COLLECTION AND TESTING OF DONATED BLOOD

TITLE / DESCRIPTION
COLLECTION AND TESTING OF DONATED BLOOD

POLICY INDEX
LAB-BB-003

VERSION
001

SCOPE
Hospital Wide

ISSUE DATE
10-07-2019

RESPONSIBLE PARTY
Blood Bank

EFFECTIVE DATE
24-07-2019

REVISION DATE
10-07-2021

POLICY:
I. Blood is collected by trained blood bank staff under the supervision of the blood bank physician. Blood collection is done by aseptic methods using a sterile closed system. All donations should be tested before becoming available for transfusion.

PURPOSE:
I. Describe the whole process of collecting and testing blood from donors

COLLECTION PROCEDURES:
I. Blood Container
   A. Blood bags available at the blood bank of King Fahad Hospital are quadruple with 42 days storage time for PRBCs with integral leucocytes filters to remove WBCs from PRBCs units.
   B. All blood collection bags and apheresis collection sets are pyrogen-free and provided with sample pouch. Before donation, bags should be checked for puncture, discoloration and expiry date.

II. Identification:
   A. A numeric system is used that identify the donor, donor record, collection bag, specimens used for testing and all components prepared from that unit. The number used is started with last two digits of the Gregorian calendar followed by dash and serial number.
   B. Before the number the 3 letters (OGH) are indicating internal donation and a letter.
   C. Upon entering the donation area, every donor will get a unique donor number. The donor record, whole blood collection container, attached satellite bags and tubes for donor samples will be labeled with this unique number.
   D. The name of the donor will be written on the primary whole blood collection bag with the initial blood group of the donor.
   E. Before beginning the collection, the phlebotomist must identify the donor, by full name and ID number, with the donor.

III. Preparing Venipuncture Site
   A. Inspect both arms of the donor for a suitable vein; blood is drawn from a large firm vein in an area (usually the ante cubital space) that is free of skin lesions. Put a tourniquet or
blood pressure cuff above the intended venipuncture site approximately 2 inches above to make the vein more prominent. Having the donor open and close the hand a few minutes is also helpful.

B. Prepare donor arm (sterilize the venipuncture site):
   1. Scrub area at least 4 cm (1.5 inches) in all directions from the intended site of venipuncture (ie, 8 cm or 3 inches in diameter) for a minimum of 30 seconds with 0.7% aqueous solution of iodophor compound, using a disposable 7% povidone-iodine sterile swab or sterile swab stick. Excess foam may be removed, but the arm need not be dry before the next step.
   2. Apply 10% povidone-iodine swab stick, starting at the intended site of venipuncture and moving outward in a concentric spiral let stand for 30 sec.
   3. For donors sensitive to iodine (tincture or povidone preparations), another method (eg. ChloraPrep 2% chlorhexidine) should be used. For donors sensitive to both iodine and chlorhexidine, a method using only 70% isopropyl alcohol could be considered. The preferred procedure is the use of a 30-second up-and-down scrub, followed by enough time for the skin to dry. A second scrub is then applied.
   4. If not ready to do venipuncture immediately, cover the area with dry sterile gauze.
   5. If the donor bends the arm, or the prepared site is touched with the fingers or with any other non-sterile object, the complete arm preparation must be repeated.

IV. Phlebotomy and Collection of Samples:
   A. Ask donor to confirm his or her identification.
   B. Ensure that all labels on blood container, testing tubes and donor record is correct and identical.
   C. Prepare donor arm as described above.
   D. Inspect bag for any defects, leakage, particles contamination and discoloration
   E. Position the bag below the level of the donor arm.
   F. The phlebotomist will clamp the tubing near the needle before the needle is removed in order to prevent air from entering.
   G. Remove the needle cover and perform phlebotomy, by inserting the needle with its bevel upward in straight steady motion in the vein and slight stretch of the skin.
   H. Remove the clamp from the tubing and observe the blood flow (fairly rapid and steady). Collect first 10-40 ml of blood in the diversion pouch.
   I. If more than one puncture is needed, another bag must be used.
   J. Tap needle in place with adhesive strips and cover with gauze
   K. Switch on blood mixer, mixing blood with the anticoagulant may be done manually by gentle lift and tilt the bag every 100 ml.
   L. Have donor open and close fist (squeezing foam ball, if available, every 10-12 sec.)
   M. Keep the donor under observation throughout the donation process.
   N. Be sure blood flow remains fairly brisk, so that coagulation activity is not triggered.
      When 450 ± 10% (405-495) ml 430 – 525 g of blood has been collected, stop the collection. Donation Completed within 10 min can be separated to all blood components, units take between 10 -15 minutes only PRBC could be prepared. Donations require more than 15 minutes to be completed should be terminated and blood discarded.
   O. Donor blood specimens must be properly labeled with the unique donor identification number. Donor specimens must be collected during donation and crosschecked.
immediately with the collected bag label and donor label. Specimens are stored under appropriate conditions.

