Letter of Accreditation

Date: July 1, 2013

From: Juan Merayo-Rodriguez, Medical Director and
Jill Evans, Vice President of Quality

Subject: Information needed for an AABB Assessment or Self Audit

To: Hospital Blood Banks and Other Customers

All units of blood components are collected from volunteer blood donors, in accordance with Food and Drug Administration (FDA) requirements and the most recent edition of the AABB Standards. LifeSouth is licensed by the FDA (U.S. license # 1647).

LifeSouth's contract laboratory practices and procedures conform to the requirements of the FDA, the AABB, the Clinical Laboratory Improvement Act of 1988 (CLIA'88), and current Good Manufacturing Practices (cGMPs) (as per Title 21 of the Code of Federal Regulations).

The laboratory uses FDA-approved in vitro diagnostic products or products under an FDA-approved IND to test the presence of the reactive serologic markers. All reagents are properly maintained and used in conformity with manufacturer's directions. Laboratory procedures prohibit interchanging reagents from different lots except as manufacturer's direction allow. The following assays are presently in use:

Test	Test Kit Name	Manufacturer
HBsAg	ABBOTT PRISM HBsAg	Abbott Laboratories
anti-HBc	ABBOTT PRISM HBcore	Abbott Laboratories
anti-HCV	ABBOTT PRISM HCV	Abbott Laboratories
anti-HIV-1/2	ABBOTT PRISM HIV O Plus	Abbott Laboratories
anti-HTLV-I/II	ABBOTT PRISM HTLV I/HTLV II	Abbott Laboratories
anti-*T.cruzi*	ABBOTT PRISM Chagas	Abbott Laboratories
anti-CMV	Beckman Coulter PK CMV-PA System	Fujirebio Diagnostics, Inc.
Syphilis	Beckman Coulter PK TP System	Fujirebio Diagnostics, Inc.
HIV RNA / HCV RNA / HBV DNA	Procleix Ultrio Plus Assay	Gen-Probe, Inc.
	cobas TaqScreen MPX Test	Roche Molecular Systems, Inc.
WNV RNA	Procleix WNV Assay	Gen-Probe, Inc.
	Cobas TaqScreen West Nile Virus Test	Roche Molecular Systems, Inc.

In addition to the above tests:

- Donor blood is routinely tested for ABO Group and RH type, antibody screening, total cholesterol, and red cell antigen screening (as needed).
- Apheresis platelets and pooled whole-blood-derived platelets are tested for bacterial contamination in accordance with manufacturer's instructions using the FDA-cleared Pall eBDS Oxygen Analyzer.

LifeSouth and CTS are members of the AABB. LifeSouth is also enrolled in the College of American Pathologist (CAP) proficiency surveys. LifeSouth laboratories and CTS operate under the following licenses:

Laboratory Name	FDA Registration #	CLIA License #	State License #
Creative Testing Solutions, Inc. (CTS)	3008082972	10D2002322	800025687
Immunohematology Reference Laboratory	3003707120	10D0271833	800000840

Refer to www.lifesouth.org for copies of our laboratory certifications.

If you have questions regarding this information, or if we can be of service, please contact call (352) 224-1600 or e-mail jaevans@lifesouth.org or jamerayo-rodriguez@lifesouth.org.