



ViroMed Laboratories

Donor Screening Tests with Approved Indications for Living HCT/P Donors

HIV Ag/Ab Combo (138948); HIV Ag/Ab Combo With Reflex to HIV Ab Confirmation (138931)	
*note, assay includes group O	
Trade Name Abbott Alinity s HIV Combo	FDA STN#: BL125679
Sample: Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
HBsAg (138874); HBsAg With Reflex to Confirmatory Assay (138749)	
Trade Name Abbott Alinity s HBsAg	FDA STN#: BL125674
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
Anti-Hepatitis B Core (HBc) Total (138699); HBc Total With Reflex to IgM (138979)	
Trade Name Abbott Alinity s HBcore	FDA STN#: BL125681
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
Anti-Hepatitis C Virus (138907)	
Trade Name Abbott Alinity s HCV	FDA STN#: BL125677
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
RPR (139878) with Reflex to Syphilis (Tpallidum) Antibodies	
Trade Name ASI Automated RPR test for Syphilis for use on the ASI Evolution	FDA STN#: BK200539
Sample Serum, plasma	Use Donor Screen
Manufacturer Arlington Scientific, Inc.	Format Flocculation
Syphilis (<i>T. pallidum</i>) Antibodies (139872)	
Trade Name CAPTIA Syphilis (T.pallidum)-G	FDA STN#: K014233
Sample Serum, plasma	Use Donor Screen
Manufacturer Trinity BioTech	Format EIA
Anti-HTLV I/II (138922); HTLV I/II With Reflex to Immunoblot (138780)	
Trade Name Abbott Alinity s HTLV-I/HTLV-II	FDA STN#: BL125675
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
CMV Total Antibodies (138662)	
Trade Name Capture- CMV	FDA STN#: BK200542
Sample: Serum, plasma	Use Donor screen
Manufacturer Immucor	Format Red Cell Adherence

These tests are FDA licensed, approved, or cleared for the use(s) listed. Contact Account Management at 800-582-0077 with any questions.

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CMV Total Antibodies With Reflex to IgM (138697); CMV Total With Reflex to IgM/IgG (138930)	
Trade Name Capture- CMV w/ reflex	FDA STN#: BK200542
Sample Plasma, serum	Use Donor screen
Manufacturer Immucor	Format Red Cell Adherence

HIV-1 and HIV-2/HCV/HBV NAT (139783)	
Trade Name Procleix Ultrio Elite (Multiplex HIV, HCV & HBV NAT)	FDA STN#: BL125652
Sample Serum, plasma	Use Donor screen
Manufacturer Grifols Diagnostic Solutions Inc.	Format Nucleic Acid Test (NAT)

West Nile Virus NAT (139806)	
Trade Name Procleix WNV	FDA STN#: BL125121
Sample Plasma	Use Donor screen
Manufacturer Grifols Diagnostic Solutions Inc.	Format Nucleic Acid Test (NAT)

Reproductive Testing

Chlamydia trachomatis (CT)/Neisseria gonorrhoea (NG) (138828)	
Trade Name APTIMA Combo 2 Assay*	FDA STN#: K180681
Sample Genital swabs, urine	Use Diagnostic
Manufacturer Hologic	Format Nucleic Acid Test (NAT)

Additional Testing

Trypanosoma cruzi Antibodies (Chagas Disease) (139290)	
Trade Name Abbott Alinity s Chagas	FDA STN#: BL125689
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA

Cellular Product Sterility Testing* with ID, (139299, 139782) ; Cellular Product Sterility Testing with ID and Susceptibility (139245, 139674)	
Trade Name BacT/ALERT®	FDA STN#: BK020022, BK020023
Sample Concentrated HPC	Use Diagnostic
Manufacturer bioMérieux, Inc.	Format Microbial Detection System

ABO/Rh (139670)	
Trade Name ABO/Rh	FDA STN#: BK210560
Sample Whole Blood	Use Donor Screen
Manufacturer Immucor	Format Hemagglutination

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*This test validated by ViroMed Laboratories according to CFR 1271 and Guidance for Industry, Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications, October 2009 (CFR 610.12, CFR 211.165).

Contact ViroMed at 800-582-0077 with any questions.

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