P. When collection is completed, release tourniquet and tell donor you are going to remove needle.
Q. Clamp tubing to stop flow.
R. Pull skin taut and remove needle quickly.
S. Apply pressure to gauze once needle is removed.
T. Have donor press firmly on gauze and elevate arm for about 1 minute.
U. Inspect arm for evidence of bleeding.
V. Apply pressure dressing.
W. Provide donor with juice and observe him, allow donor to leave after 10 min, rest in the absence of any adverse reaction.
X. Give the post donation instructions to the donators; as increase fluid intake, don't smoke for the next hour or 30 min, don't remove the bandage for few hours and if you feel dizzy, sit down with your head lowered than your knees or lie down with your feet elevated.
Y. Thank the donor and encourage him to donate again.

TESTING DONATED BLOOD:

I. Sent all testing for donated blood to King Fahad Hospital – Hfof
II. Every donated unit is tested for the following in compliance with the MOH instructions:
   A. ABO determination by forward and reverse grouping
   B. Rh D phynotyping and every Rh D negative is confirmed by Dweak test.
      1. When either test is positive, the collected unit must be considered "Rh POSITIVE".
      2. When the tests for both D and weak D are negative, the collected unit must be considered "Rh NEGATIVE".
   C. Antibody screening for detection of unexpected antibodies to RBCs antigens.
   D. If there is a history of previous donation, the donor current grouping and typing must be identical to the previous blood grouping and typing. Any discrepancies in ABO/Rh grouping and donor’s history must be resolved before approving the blood group and releasing the bag.
   E. Transfusion transmitted diseases testing:
      1. HBs Ag (ELISA/CIA)
      2. Anti-HBc antibodies (ELISA/CIA)
      3. HBs antibodies for all anti HBc positive samples (ELISA/CIA)
      4. Anti HCV by (ELISA/CIA)
      5. HIV I/II antibodies and P24 antigen by (ELISA/CIA)
      6. Syphilis by (RPR/CIA)
      7. HTLV I/II antibodies by (ELISA/CIA)
      8. Malaria testing by (THICK SMEAR or ELISA).
      9. Testing for HIV, HCV, HBV genome by Nucleic Acid Technology (NAT unit)
III. For Bacterial contamination detection of platelet components; eBDS (Enhanced Bacterial Detection System) Device is used. The eBDS system uses oxygen concentration as a surrogate marker of bacterial growth. If this device is not working or its accessories are not available, this test will be done in microbiology unit.
IV. All untested blood and blood components are stored in separate storage places labeled in red print as "unscreened blood components please don't use"
V. All units with positive screen are repeated in duplicate one sample from blood unit and another sample from the test tube before release the whole batch of donation, to solve any problems about labeling.

VI. All repeat TTD positive screen test results must be confirmed by neutralization or western blot tests (or LIA) approved from FDA or CE. Positive HBs Ag confirmatory assay is by neutralization. Positive HCV antibody is confirmed by LIA (or RIBA), positive HIV has to be confirmed by LIA and neutralization, positive syphilis result has to be confirmed by TPHA test and positive malaria Abs confirmed by thick film slide examination.

VII. Solely anti HBc positive will be followed by anti HBs titration. Unit can be used only if Anti HBs titer is more than 100 IU.

VIII. Donation samples reactive in NAT testing will be subjected to further identification by quantitative PCR.

IX. Defer permanently all donors with positive confirmatory results of HIV, HCV, HTLV and HBV.

X. Defer for three years all donors with positive malaria test from the date of treatment.

XI. Defer for one year all donors with positive syphilis test from the date of treatment and donors with positive screening tests results and negative confirmatory results for HIV, HCV, HTLV and HBV.

