

TEST METHODS

SCREENING TESTS performed using the following assays:

Test	Assay Methodology
ABO/Rh Blood Group	Beckman Coulter PK7400 Blood Grouping System
Atypical Red Blood Cell (RBC) Antibody Screen	Werfen NEO-Iris Capture-R Ready-Screen Solid Phase
STS <i>Treponema Pallidum</i> (TP)	Beckman Coulter PK7400 TPHA System
Cytomegalovirus Total Antibody (CMV)	Werfen NEO-Iris Capture-CMV Solid Phase System
Chagas Antibody (<i>T. cruzi</i>)	Abbott Alinity Chagas CMIA
Hepatitis B Core Antibody (HBc)	Abbott Alinity Anti-HBcore CMIA
Hepatitis B Surface Antigen (HBsAg)	Abbott Alinity HBsAg CMIA
Hepatitis C Virus Antibody (HCV)	Abbott Alinity Anti-HCV II CMIA
HIV Antibody-Antigen Combo (HIV-1/2 Ab/Ag)	Abbott Alinity HIV Ag/Ab Combo CMIA
Human T-Lymphotropic Virus Antibody (HTLV-I/II)	Abbott Alinity Anti-HTLV-I/II CMIA
Nucleic Acid Testing (NAT) HBV/HCV/HIV Multiplex	Roche Cobas MPX NAT Test (Cobas 8800)
Nucleic Acid Testing (NAT) WNV	Roche Cobas WNV NAT Test (Cobas 8800)
Nucleic Acid Testing (NAT) Babesia	Roche Cobas Babesia NAT Test (Cobas 8800)
Anti-A & Anti-B Titer (LTOWB screen 1:224 dilution)	Beckman Coulter PK7400 Blood Grouping System
C, c, E, e, K-Antigen Phenotyping	Beckman Coulter PK7400 Blood Grouping System
HLA Antibody Class I/II Donor Screen (TRALI Mitigation)	Immucor DonorScreen-HLA® Class I/II Assay (Stratec GEMINI)

CONFIRMATORY/SUPPLEMENTAL TESTS performed using the following assays by Third Party Lab when listed:

Test	Assay Methodology	Laboratory
Serological Test for Syphilis	Trinity BioTech CAPTIA <i>T. Pallidum</i> -G EIA ASI RPR Card Test (RPR Titer - if RPR positive) Zeus Scientific IFA FTA-ABS Test System	AND/OR Versiti LabCorp Quest
Cytomegalovirus Antibody	DiaSorin Liaison Chemiluminescent Immunoassay (IgG/IgM Discriminatory)	LabCorp
Chagas Antibody	Abbott ESA Chagas Roche Cobas Elecsys Chagas (<i>T. cruzi</i>) (2nd vendor/alternate licensed screen)	OR CTS IBR
HBcore Antibody HBcore Antibody IgM	Roche Cobas Elecsys Anti-HBc (2nd vendor/alternate licensed screen) OR Siemens ADVIA Centaur HBc IgM Capture Immunoassay	IBR LabCorp
HBsAg Neutralization HBs Antibody	Abbott Alinity HBsAg Confirmatory Neutralization CMIA OR Siemens ADVIA Centaur Anti-HBs2 Chemiluminometric Immunoassay (CLIA)	OR Versiti LabCorp
HCV Antibody	Roche Cobas HCVNAT repeated IDT (if not originally tested IDT) AND Roche Cobas Elecsys Anti-HCV (2nd vendor/alternate licensed screen)	AND Versiti IBR
HIV-1/2 ImmunoAssay	BioRad Geenius HIV-1/2 Supplemental Assay	Versiti
HTLV Antibody	MP Diagnostic HTLV Blot 2.4 Western Blot OR Roche Cobas Elecsys HTLV-I/II (2nd vendor/alternate licensed screen)	OR CTS IBR
HIV/HCV/HBV NAT	Grifols Procleix Ultrio Plus NAT Test (Panther) (2nd vendor licensed screen)	CTS
WNV NAT	Grifols Procleix WNV NAT Test (Panther) (2nd vendor licensed screen)	CTS
Babesia NAT	Grifols Procleix Babesia Test (Panther) (2nd vendor licensed screen)	CTS

Versiti – Versiti Blood Center of Indiana Donor Testing Lab:	FDA License FDA Registration CMS/CLIA AABB	2133 1873403 15D0664398 005486	IN SDH NY SDH CA DPH MD SDH PA SDH	14-005931-1 PFI: 7968 COS 800236 PFI: 972 033850
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CTS – Creative Testing Solutions (Tempe, AZ)	CMS/CLIA	03D0911463
LabCorp – LabCorp of America, Inc. (Raritan, NJ)	CMS/CLIA	31D0125232
LabCorp – LabCorp of America, Inc. (Dublin, OH)	CMS/CLIA	36D0327333
Quest – Quest Diagnostics Nichols Institute (Chantilly, VA)	CMS/CLIA	49D0221801
IBR – Innovative Blood Resources/Memorial Blood Center (St. Paul, MN)	CMS/CLIA	24D0663800