

IBC Testing Methods (Ortho/Grifols Platforms)

TEST METHODS		
SCREENING TEST performed using the following assays:		
Test	Assay	
ABO/Rh Blood Type	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	Grifols Tigris Procleix Ultrio Plus Assay	
Nucleic Acid Testing (NAT) WNV	Grifols Tigris Procleix WNV Assay	
Nucleic Acid Testing (NAT) Zika	Roche Cobas Zika Test (Cobas 8800)	
Nucleic Acid Testing (NAT) Babesia (<i>investigational test</i> – IND)	Roche Cobas Babesia (IND) 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 (<i>2nd vendor licensed screen</i>) OR Phoenix BioTech TrepSure EIA AND/OR ASI RPR Card Test (RPR Titer - if RPR positive) OR Zeus Scientific IFA FTA-ABS Test System	QualTex IBC IBC Quest
Cytomegalovirus Antibody	BIO-RAD Chemiluminescent Immunoassay (IgG/IgM Discriminatory)	SBMF
Chagas Antibody	Abbott ESA Chagas Abbott Prism Chagas ChLIA (<i>2nd vendor licensed screen</i>) OR	CTS/ARC IBC
HBcore Antibody	Abbott Prism HBcore ChLIA (<i>2nd vendor licensed screen</i>)	IBC
HBsAg Neutralization	BioRad GS HBsAg Confirmatory EIA 3.0	MBC
HCV Antibody	Abbott Prism HCV ChLIA (<i>2nd vendor licensed screen</i>)	IBC
HIV-1 Western Blot	BioRad Genetic System (GS) HIV-1 Western Blot (manual)	MBC
HIV-2 Antibody EIA Screen	BioRad Genetic System (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 Abbott Prism HTLV-I/HTLV-II ChLIA (<i>2nd vendor licensed screen</i>) OR InnoGenetics INNO-LIA HTLV I/II Score Immunoblot Assay	CTS/ARC IBC Quest
HIV/HCV/HBV NAT	Roche Cobas TaqScreen MPX Test (s 201) (<i>2nd vendor licensed screen</i>)	IBC
WNV NAT	Roche Cobas TaqScreen WNV Test (s 201) (<i>2nd vendor licensed screen</i>)	IBC
Zika NAT	Roche Cobas Zika Test (x2) Zika Virus Antibody (IgM) MAC-ELISA	IBC Quest
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 in South Bend	CMS/CLIA	15D0357169
CTS/ARC – CTS/American Red Cross-Charlotte, NC Lab	CMS/CLIA	34D0881210
MBS – Memorial Blood Center/Innovative Blood Resources	CMS/CLIA	24D0663800
ViroMed – ViroMed/LabCorp	CMS/CLIA	24D0400424
Quest – Quest Diagnostics Nichols Institute (Chantilly, VA)	CMS/CLIA	49D0221801
QualTex (San Antonio)	CMS/CLIA	45D0500519