Rock River Valley
BLOOD CENTER

VENDOR SUPPLY STATEMENT

Northern Illinois Blood Bank dba Rock River Valley Blood Center (RRVBC) holds FDA license number 249. RRVBC maintains three FDA registered collection-only sites in addition to the main collection, manufacturing, storage, and distribution center located at 419 N. 6th St, Rockford, IL 61107. All donation, testing, and production records are maintained at the main collection facility. In keeping with FDA requirements, all blood components shipped in interstate commerce are licensed and labeled in accordance with FDA regulations.

RRVBC outsources donor viral marker screening, ABO/Rh type, and antibody screens to LifeSouth Donor Testing Laboratory located in Stone Mountain, GA which holds FDA Registration number 3015738441, CLIA registration 11D2166017, and AABB ID 1794504. RRVBC assures all required FDA testing is performed using FDA licensed/cleared methods. All confirmatory testing, not performed by LifeSouth Donor Testing Laboratory, is referred to FDA registered and CLIA approved laboratories. Babesia testing is performed on blood donations collected in the state of Wisconsin.

RRVBC laboratory holds current certification for the Clinical Laboratory Improvement Act (CLIA) for "high complexity" laboratory testing and meets personnel and external proficiency requirements for Immunohematology, CMV, Sickle Cell, and Quality Control testing. RRVBC laboratory CLIA registration number is 14D0646750. RRVBC also maintains AABB accreditation, member ID number 006825. CLIA compliance is accessed through AABB accreditation assessments as part of AABB/CLIA deemed status. All collection-only sites are registered as "waived testing" under CLIA.

RRVBC is licensed by the FDA to manufacture Red Blood Cells, Leukoreduced (including irradiated) CPD, AS-3, AS-5, and AS-1 using both whole blood and automated collection methods; Platelets Pheresis, Leukoreduced (including irradiated); Fresh Frozen Plasma; Plasma Frozen within 24 hours after Phlebotomy; Cryoprecipitate Reduced Plasma; Cryoprecipitated AHF; Pooled Cryoprecipitated AHF; and Liquid Plasma. All donor eligibility, product manufacturing, and component distribution records are maintained at the main collection facility.

RRVBC maintains a Transfusion-Associated Acute Lung Injury (TRALI) mitigation policy. All transfusable plasma and platelets are manufactured from male donors and female donors with no history of pregnancy or HLA antibody negative. Donors implicated in a TRALI reaction are deferred from donating. An implicated donor is defined as a donor associated with a definite TRALI reaction and that tests positive for HLA or neutrophil antibodies. Any donor implicated in two or more probable or definite TRALI reactions are deferred regardless of test results.

Blood components are manufactured in conformance with current good manufacturing practices (cGMP) as outlined in the FDA guidance document (1995) *Guideline for Quality Assurance in*

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Blood Establishments. RRVBC uses and maintains 510(k) cleared blood establishment computer system, testing equipment, and collection devices.

Labeling of all blood and blood components at RRVBC is performed in accordance with United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128. ISBT Facility Identification Number (FIN) for RRVBC is W0444.

Except for apheresis platelets treated with an FDA approved pathogen reduction process, RRVBC performs bacterial detection of apheresis platelets using BioMerieux BacT-ALERT system. Product sampling occurs no sooner than 48 hours after collection. 16 mLs are removed and split between an aerobic and anaerobic culture bottle. Platelet products are released following a 12-hour incubation period after inoculation. Inoculated bottles are incubated for 5 days post sampling. Products for external (non-system) customers, with prior mutual agreement, may be tagged with “Bac-T results pending" and released prior to completion of the 12-hour incubation test result; results are faxed to the customer. Consignees of units identified as positive for bacterial contamination will be notified via telephone and fax. Gram stain and subsequent culture results will be phoned and faxed as available.

RRVBC maintains a Quality Plan that is defined, documented, implemented, and maintained as required per FDA regulations and AABB standards. RRVBC has processes in place for the following:

- Performance of regular internal quality audits
- Quality Monitoring, Corrective Action, and Customer Feedback
- Lot Release Process
- Shipment of products via validated shipping methods
- Consignee notification for blood product recall or withdrawal
- Reporting of adverse events associated with transfusion of products provided by RRVBC

Copies of current registrations and accreditations are available on our website at https://www.rrvbc.org/hospitals/

For questions or additional information, please contact our Quality department at QA@rrvbc.org.