XII. Preventive medicine department will be notified about any donor with confirmed positive infectious disease. Notification will minimally include donor's name, sex, age, nationality, contact address and serology results.

XIII. Units with positive ICT should be discarded.

XIV. Serology and NAT tests Results of all donors will be submitted from the responsible departments on the hospital information system (OASIS). These results will be documented in the serology register and checked again by another staff (blood bank physician, supervisor or his deputy). The number of the units with positive serology result (s) will be marked by red pen and the numbers of the units with the accepted results are left without highlighting.

XV. All blood components with any positive infectious marker will be discarded from the first screen test results after been written in the discarded blood register and before initial labeling of the blood bags.

XVI. All blood components must be inspected visually for presence of discoloration, clots, fibrin or hemolysis and adequacy of sealing before labeling.

XVII. The process of identification and discarding of unacceptable blood/blood products must be done by two qualified staff members.

XVIII. Donors with positive screening TTDs results and negative confirmed results will be deferred temporary by blood bank pathologist or his deputy on the blood bank information system (BBIS), donors with positive screening and positive confirmed TTDs results will be permanently deferred by blood bank pathologist or his deputy on the blood bank information system (BBIS). So, these donors will be deferred from further donation.

XIX. Blood components negative for all infectious markers will be labeled as serology negative and by ABO/Rh. These bags will be segregated in properly labeled corresponding storage places and added to blood bank inventory ready to be issued. It is the responsibility of blood bank physician to review the serology results and donor blood grouping and dispatching the blood components according to these results.

XX. If positive cases of bacterial contamination of blood components are identified after the unit has been released and transfused; the treating physician must be informed and culture of any residual component, if available, to confirm the initial result, and blood cultures of the patient,
even in the absence of apparent sepsis, to be certain that clinically silent infections are not missed. A Gram’s stain should be performed immediately on any retained portion of the unit. The microorganism should be identified and susceptibility testing performed promptly. Post transfusion patient follow-up care will depend on the clinical status of the patient and the judgment of the treating physician.

XXI. Identification of a culture indicating endogenous bacteremia (e.g., gram-negative organisms) will likely result in deferral of the donor from future blood donation until the donor successfully completing his treatment.

XXII. Confirmatory testing for ABO and Rh must be done before releasing the PRBCs from a segment of RBCs component after the original ABO and Rh label has been affixed to the unit, to permit detection of labeling errors. Any discrepancies must be resolved before releasing the PRBCs and the other components prepared having the same label number.

XXIII. In an emergency situation, blood/blood components may be transfused before completion of NAT or serology testing. Treating physician should send a written request to indicate the approval to release the blood/blood components before completion of tests after the consent of the patient or next of kin, when applicable and after contacting blood bank physician. Once permission has been obtained, a label will be attached to the released unit indicating the marker that the unit is not tested for. Testing of the blood/blood components must be completed and reported promptly to the treating physician. This procedure is only approved for a particular patient and only for one transfusion event.

**LABELING OF BLOOD AND BLOOD COMPONENTS:**

I. Blood/Blood components which are negative for all infectious markers will be labeled by specific labels for each blood components.

II. BBIS will not allow printing any labels for any blood components prepared from the donor without entering the serology and NAT test results of this donor. BBIS will allow printing labels for components with only negative serology and NAT test.

III. Before printing blood/blood components label from BBIS all the results of serology and NAT tests of the donors must be entered on BBIS to allow label printing.

IV. Each label will include the following items:
   A. Name of blood component
   B. Donation identification number followed by a letter 'R' for RCC, 'F' for frozen plasma, 'C' for cryoprecipitate and 'P' for platelets concentrate.
   C. Identity of anticoagulant or other preservative solution
   D. Approximate volume
   E. Facility collecting component
   F. Storage temperature
   G. Expiration date and time
   H. ABO group and Rh type
   I. Recording transfusion transmitted disease (TTD) results and for pathologist’s signature for TTD revision.
   J. Instructions to the transfusionist
   K. Phrase "Volunteer Donor"
   L. For autologous donation, phrase "For Autologous use only", recipient name and ID number.
V. Handwritten additions or changes must be legible and applied with permanent, moisture proof ink.
VI. Two qualified staff members must ensure the accuracy of identification information on donor records and units labeled and agreement of theses information.

REFERENCE(S):

Approval:

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