


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

<b>HIV Ag/Ab Combo (138948); HIV Ag/Ab Combo With Reflex to HIV Ab Confirmation (138931)</b>	
<b>*note, assay includes group O</b>	
Trade Name Abbott Alinity s HIV Combo	
Sample: Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
<b>HBsAg (138874); HBsAg With Reflex to Confirmatory Assay (138749)</b>	
Trade Name Abbott Alinity s HBsAg	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
<b>Anti-Hepatitis B Core (HBc) Total (138699); HBc Total With Reflex to IgM (138979)</b>	
Trade Name Abbott Alinity s HBcore	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
<b>Anti-Hepatitis C Virus (138907)</b>	
Trade Name Abbott Alinity s HCV	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
<b>Syphilis (<i>T. pallidum</i>) Antibodies (139693)</b>	
Trade Name Beckman Coulter PK TP System (formerly Olympus PK TP System)	
Sample Serum, plasma	Use Donor Screen
Manufacturer Beckman Coulter	Format Particle Hemagglutination
<b>Anti-HTLV I/II (138922); HTLV I/II With Reflex to Immunoblot (138780)</b>	
Trade Name Abbott Alinity s HTLV-I/HTLV-II	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format CMIA
<b>CMV Total Antibodies (138662)</b>	
Trade Name Capture- CMV	
Sample Plasma, serum	Use Donor screen
Manufacturer Immucor	Format Red Cell Adherence
<b>CMV Total Antibodies With Reflex to IgM (138697); CMV Total With Reflex to IgM/IgG (138930)</b>	
Trade Name Capture- CMV w/ reflex	
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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<b>HIV-1 and HIV-2/HCV/HBV NAT (139783)</b>	
<b>Trade Name</b> cobas MPX (Multiplex HIV, HCV & HBV NAT)	
<b>Sample</b> Serum, plasma	<b>Use</b> Donor screen
<b>Manufacturer</b> Roche Molecular Systems	<b>Format</b> Nucleic Acid Test (NAT)

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

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

## Reproductive Testing

<b><i>Chlamydia trachomatis</i> (CT)/<i>Neisseria gonorrhoea</i> (NG) (138828)</b>	
<b>Trade Name</b> APTIMA Combo 2 Assay <sup>®</sup>	
<b>Sample</b> Genital swabs, urine	<b>Use</b> Diagnostic
<b>Manufacturer</b> Hologic	<b>Format</b> Nucleic Acid Test (NAT)

## Additional Testing

<b><i>Trypanosoma cruzi</i> Antibodies (Chagas Disease) (139290)</b>	
<b>Trade Name</b> Abbott Alinity s Chagas	
<b>Sample</b> Serum, plasma	<b>Use</b> Donor screen
<b>Manufacturer</b> Abbott Laboratories	<b>Format</b> CMIA

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

<b>ABO/Rh (139670)</b>	
<b>Trade Name</b> ABO/Rh	
<b>Sample</b> Whole Blood	<b>Use</b> Donor Screen
<b>Manufacturer</b> Beckman Coulter	<b>Format</b> 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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