



Versiti DTL Test Methods (Ortho-Roche Platforms)

TEST METHODS			
SCREENING TEST performed using the following assays:			
Test	Assay		
ABO/Rh Blood Group	Beckman Coulter PK Blood Grouping System		
Atypical Red Blood Cell (RBC) Antibody Screen	Immucor NEO Capture-R Ready-Screen Solid Phase		
STS <i>Treponema Pallidum</i> (TP)	Beckman Coulter PK-TP System		
Cytomegalovirus Antibody (CMV)	Beckman Coulter PK CMV-PA System		
Chagas Antibody (<i>T. cruzi</i>)	Ortho T.cruzi Whole Cell Lysate Antigen ELISA on Verseia		
Hepatitis B Core Antibody (HBc)	Ortho HBcore ELISA on Ortho Verseia		
Hepatitis B Surface Antigen (HBsAg)	BioRad GS HBsAg EIA 3.0 on Ortho Verseia		
Hepatitis C Virus Antibody (HCV)	Ortho HCV Encoded Antigen ELISA 3.0 on Ortho Verseia		
Human Immunodeficiency Virus Antibody (HIV-1/2/O)	BioRad GS HIV 1/0/2 EIA on Ortho Verseia		
Human T-Lymphotropic Virus Antibody (HTLV-I/II)	Avioq HTLV-I/II MicroELISA System on Ortho Verseia		
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) Zika	Roche Cobas Zika 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 <i>T. Pallidum</i> -G EIA	AND/OR	Versiti
	ASI RPR Card Test (RPR Titer - if RPR positive)	OR	Versiti
	Zeus Scientific IFA FTA-ABS Test System		Quest
Cytomegalovirus Antibody	BIO-RAD Chemiluminescent Immunoassay (IgG/IgM Discriminatory)		LabCorp
Chagas Antibody	Abbott ESA Chagas	OR	CTS
	Abbott Prism Chagas ChLIA (2nd vendor licensed screen)		Versiti
HBcore Antibody	Abbott Prism HBcore ChLIA (2nd vendor licensed screen)		Versiti
HBsAg Neutralization	BioRad GS HBsAg Confirmatory Assay 3.0		MBC
HCV Antibody	Roche Cobas HCVNAT repeated IDT (if not originally tested IDT)	AND	Versiti
	Abbott Prism HCV ChLIA (2nd vendor licensed screen)		Versiti
HIV-1 Western Blot	BioRad Genetic System HIV-1 Western Blot (manual)	AND	MBC
HIV-2 Antibody EIA Screen	BioRad Genetic System HIV-2 EIA (manual)	AND	MBC
HIV-2 Western Blot	Trinity Biotech HIV-2 Immunostripe (lab-developed) Immunoblot Assay		ViroMed
HTLV Antibody	MP Diagnostic HTLV Blot 2.4 Western Blot	OR	CTS
	Abbott Prism HTLV-I/HTLV-II ChLIA (2nd vendor licensed screen)		Versiti
HIV/HCV/HBV NAT	Grifols Procleix Ultrio Plus NAT Test (Tigris) (2nd vendor licensed screen)		CTS
WNV NAT	Grifols Procleix WNV NAT Test (Tigris) (2nd vendor licensed screen)		CTS
Zika NAT	Grifols Procleix Zika Test (Panther) (2nd vendor licensed screen)	OR	CTS
	Roche Cobas Zika Test (x2)	OR	Versiti
	Zika Virus Antibody (IgM) MAC-ELISA		Quest
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 Indiana, Inc. (South Bend, IN)	CMS/CLIA	15D2171417
CTS – Creative Testing Solutions (Tempe, AZ)	CMS/CLIA	03D0911463
MBC – Memorial Blood Centers/Innovative Blood Resources (St. Paul, MN)	CMS/CLIA	24D0663800
ViroMed – ViroMed/LabCorp (Burlington, NC)	CMS/CLIA	24D0400424
Quest – Quest Diagnostics Nichols Institute (Chantilly, VA)	CMS/CLIA	49D0221801