R-133: VENDOR SUPPLY STATEMENT

Mississippi Valley Regional Blood Center (MVRBC) holds the license number 366 from the FDA and maintains its headquarters in Davenport, Iowa. MVRBC has several blood collection facilities in Iowa, Illinois, and Missouri. In keeping with the FDA requirements, all blood components are labeled in accordance with the Code of Federal Regulations and FDA Guidance documents. In addition to routine FDA and CLIA inspections, the organization also maintains accreditation by the AABB (member ID 6059).

MVRBC is licensed to manufacture Whole Blood; Whole Blood, Leukocytes Reduced; Red Blood Cells, Leukocytes Reduced (including irradiated); Whole Blood Derived Platelets (including irradiated and pooled); Platelet Pheresis, Leukocytes Reduced (including irradiated); Platelets Pheresis Leukocytes Reduced Psoralen-Treated; Plasma Frozen Within 24 Hours After Phlebotomy; Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy; Plasma, Cryoprecipitate Reduced; Cryoprecipitated AHF; Pooled Cryoprecipitated AHF; and Liquid Plasma.

MVRBC ensures testing required by the FDA is performed using FDA cleared methods. All confirmatory testing is performed by FDA/CLIA approved laboratories. 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 Establishments.

Except for apheresis platelets treated using an FDA-approved pathogen reduction process, MVRBC performs bacterial detection on apheresis platelets using the BacT/ALERT system. Products are held for 24 hours after collection and prior to sampling. Eight mLs are inoculated into an aerobic culture bottle. Products are released for shipment immediately following inoculation. Inoculated BacT/ALERT bottles are incubated for the full 5 days of the apheresis platelets' shelf life. Consignees of units identified as positive for bacterial detection will be notified immediately via telephone and fax. Gram stain results will be communicated as soon as the test is complete. Subsequent complete culture results will be phoned and mailed to hospital when available from our reference microbiology laboratory.

MVRBC maintains a Transfusion-Associated Acute Lung Injury (TRALI) Mitigation policy. According to this policy, MVRBC ships male and never pregnant or HLA antibody negative female plasma and apheresis platelets for transfusion. Donors implicated in a TRALI reaction by HLA or neutrophil antibody testing are deferred in the blood establishment computer system, and any donor implicated in a single definite or two or more probable TRALI reactions is deferred regardless of any test results.

The following table indicates the MVRBC facilities performing testing and/or product distribution.

Facility Name	Address	FDA Reg. #	CLIA ID	Immunohematology Reference Testing	Product Distribution
Mississippi Valley Regional Blood Center	5500 Lakeview Pkwy Davenport, IA 52807	1970356	16D0387896	X	X
Mississippi Valley Regional Blood Center	1007 E Pennsylvania Ave Ottumwa, IA 52501	1970361			X
Mississippi Valley Regional Blood Center	6330 Copps Ave Unit A Monona, WI 53716	3015522161	52D2181077	X	X
Mississippi Valley Regional Blood Center	3420 Rider Trail South Earth City, MO 63045	3004157291	26D1063322	X	X
Mississippi Valley Regional Blood Center	2404 W Nebraska Ave Peoria, IL 61604	3015248225			X
Mississippi Valley Regional Blood Center	2801 South 10th Street Springfield, IL 62703	3011078001	10D0665212	X	X
Mississippi Valley Regional Blood Center	1408 W. University Ave Urbana, IL 61801	1470270	14D0432615	X (limited)	X

The MVRBC Quality Program has processes in place for the following:

- Performance of regular internal quality assessments.
- Corrective action program.
- Defined batch release process.
- Shipment of products via a temperature validated shipping method and credit for damaged shipments on a case-by-case basis.
- Blood product recall or withdrawal. (Consignees are notified immediately, but no later than 72 hours, via telephone and fax or email for in-date products. Consignees are notified via fax or email for expired products, when required.)
- Reporting of adverse events associated with transfusion of products provided by MVRBC.

Copies of current certificates and this document can be found at www.bloodcenter.org/hospitals/licensing.aspx.

For additional information please contact the Quality department at 1-800-747-5401 or 2-Quality@mvrbc.org.