ImpactLife holds the license number 2276 from the FDA and maintains its headquarters in Davenport, Iowa. ImpactLife has several blood collection facilities throughout Iowa, Illinois, Missouri, and Wisconsin. In keeping with the FDA requirements, all blood components are manufactured and 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).

ImpactLife 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.

ImpactLife ensures testing required by the FDA is performed using FDA cleared methods. All confirmatory testing is performed by FDA/CLIA approved laboratories. Blood collections in Wisconsin are tested for Babesia according to the FDA Babesia Guidance requirements. 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, ImpactLife performs bacterial detection on apheresis and pooled platelets using the BacT/ALERT system. Products are held for up to 48 hours after collection and prior to sampling sixteen mLs are removed and split between an aerobic and anaerobic culture bottle. Products are held for a 12-hour incubation period after inoculation before released for shipment. Inoculated BacT/ALERT bottles are incubated for 7 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 communicated to hospital when available.

ImpactLife maintains a Transfusion-Associated Acute Lung Injury (TRALI) Mitigation policy. According to this policy, ImpactLife manufactures transfusable plasma and apheresis platelets from never pregnant or previously pregnant HLA antibody negative donors. 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 ImpactLife facilities performing testing and/or product distribution.

Facility Name	Address	FDA Reg #	CLIA ID	Immunohematology Reference Testing	Product Distribution
ImpactLife	5500 Lakeview Pkwy Davenport, IA 52807	1970356	16D0387896	X	X
ImpactLife	1007 E Pennsylvania Ave Ottumwa, IA 52501	1970361			X
ImpactLife	5001 World Dairy Dr Madison, WI 53718	3020605119	52D2181077	X	X
ImpactLife	3420 Rider Trail South Earth City, MO 63045	3004157291	26D1063322	X	X
ImpactLife	2404 W Nebraska Ave Peoria, IL 61604	3015248225			X
ImpactLife	2801 South 10th Street Springfield, IL 62703	3011078001	10D0665212	X	X
ImpactLife	1408 W. University Ave Urbana, IL 61801	1470270			X

The ImpactLife 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 ImpactLife.

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@impactlife.org.