

ViroMed Laboratories

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

HIV-1/HIV-2 (138948); HIV-1/HIV-2 With Reflex to HIV-1 Western Blot (138931)	
Trade Name Abbott Prism HIV O Plus	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
HBsAg (138874); HBsAg With Reflex to Confirmatory Assay (138749)	
Trade Name Abbott Prism HBsAg	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Hepatitis B Core (HBc) Total (138699); HBc Total With Reflex to IgM (138979)	
Trade Name Abbott Prism HBcore	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Hepatitis C Virus (138907)	
Trade Name Abbott Prism HCV	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
Syphilis (<i>T. pallidum</i>) (139693)	
Trade Name Syphilis (<i>T. pallidum</i>)	
Sample Serum, plasma	Use Donor Screen
Manufacturer Beckman Coulter	Format Particle Hemagglutination
HTLV I/II (138922); HTLV I/II With Reflex to Immunoblot (138780)	
Trade Name Abbott Prism HTLV-I/HTLV-II	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA
CMV Total (138662)	
Trade Name CMV Assay	
Sample Plasma, serum	Use Donor screen
Manufacturer Beckman Coulter	Format Particle Hemagglutination
CMV Total With Reflex to IgM (138697); CMV Total With Reflex to IgM/IgG (138930)	
Trade Name CMV w/ reflex	
Sample Plasma, serum	Use Donor screen
Manufacturer Beckman Coulter	Format Particle Hemagglutination
HIV-1 and HIV-2/HCV/HBV NAT (139783)	
Trade Name Multiplex HIV, HCV & HBV NAT	
Sample Serum, plasma	Use Donor screen
Manufacturer Roche	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 WNV Assay	
Sample Plasma	Use Donor screen
Manufacturer Roche	Format nucleic acid test (NAT)

Zika virus NAT (139828)	
Trade Name Zika Assay	
Sample Plasma	Use Donor screen
Manufacturer Roche	Format nucleic acid test (NAT)

Reproductive Testing

<i>Chlamydia trachomatis</i> (CT)/<i>Neisseria gonorrhoeae</i> (NG) (138828)	
Trade Name APTIMA Combo 2 Assay [®]	
Sample Genital swabs, urine	Use Diagnostic
Manufacturer Hologic	Format NAT

Additional Testing

<i>Trypanosoma cruzi</i> (Chagas Disease) (139290)	
Trade Name Abbott Prism 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

These tests are FDA licensed, approved, or cleared for the use(s) listed.
 *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.