

ViroMed Laboratories

Donor Screening Tests with Approved Indications for Living HCT/P Donors and Hematopoietic Progenitor Cells (HPC)

HIV-1/HIV-2 (138948); HIV-1/HIV-2 With Reflex to HIV-1 Western Blot (138931)	
Trade Name Genetic Systems HIV-1/HIV-2 Plus O EIA	
Sample: Serum, plasma	Use Donor screen
Manufacturer Bio-Rad Laboratories	Format EIA

HBsAg (138874); HBsAg With Reflex to Confirmatory Neutralization Assay (138749)	
Trade Name Genetic Systems HBs Ag EIA 3.0	
Sample Serum, plasma	Use Donor screen
Manufacturer Bio-Rad Laboratories	Format EIA

Hepatitis B Core (HBc) Total (138699); HBc Total With Reflex to IgM (138979)	
Trade Name Ortho HBc ELISA Test System	
Sample Serum, plasma	Use Donor screen
Manufacturer Ortho-Clinical Diagnostics, Inc.	Format EIA

Hepatitis C Virus (138907); HCV With Reflex to Confirmatory RIBA (138915)	
Trade Name Ortho HCV Version 3.0 ELISA Test System	
Sample Serum, plasma	Use Donor screen
Manufacturer Ortho-Clinical Diagnostics, Inc.	Format EIA

Syphilis (<i>T pallidum</i> IgG) (139280)	
Trade Name CAPTIA™ Syphilis (<i>T pallidum</i>)-G	
Sample Serum	Use Donor Screen
Manufacturer Trinity Biotech	Format Treponemal

HTLV I/II (138922); HTLV I/II With Reflex to Immunoblot (138780)	
Trade Name Abbott Prism HTLV-I/HTLV-II Assay	
Sample Serum, plasma	Use Donor screen
Manufacturer Abbott Laboratories	Format ChLIA

CMV Total (138662)	
Trade Name Capture-CMV®	
Sample Plasma	Use Donor screen
Manufacturer Immucor, Inc.	Format Solid phase red cell adherence

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



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CMV Total With Reflex to IgM (138697), CMV Total With Reflex to IgM/IgG (138930)	
Trade Name Capture-CMV®	
Sample Plasma and serum	Use Donor screen
Manufacturer Immucor, Inc.	Format Solid phase red cell adherence

HIV-1/HCV/HBV NAT (139240)	
Trade Name Procleix Ultrio	
Sample Serum, plasma, cadaveric serum or plasma	Use Living, organ, cadaveric
Manufacturer Gen-Probe, Inc.	Format TMA

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 Gen-Probe, Inc.	Format TMA

Additional Testing

West Nile Virus NAT (138896)	
Trade Name Procleix WNV Assay	
Sample Plasma	Use Living, organ, cadaveric
Manufacturer Gen-Probe, Inc.	Format TMA

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

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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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