



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 and ABO/Antibody testing to Versiti Indiana testing laboratory, located in Indianapolis, IN which holds FDA license number 2132, FDA Registration number 1873403, and CLIA number 15D0664398. RRVBC assures all required FDA testing is performed using FDA licensed/cleared methods. All confirmatory testing, not performed by IBC testing lab, is referred to FDA registered and CLIA approved laboratories.

Babesia testing is performed on blood from each donation collected in the state of Wisconsin. The testing is performed by Versiti Indiana testing laboratory.

The 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 audits 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 and red blood cells leukoreduced (including irradiated) CPD, AS-3, AS-5, and AS-1 using both whole blood and automated collection methods; platelets apheresis and platelets apheresis leukoreduced (including irradiated); fresh frozen plasma; plasma frozen within 24 hours of phlebotomy; cryo-reduced plasma; cryoprecipitate AHF; and pooled cryoprecipitate. 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 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.

RRVBC performs bacterial detection of apheresis platelets using BioMerieux BacT-Alert system. Parent product sampling occurs 24 hours after collection. RRVBC uses an eight mL inoculation volume in an aerobic culture bottle. Products are released following a 12-hour incubation period. 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. All consignees of units identified as positive for bacterial contamination will be notified via phone 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 and AABB regulations and standards. RRVBC has processes in place for the following:

- Performance of regular internal quality audits
- Validation of processes and equipment
- Shipment of products via validated shipping methods
- Management review and analysis of quality metrics with a defined process for improvement
- Formal Change Control Process
- Consignee notification for blood product recall or withdrawal
- Customer complaint reporting and feedback process

RRVBC does not routinely provide copies of registration or audit reports to customers since it maintains multiple registrations and accreditations for FDA, CLIA, and AABB. Copies of these registrations and accreditations are available on our website at www.rrvbc.org

VENDOR/SUPPLY QUALIFICATION STATEMENT

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Please retain this statement for your files.

Cathy Midtsem, MT (ASCP), CQA (ASQ)

Quality Systems Director

Rock River Valley Blood Center

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