

Blood Donor Screening Tests Reference Document

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	US License #	Manufacturer
HBsAg/CTS: HBSA	ABBOTT PRISM HBsAg	43	Abbott Laboratories
anti-HBc/CTS: HBC	ABBOTT PRISM HBcore	43	Abbott Laboratories
anti-HCV/CTS: HCV	ABBOTT PRISM HCV	43	Abbott Laboratories
anti-HIV-1/2/CTS: HIV	ABBOTT PRISM HIV O Plus	43	Abbott Laboratories
anti-HTLV-I/II/CTS: HTLV	ABBOTT PRISM HTLV I/HTLV II	43	Abbott Laboratories
anti-T.cruzi	ABBOTT PRISM Chagas	43	Abbott Laboratories
anti-CMV	Beckman Coulter PK CMV-PA System	BK070030	Fujirebio Diagnostics, Inc.
Syphilis/CTS: SYP	Beckman Coulter PK TP System	BK060062	Fujirebio Diagnostics, Inc.
HIV RNA/CTS: HIV-NAT HCV RNA/CTS: HCV-NAT HBV DNA/CTS: HBV-NAT	Procleix Ultrio Plus Assay	2032	Grifols Diagnostic Solutions, Inc.
WNV RNA/CTS: WNV	Procleix WNV Assay	2032	Grifols Diagnostic Solutions, Inc.
ZIKA	Procleix Zika Virus Assay	IND B10383-ZIKVPS-CSP-01	Hologic, 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 or BacT/ALERT 3D Microbial Detection System.

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 call (352) 224-1600 or e-mail lhm@lifesouth.org.