VENDOR/SUPPLY QUALIFICATION STATEMENT

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

RRVBC outsources donor viral marker screening and ABO/ANTIBODY testing to INDIANA BLOOD CENTER (IBC) testing laboratory, FDA license # 1759, FDA Registration number 1873403 and CLIA number 15D0664398, located in Indianapolis, IN. RRVBC assures all required FDA testing is performed using FDA licensed/cleared methods. All confirmatory testing not done by IBC testing lab is referred to FDA registered and CLIA approved laboratories.

RRVBC laboratory is registered with **CLIA, number 14D0646750**, as a "high complexity" laboratory and meets personnel and external proficiency requirements for Immunohematology, CMV, Sickle Cells and Quality Control testing. RRVBC also maintains **AABB accreditation, member ID number 006825**. CLIA compliance is accessed through AABB accreditation audits as part of AABB/CLIA deemed status. In addition 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 with 24 hours of phlebotomy; plasma, cryo-reduced; cryoprecipitated AHF; and pooled cryo. All donor eligibility, product manufacturing, and component distribution records are maintained at the main collection facility.

Blood components are manufactured in conformance with current good manufacturing practices (cGMP) as stated in the Code of Federal Regulations and outlined in the 1995 Guidelines for Quality Assurance in Blood Establishment and delineated in the AABB Standards for Blood Banks and Transfusion Services. 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 according to United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components using ISBT 128, issued by ICCBBA. ISBT Facility Identification Number (FIN) for RRVBC is **W0444**. For more information please visit www.iccbba.org

Donors with no historical Chagas' test results are tested prior to labeling. All products have at least one negative Chagas' test result prior to product release.

RRVBC performs bacterial detection of apheresis platelets using BioMerieux BacT-Alert system. Parent product sampling occurs no less than 24 hours post collection. RRVBC uses an 8mL/aerobic bottle testing protocol, with an incubation of at least 12 hours prior to product labeling and distribution. **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 will be faxed to customer.** All bottles are monitored for a full 5 days with notification of a consignee of positive bacterial detection during that time.

All consignees of platelet apheresis, including concurrently collected products, will be notified via phone and fax. Gram stain and subsequent culture results will be phoned and faxed as available.

In compliance with AABB Standards RRVBC has implemented a TRALI Mitigation Strategy. All transfusable plasma and platelets are manufactured from male donors or female donors with no history of term pregnancy. Effective October 1st, 2016, RRVBC has implemented HLA testing for all Platelets females donors with history of pregnancy. Only platelets from HLA negative donors are distributed. Any donors with positive HLA antibodies are routed to donation of products other than transfusible plasma or platelets.

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 tests positive for HLA or neutrophil antibodies. Donors implicated in two or more probable or definite TRALI reactions are deferred regardless of test results.

In addition to the above, RRVBC maintains a Quality Plan and has processes and procedures in place, not limited to, but including the following:

- Performance of regular internal quality assessments
- Change Control
- Product review prior to labeling and release of product for distribution
- Product/Donor Deviation reporting and trending, including corrective action analysis
- Customer complaint reporting and analysis with feedback to customer
- Consignee Notification for: Test results, product recall and Post Donation Information

- Reporting of adverse events associated with transfusion

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.www.rrvbc.org/hospitals/

Please retain this statement for your files.

Safet Ibisevic,
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Effective October 1, 2016

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Rock River Valley
BLOOD CENTER
Straight From the Heart