Versiti DTL Test Methods (Abbott-Roche Screening Platforms)

TEST METHODS	
SCREENING TEST performed using the following assays:	
Test	**Assay**
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 *Treponema Pallidum* (TP)	Beckman Coulter PK7400 TPHA System
Cytomegalovirus Total Antibody (CMV)	Werfen NEO-Iris Capture-CMV Solid Phase System
Chagas Antibody (*T. cruzi*)	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
Human Immunodeficiency Virus Antibody (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)

CONFIRMATORY/SUPPLEMENTAL TEST performed using the following assays by Third Party Lab listed:		
Test	**Assay**	**Laboratory**
Serological Test for Syphilis	Trinity BioTech CAPTIA *T. Pallidum*-G EIA AND/OR ASI RPR Card Test (RPR Titer - if RPR positive) OR Zeus Scientific IFA FTA-ABS Test System	Versiti LabCorp Quest
Cytomegalovirus Antibody	DiaSorin Liaison Chemiluminescent Immunoassay (IgG/IgM Discriminatory)	LabCorp
Chagas Antibody	Abbott ESA Chagas OR Roche Cobas Elecsys Chagas (*T.cruzi*) *(2nd vendor/alternate licensed screen)*	CTS NBTC
HBcore Antibody HBcore Antibody IgM HBs Antibody	Roche Cobas Elecsys Anti-HBc *(2nd vendor/alternate licensed screen)* OR Siemens ADVIA Centaur HBc IgM Capture Immunoassay OR Siemens ADVIA Centaur Anti-HBs2 Chemiluminometric Immunoassay (CLIA)	NBTC LabCorp LabCorp
HBsAg Neutralization	Abbott Alinity HBsAg Confirmatory Neutralization CMIA	Versiti
HCV Antibody	Roche Cobas HCVNAT repeated IDT *(if not originally tested IDT)* AND Roche Cobas Elecsys Anti-HCV *(2nd vendor/alternate licensed screen)*	Versiti NBTC
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)*	CTS NBTC
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 – Donor Testing Lab:	FDA License	2132	NY SDH	PFI: 7968
	FDA Registration	1873403	PA SDH	033850
	CMS/CLIA	15D0664398	CA DPH	COS 800236
	AABB	005486	MD SDH	PFI: 972
	ASHI	08-4-IN-06-1	IN SDH	14-005931-1

LabCorp – LabCorp of America (Dublin, OH)	CMS/CLIA	36D0327333
CTS – Creative Testing Solutions (Tempe, AZ)	CMS/CLIA	03D0911463
Quest – Quest Diagnostics Nichols Institute (Chantilly, VA)	CMS/CLIA	49D0221801
NBTC – National Blood Testing Cooperative (Stone Mountain, GA)	CMS/CLIA	11D2166017