LB.40 The blood bank develops a system for managing adverse donation events.

LB.40.1 The laboratory has a system for managing adverse donation events that covers:

LB.40.1.1 Recognition and handling of adverse donation events.

LB.40.1.2 Reporting and monitoring of adverse donation events.

Standard Intent:

Adverse reactions are seen at the time of donation or reported later in about 3.5% of donations, on average. The adverse events reporting system of the blood bank should cover detecting, and responding to adverse reactions to donation. Personnel performing whole blood or blood components collection should be trained in recognizing and handling adverse reactions. Also, the blood bank has the provisions to obtain emergency services for treatment of severe adverse donor reactions.

LB.41 The blood bank develops a process for the collection of donor blood specimen.

LB.41.1 The Laboratory implements a process to ensure that donor blood specimens are:

LB.41.1.1 Collected during the donation.

LB.41.1.2 Properly labeled and crosschecked with the collected product label.

LB.41.1.3 Stored under appropriate and controlled conditions.

Standard Intent:

Assignment of blood components and test results to the properly identified donor is critical to ensuring the transfusion recipient's safety. Those elements should match before blood collection can proceed, as well as during and after the collection. Before phlebotomy, the donor is asked to present appropriate identification. Donor identifying information commonly includes the donor's full name and ID number. The donor records and blood sample tubes are similarly labeled. Electronic records of the donation are also assigned the same number.

LB.42 The blood bank develops a system for the preparation, storage, transportation, and quality control of Red Blood Cells (RBC) components.

LB.42.1 RBC components are prepared by separating the RBC from the plasma proteins.

LB.42.2 RBC components are stored under properly controlled conditions between 1 and 6°C.

LB.42.3 RBC components are transported in properly insulated container between 1 and 10°C.

LB.42.4 RBC components are assigned an expiration date according to the manufacturer's recommendations or:

LB.42.4.1 21 Days for RBC in CPD.

LB.42.4.2 35 Days for RBC in CPDA-1.

LB.42.4.3 42 Days for RBC in additive solution.

LB.42.4.4 24 hours' post opening the RBC unit.

LB.42.5 Policies and procedures ensure that 1% of the monthly production- but not less than 4 units every month- are subjected to quality control testing. All tested RBC units have a hematocrit of less than 80% (RBC in additive solution are exempted from quality control requirement).

Standard Intent:

There are two commonly used whole blood collection systems from which two RBC components are derived; RBC preserved in CPDA-1 with a 35 days' shelf life and RBC preserved in CPD- or CP2D and Additive Solutions (AS) with a shelf life of 42 days.

The blood bank must employ a validated technique to ensure that RBC preserved in CPDA-1 have adequate residual plasma to maintain the hematocrit at <80%. As for RBC preserved in CPD- or CP2D and AS, the residual plasma need to be reduced to <50 mL, to which 100 to 110 mL of AS is added within 72 hours of the blood collection. If the AS solution is not added, the RBC have a shelf life of 21 days and should have adequate residual plasma to maintain the hematocrit at <80%.

LB.43 The blood bank develops a system for the preparation, storage, transportation, and quality control of Platelet Concentrates (PC) components.

LB.43.1 PC components are prepared by separating the platelets from whole blood within eight hours of collection.

LB.43.2 PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.

LB.43.3 PC components are transported in properly insulated container as close as possible to 20 and 24°C.

LB.43.4 PC components are assigned an expiration date of twenty-four hours to five days from the day of whole blood collection according to the manufacturer's recommendations or four hours of opening PC unit.

LB.43.5 Policies and procedures ensure that 1% of the monthly production but not less than four units every month are subjected to quality control testing. On the expiration date or at issue, 90% of the subjected units have a platelet count of 5.5X1010 platelets/unit or more and a minimum pH of 6.2.

Standard Intent:

Two major methods are used in preparing Platelets from WB. The first is the Platelet Rich Plasma (PRP) method, consisting of a soft spin followed by a hard spin. The second is the Buffy-Coat (BC) method, consists of a hard spin of WB that enables removal of the supernatant Platelet Poor Plasma (PPP) from the top of the container and the RBCs from the bottom into transfer packs. The buffy coat that remains in the primary container is used to harvest platelets.

Platelets must be continuously agitated during storage at a temperature between 20 and 24 C. However, platelets are not necessarily agitated during transport.