

ViroMed Laboratories

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

Anti-HIV-1/HIV-2 Plus O (138948); HIV-1/HIV-2 With Reflex to HIV^{1/2} Supplemental Assay (138931)	
Trade Name Abbott Alinity s HIV Ag/Ab Combo	
Sample: Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
HBsAg (138874); HBsAg With Reflex to Confirmatory Assay (138749)	
Trade Name Abbott Alinity s HBsAg	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Anti-Hepatitis B Core (HBc) Total (138699); HBc Total With Reflex to IgM (138979)	
Trade Name Abbott Alinity s HBcore	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Anti-Hepatitis C Virus (138907)	
Trade Name Abbott Alinity s HCV	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Syphilis (<i>T. pallidum</i>) Antibodies (139693)	
Trade Name Beckman Coulter PK TP System(formerly Olympus PK TP System)	
Sample Serum, plasma	Use Donor Screen
Manufacturer Beckman Coulter	Format Particle Hemagglutination
Anti-HTLV I/II (138922); HTLV I/II With Reflex to Immunoblot (138780)	
Trade Name Abbott Alinity s HTLV-I/HTLV-II	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
CMV Total Antibodies (138662)	
Trade Name Capture-CMV	
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	
Sample Plasma, serum	Use Donor screen
Manufacturer Immucor	Format Red Cell Adherence
HIV-1 and HIV-2/HCV/HBV NAT (139783)	
Trade Name cobas MPX (Multiplex HIV, HCV & HBV NAT)	
Sample Serum, plasma	Use Donor screen
Manufacturer Roche Molecular Systems	Format Nucleic Acid Test (NAT)

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

West Nile Virus NAT (139806)	
Trade Name cobas WNV	
Sample Plasma	Use Donor screen
Manufacturer Roche Molecular Systems	Format Nucleic Acid Test (NAT)

Zika virus NAT (139828)	
Trade Name cobas Zika	
Sample Plasma	Use Donor screen
Manufacturer Roche Molecular Systems	Format Nucleic Acid Test (NAT)

Reproductive Testing

<i>Chlamydia trachomatis</i> (CT)/<i>Neisseria gonorrhoea</i> (NG) (138828)	
Trade Name APTIMA Combo 2 Assay®	
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	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA

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

ABO/Rh (139670)	
Trade Name ABO/Rh	
Sample Whole Blood	Use Donor Screen
Manufacturer Beckman Coulter	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).

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