounts when required.
 - 4.4.4.3 Preparation of thick film:
 - 4.4.4.3.1 A drop of blood (3-5 mm in diameter) is put into the center of glass slide and spread with the corner of another slide or swab stick to cover an oval area of approximately 10-15 mm in diameter.
 - 4.4.4.3.2 Thoroughly dry the smear, in an incubator at 37 °C for one hour. Or leave at room temperature to the next morning.
 - 4.4.4.4 Staining of the slide:
 - 4.4.4.4.1 Cover the slide with diluted stain (1: 10 with distilled water) for 30 minutes.
 - 4.4.4.4.2 Wash in tap water.
 - 4.4.4.4.3 Wipe the back of the slides clean and set it up right to dry.
 - 4.4.4.5 Examination of the Film:
 - 4.4.4.5.1 Examine the film by microscope under high power lens (x100) for the presence of malaria parasites.
 - 4.4.4.6 Procedure Note:
 - 4.4.4.6.1 The staining time may need changing, especially when a new batch of stain is received or the stain has been stored for a long time.
 - 4.4.4.6.2 Films of all suspected or positive cases should be examined by two observers.

5. MATERIALS AND EQUIPMENT:

5.1 Forms and records:

- 5.1.1 Sent Samples Register.
- 5.1.2 NAT and Serology result Register.
- 5.1.3 Malaria results Register.
- 5.1.4 Disposal of blood and blood components Register.
- 5.1.5 Whole blood donation Record.
- 5.1.6 Deferred Donors Record.
- 5.1.7 Hematos system of blood bank

5.2 Equipment:

- 5.2.1 For malaria testing:
 - 5.2.1.1 Two glass rods either over a sink or over a staining rack.
 - 5.2.1.2 Giemsa stain (Ready for use).
 - 5.2.1.2.1 In case of unavailability of ready-to-use stain, Giemsa powder 3.8 gm, methyl alcohol 250 ml, and glycerol 250 ml.
 - 5.2.1.3 Glass slide for film preparation.
 - 5.2.1.4 Wash bottle containing buffered water.
 - 5.2.1.5 Rack for drying slides.
 - 5.2.1.6 Light microscope.

6. RESPONSIBILITIES:

- 6.1 Sampling is the responsibility of phlebotomist, and technician/ specialist of the donor room.
- 6.2 Reception, separation, and keeping of samples until transportation for testing are the responsibility of Technician/ specialist of the component preparation room.
- 6.3 Head of Lab and Blood Bank or his deputy is responsible for providing the facility for sending samples and forms to the Central Lab and Blood Bank. He has to follow the safety transportation directions.
- 6.4 It is the responsibility of blood bank technicians/specialists to:
 - 6.4.1 Sending samples for malaria screening to hematology unit (or performing the screening as per availability).
 - 6.4.2 Screening donor's blood groups.
 - 6.4.3 Screening of unexpected antibodies .
 - 6.4.4 Registering the previous results in the specific register.
- 6.5 It is the responsibility of blood bank technician/specialist or supervisor to cross-check the process of immunohematologic and transfusion transmitted diseases testing of donor samples.

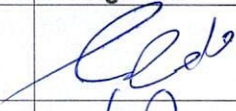
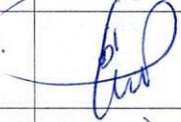
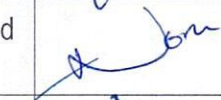



7. APPENDICES:

- 7.1 Agreement between the MCH blood bank and Hafr Al Batin Central Laboratory And Blood Bank

8. REFERENCES:

- 8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.
- 8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.
- 8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.
- 8.4 AABB Technical manual, 18th edition, 2014.
- 8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.

9. APPROVALS:

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