

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>)	Abbott Prism Chagas ChLIA		
Hepatitis B Core Antibody (HBc)	Abbott Prism HBcore ChLIA		
Hepatitis B Surface Antigen (HBsAg)	Abbott Prism HBsAg ChLIA		
Hepatitis C Virus Antibody (HCV)	Abbott Prism HCV ChLIA		
Human Immunodeficiency Virus Antibody (HIV-1/2/O)	Abbott Prism HIV O Plus ChLIA		
Human T-Lymphotropic Virus Antibody (HTLV-I/II)	Abbott Prism HTLV-I/HTLV-II ChLIA		
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 (<i>investigational test</i> – IND)	Roche Cobas Babesia (IND) 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 ASI RPR Card Test (RPR Titer - if RPR positive) OR Zeus Scientific IFA FTA-ABS Test System		IBC IBC Quest
Cytomegalovirus Antibody	BIO-RAD Chemiluminescent Immunoassay (IgG/IgM Discriminatory)		SBMF
Chagas Antibody	Abbott ESA Chagas OR Ortho <i>T.cruzi</i> Whole Cell Lysate ELISA (<i>2nd vendor licensed screen</i>)		CTS IBC
HBcore Antibody	Ortho HBcore ELISA on Ortho Verseia (<i>2nd vendor licensed screen</i>)		IBC
HBsAg Neutralization	Abbott Prism HBsAg Confirmatory Neutralization ChLIA		IBC
HCV Antibody	Ortho HCV Encoded Antigen ELISA on Verseia (<i>2nd vendor licensed screen</i>)		IBC
HIV-1 Western Blot	BioRad Genetic System HIV-1 Western Blot (manual)		MBC
HIV-2 Antibody EIA Screen	BioRad GS HIV-2 EIA (manual)		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 Avioq HTLV-I/II MicroELISA on Verseia (<i>2nd vendor licensed screen</i>) OR InnoGenetics INNO-LIA HTLV I/II Score Immunoblot Assay		CTS IBC Quest
HIV/HCV/HBV NAT	Grifols Procleix Ultrio Plus NAT Test (Tigris) (<i>2nd vendor licensed screen</i>)		IBC
WNV NAT	Grifols Procleix WNV NAT Test (Tigris) (<i>2nd vendor licensed screen</i>)		IBC
Zika NAT	Roche Cobas Zika Test (x2) Zika Virus Antibody (IgM) MAC-ELISA Grifols Procleix Zika Virus Assay (Panther) (<i>2nd vendor licensed screen</i>)		IBC Quest CTS
Babesia NAT (<i>investigational</i>)	Confirmatory tests defined by FDA approved IND Clinical Study Protocol		

IBC - Indiana Blood Center:	FDA License	1759	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

SBMF – The Medical Foundation (South Bend, IN)	CMS/CLIA	15D0357169
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
QualTex (San Antonio, TX)	CMS/CLIA	45D0500519