DONOR TESTING

# One lab for your reproductive donor testing needs

An experienced leader in testing for reproductive donor communities, through an FDA-registered laboratory (ViroMed) for donor screening with nationally recognized expertise in infectious disease testing.

### Key Features of Reproductive Donor Testing Services Include:

- Comprehensive donor testing portfolio
- FDA-registered, CAP-accredited, and CLIA-certified
- ISO 15189 certified
- Services provided 7 days a week
- Experienced and dedicated quality assurance department
- Dedicated account management staff and technical consultation available 24 hours a day
- Approximately 2000 Patient Service Centers with online appointment scheduling
- International donor shipping program

### International Donor Shipping Program

Provides personalized service and support for international donor shipping to most areas of the world.

- Both single- and dual-donor collection kits available
- Dedicated logistics staff to manage the international shipping process
- Individualized shipment monitoring, tracking, and notification
- More than 10 years of experience in international specimen shipping
- Program includes international forms and commercial invoices, along with all of the necessary supplies for donor testing
- Easy-to-use NanoCool™ 2°C – 8°C cooling technology activated by pressing a button
- Instructions available in English, Spanish, or Chinese
- Specialized test requisition form and comprehensive donor testing menu
- Donor convenience, direct shipment to ViroMed for testing, and rapid result turnaround time

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## Donor Eligibility Requirements

A donor eligibility determination based on donor screening and testing for relevant communicable agents and diseases is required for all donors of cells or tissues identified as human cell, tissue, and cellular- and tissue-based products (HCT/Ps) unless subject to exemption.

Infectious disease testing should be performed in an FDA-registered laboratory. Testing should be performed using tests that have been licensed, approved, or cleared by the FDA specifically for use in donor screening (when available) or approved/cleared for use in low prevalence, asymptomatic populations.

## Basic Donor Eligibility Testing Includes:

### Serology

- HIV-1/O/2
- HBsAg
- HBc Total
- HCV
- Syphilis *(T pallidum)*

### Additional Serology Tests for Donors of Viable Leukocyte-Rich Cells and Tissue

- HTLV I/II
- CMV Total Antibody

### Nucleic-Acid Amplification Tests (NAT)

- *Chlamydia trachomatis/Neisseria gonorrhoeae* NAT
- HIV/HCV/HBV NAT
- WNV NAT*

*FDA recommends performing WNV testing on HTC/Ps recovered in the United States from June 1st through October 31st every year.

**Other:** CMV IgG, CMV IgM, *Trypanosoma cruzi* (Chagas) Antibody, Zika virus NAT

# Reproductive Donor Panels performed at Labcorp's ViroMed Laboratory

| Test No. | Test Name | Test Includes |
|---|---|---|
| **139060** | FDA Female, No Reflex | HBsAg, HBcore Total, HCV, HIV-1/HIV-2 PLUS O, Syphilis (*T pallidum*), CT/NG NAA, HIV/HCV/HBV NAT |
| **139061** | FDA Female, With Reflex | HBsAg With Reflex to Neutralization, HBcore Total With Reflex to IgM, HCV, HIV-1/HIV-2 PLUS O With Reflex to HIV-1 WB, Syphilis (*T pallidum*), CT/NG NAA, HIV/HCV/HBV NAT |
| **139062** | FDA Male, No Reflex | HBsAg, HBcore Total, HCV, HIV-1/HIV-2 PLUS O Syphilis (*T pallidum*), HTLV-I/II, CMV Total, CT/NG NAA, HIV/HCV/HBV NAT |
| **139063** | FDA Male, With Reflex | HBsAg With Reflex to Neutralization, HBcore Total With Reflex to IgM, HCV, HIV-1/HIV-2 PLUS O With Reflex to HIV-1 WB, Syphilis (*T pallidum*), HTLV-I/II With Reflex to Immunoblot, CMV Total With Reflex to IgM, CT/NG NAA, HIV/HCV/HBV NAT |
| **139323** | Donor Screening Panel 134<br>*FDA Female With WNV, No Reflex* | HBsAg, HBcore Total, HCV, HIV-1/HIV-2 PLUS O, Syphilis (*T pallidum*), CT/NG NAA, HIV/HCV/HBV NAT, WNV NAT |
| **139472** | FDA Female With WNV, With Reflex | HBsAg With Reflex to Neutralization, HBcore Total With Reflex to IgM, HCV, HIV-1/HIV-2 PLUS O With Reflex to HIV-1 WB, Syphilis (*T pallidum*), CT/NG NAA, HIV/HCV/HBV NAT, WNV NAT |
| **139496** | FDA Male With WNV, With Reflex | HBsAg With Reflex to Neutralization, HBcore Total With Reflex to IgM, HCV, HIV-1/HIV-2 PLUS O With Reflex to HIV-1 WB, Syphilis (*T pallidum*), HTLV-I/II With Reflex to Immunoblot, CMV Total With Reflex to IgM, CT/NG NAA, HIV/HCV/HBV NAT, WNV NAT |
| **139506** | FDA Male With WNV, No Reflex | HBsAg, HBcore Total, HCV, HIV-1/HIV-2 PLUS O Syphilis (*T pallidum*), HTLV-I/II, CMV Total, CT/NG NAA, HIV/HCV/HBV NAT, WNV NAT |

For additional panels, please visit www.ViroMed.com or contact your sales representative.

## Current Guidance for Donor Eligibility Determination

*The FDA's latest Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissue, and Cellular- and Tissue-based Products (HCTPs)* was released in August 2007. The current federal guidance assists establishments in complying with donor eligibility determinations as set forth in Title 21 Code of Federal Regulations, part 1271, subpart C. This guidance applies to cells and tissues procured on or after May 25, 2005.

Specimens for testing must be obtained at the same time as cells or tissue are recovered from the donor or within 7 days before or after recovery. In the case of oocytes, a specimen may be collected for testing as long as 30 days before recovery. For anonymous semen donors, a new specimen should also be collected at least 6 months after the date of donation and tested for relevant communicable diseases.

For more information about our comprehensive menu of donor testing services, call **800-582-0077.**

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