



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

Syphilis (<i>T. pallidum</i>) Antibodies (139693)	
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 Plasma, serum	Use Donor screen
Manufacturer Immucor	Format Red Cell Adherence

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

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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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

<i>Chlamydia trachomatis</i> (CT)/<i>Neisseria gonorrhea</i> (NG) (138828)	
Trade Name APTIMA Combo 2 Assay [®]	FDA STN#: BK180681
Sample Genital swabs, urine	Use Diagnostic
Manufacturer Hologic	Format Nucleic Acid Test (NAT)

Additional Testing

<i>Trypanosoma cruzi</i> 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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