JA-21003: MASTER DONOR TESTING KIT LISTING

Routine donor testing performed at:

Testing Facility	Test	Assay	Manufacturer	STN
National Blood Testing Partners 1625 Rock Mountain Blvd Suite R Stone Mountain, GA 30083 FDA FEI #: 3015738441 U.S. License #: 1647 CLIA ID: 11D2166017 AABB: 1794505	ABO/Rh	Blood Grouping Reagents	Beckman Coulter, Inc. U.S. License 1744	BK060024
	Antibody Screen	Antibody Screen (DG Gel® Cards)	Grifols Diagnostic Solutions U.S. License 1740	BK170130
	Babesia	cobas Babesia	Roche Diagnostics U.S. License 1636	STN125699/0
	HBsAg	Antibody to Hepatitis B surface Antigen (Mouse Monoclonal) GS HBsAg EIA 3.0	Bio-Rad Laboratories U.S. License 1109	BL103590
	anti-HTLV-I/II	Avioq HTLV-I/II Microelisa System	Avioq, Inc. U.S. License 1856	BL125394
	anti-CMV (Cytomegalovirus)	Beckman Coulter PK CMV-PA System	Fujirebio Diagnostics, Inc.	BK070030
	Syphilis - Treponemal	Beckman Coulter PK TP System	Fujirebio Diagnostics, Inc.	BK060062
	HIV-1 RNA, HCV RNA, HBV DNA	cobas MPX	Roche Diagnostics U.S. License 1636	BL125576/11
	WNV RNA (West Nile Virus)	cobas WNV	Roche Diagnostics U.S. License 1636	BL125575
	anti-HIV	GS HIV-1/HIV-2 PLUS O EIA	Bio-Rad Laboratories U.S. License 1109	BL125030
	anti-HBc	ORTHO HBc ELISA Test System	Ortho Clinical Diagnostics U.S. License 1236	BL103062
	anti-HCV	ORTHO HCV Version 3.0 ELISA Test System	Ortho Clinical Diagnostics U.S. License 1236	BL103065
	anti-T. cruzi (Chagas)	ORTHO T. cruzi ELISA Test System	Ortho Clinical Diagnostics U.S. License 1236	BL125161
	HLA-AB	LABScreen	One Lambda Inc.	BK130009

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National Blood Testing Partners 1625 Rock Mountain Blvd Suite R Stone Mountain, GA 30083 FDA FEI #: 3015738441 U.S. License #: 1647 CLIA ID: 11D2166017 AABB: 1794505	HBsAg (Confirmatory)	Genetic Systems HBsAg Confirmatory Assay 3.0	Bio-Rad Laboratories U.S. License 1109	BL103590
	Syphilis (Treponemal) (Confirmatory)	CAPTIA™ Syphilis (T.Pallidum) - G	Trinity Biotech	K014233
	Syphilis (Non-Treponemal) (Confirmatory)	ASI Automated Rapid Plasma Reagin (RPR) Test for Syphilis	Arlington Scientific	BK020031
	HTLV (Confirmatory)	HTLV Blot 2.4 Western Blot Assay	MP Diagnostics	BL125475
	HTLV (Reentry) *	ABBOTT Alinity S HTLV-I/II	Abbott GmBH & Co. KG	BL 125675
	HIV-1/2 (Confirmatory)	Geenius HIV 1/2 Supplemental Assay	Bio-Rad Laboratories U.S. License 1109	BL 125670
	ESA Chagas (Confirmatory) *	Abbott ESA Chagas	Abbott GmBH & Co. KG	STN125361/23
	HCV (Confirmatory) *	ABBOTT Alinity s Anti-HCV	Abbott GmBH & Co. KG	BL125677

*to be performed at a send out lab.

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Routine donor testing performed at:

Testing Facility	Test	Test Kit/Manufacturer
ImpactLife 5500 Lakeview Parkway Davenport, IA 52807 FDA Registration #: 1970356 U.S. License #: 2276 CLIA ID: 16D0387896	Platelet Count	Sysmex XE 2100D
	Sickle Cell	Streck Sickledex Solubility Kit
	White Blood Cell Count (residual WBC in LR components)	BD FACSCalibur Flow Cytometer
	Bacterial Detection	Biomerieux BacT/Alert
ImpactLife 3420 Rider Trail South Earth City, MO 63045 FDA Registration #: 3004157291 U.S. License #: 2276 CLIA ID: 26D1063322	Platelet Count	Sysmex XE 2100D
	Sickle Cell	Streck Sickledex Solubility Kit
	White Blood Cell Count (residual WBC in LR components)	BD FACSVia Flow Cytometer
	Bacterial Detection	Biomerieux BacT/Alert
ImpactLife 2801 S 10th St Springfield, IL 62703 FDA Registration #: 3011078001 U.S. License #: 2276 CLIA ID: 10D0665212	Sickle Cell	Streck Sickledex Solubility Kit
	Immucor PreciseType HEA Molecular Beadchip Test (Bioarray)	BioArray Solutions Ltd.
ImpactLife 6330 Copps Ave Monona, WI 53716 FDA Registration #: 3015522161 U.S. License #: 2276 CLIA ID: 52D2181077	Sickle Cell	Streck Sickledex Solubility Kit

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Routine donor testing performed at:

Testing Facility	Test	Test Kit/Manufacturer
Versiti Blood Center of Indiana 3450 N. Meridian Street Indianapolis, IN 46208 FDA Registration #: 1873403 U.S. License #: 2132 CLIA ID: 15D0664398	Routine Donor Testing (Back-up)	

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