MAYO CLINIC LABORATORIES

Test Definition: HPP12

HIV-1/HIV-2 RNA Detection Prenatal, Plasma

Overview

Useful For

Diagnosis of HIV-1 and/or HIV-2 infection in pregnant individuals with indeterminate or inconclusive HIV serologic test results

Diagnosis of HIV-1 and/or HIV-2 infection in pregnant individuals in the acute or early phase of HIV-1 and/or HIV-2 infection

Testing Algorithm

For information see HIV Prenatal Testing Algorithm, Including Follow-up of Reactive Rapid Serologic Test Results

Special Instructions

- HIV Prenatal Testing Algorithm, Including Follow-up of Reactive Rapid Serologic Test Results

Highlights

This test is to be used for qualitative detection and differentiation of HIV-1 and HIV-2 infection in a pregnant individual with indeterminate or inconclusive HIV serologic test results or who are suspected to be in the acute/early HIV infection stage (ie, "window period").

Method Name

Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

NY State Available

Yes

Specimen

Specimen Type

Plasma EDTA

Ordering Guidance

This test is indicated for qualitative detection and differentiation of HIV-1 and HIV-2 infection in pregnant individuals with indeterminate or inconclusive HIV serologic test results or who are suspected to be in the acute/early HIV infection stage (ie, "window period"). If serologic testing has not yet been performed on the patient, order either HIVSP / HIV Antigen and Antibody Prenatal Routine Screen, Plasma or HVDSP / HIV-1 and HIV-2 Antibody Confirmation and Differentiation Prenatal, Plasma, where this test will automatically be added on depending on the results of the serologic test.

Shipping Instructions

1. Ship specimen frozen on dry ice.

2. If shipment will be delayed for more than 24 hours, freeze plasma specimen at -20 to -80 degrees C before shipment and then transport on dry ice.

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Lavender top (EDTA)
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL Plasma
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot plasma into a plastic vial.

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume

Plasma: 0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Frozen (preferred)	40 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

Currently, 2 types of HIV, HIV type 1 (HIV-1) and HIV type 2 (HIV-2), are known to infect humans. HIV-1 has been isolated from patients with AIDS or AIDS-related complex, and from asymptomatic infected individuals at high-risk for AIDS. Accounting for more than 99% of HIV infection in the world, HIV-1 is transmitted by sexual contact, by exposure to infected blood or blood products, from an infected pregnant woman to fetus in utero or during birth, or from an infected mother to infant via breast-feeding. HIV-2 has been isolated from infected patients in West Africa, and it appears to be endemic only in that region. However, HIV-2 also has been identified in individuals who have lived in West Africa or had sexual relations with individuals from that geographic region. HIV-2 is similar to HIV-1 in overall genomic structure and ability to cause AIDS, but viral load tends to lower in HIV-2 than HIV-1 infection.

Reference Values

Undetected

Interpretation

A "Detected" result indicates that the presence of RNA of the specific virus in the specimen tested, consistent with the presence of this viral infection. For example, a "Detected" result for HIV-1 RNA by this assay is indicative of HIV-1 infection in the tested individual. A follow-up specimen should be collected from this individual to both verify the diagnosis and quantify the HIV RNA prior to initiation of antiviral therapy.

An "Undetected" result indicates that the assay was unable to detect RNA of the specific virus in the specimen tested.

An "Inconclusive" result indicates that the presence or absence of viral RNA could not be determined with certainty after repeat testing in the laboratory, possibly due to presence of inhibitory substances in the specimen tested. Collection of a new specimen for testing is recommended.

Cautions

This test is not licensed by the US Food and Drug Administration as a screening test for HIV-1 infection in donors of blood, human cells, tissues, or tissue products.

A single "Undetected" result may not rule out the presence of HIV infection, if the specimen is collected and tested too early after exposure (ie, less than 10 days from exposure) or if patient is infected with a rare HIV variant. Improper storage or processing (ie, incorrect temperature) of the specimen for transport to the testing laboratory may lead to falsely negative viral RNA result.

Due to the potential cross-reactivity between some nucleic acid testing assays and certain lentiviral vector-based CAR T-cell therapies, clinicians should exercise caution when ordering and interpreting HIV testing in patients who have received CAR-T cell therapy. Some lentiviral CAR-T vectors contain a target region of the test, which can lead to false positive HIV-1 results.

Clinical Reference

1. Centers for Disease Control and Prevention. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Accessed July 22, 2024. Available at https://stacks.cdc.gov/view/cdc/50872
2. Branson BM, Owen SM, Wesolowski LG, et al. Laboratory testing for the diagnosis of HIV infection: Updated recommendations. Centers for Disease Control and Prevention; June 27, 2014. Accessed July 22, 2024. Available at https://stacks.cdc.gov/view/cdc/23447
3. Duncan D, Duncan J, Kramer B, et al. An HIV diagnostic testing algorithm using the cobas HIV-1/HIV-2 Qualitative Assay for HIV type differentiation and confirmation. J Clin Microbiol. 2021;59(7):e03030-20. doi:10.1128/JCM.03030-20
4. U.S. Department of Health and Human Services, Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the use of antiretroviral drugs during pregnancy and interventions to reduce perinatal HIV transmission in the United States. HHS; January 31, 2023. Accessed July 22, 2024. Available at https://clinicalinfo.hiv.gov/en/guidelines/perinatal/whats-new

Performance

Method Description

This test is a US Food and Drug Administration approved, real-time polymerase chain reaction (PCR) assay performed on the cobas 5800/6800/8800 Systems for fully automated sample preparation (including extraction and purification of

viral nucleic acid), amplification, detection, and differentiation of HIV-1 and HIV-2 RNA. It utilizes a multi-target approach to amplify 2 highly conserved *gag* and long terminal repeat (LTR) regions of the HIV-1 genome and the LTR region of the HIV-2 genome for detection by target sequence-specific TaqMan probes. A non-HIV, RNA internal control is introduced into each specimen during sample preparation to assess substantial failures during the sample preparation and PCR amplification processes, while HIV-1 and HIV-2 positive controls and a negative control are used as assay run controls. The assay generates individual results for the presence or absence of HIV-1 RNA and HIV-2 RNA.(Package insert: cobas HIV-1/HIV-2 Qualitative-nucleic acid test for use on the cobas 5800/6800/8800 Systems. Roche Molecular Systems, Inc; Doc rev. 6.0, 02/2026)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
30 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
87535
87538

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HPP12	HIV-1/HIV-2 RNA Detect Prenatal, P	96557-4

Test Definition: HPP12

HIV-1/HIV-2 RNA Detection Prenatal, Plasma

Result ID	Test Result Name	Result LOINC® Value
616344	HIV-1 RNA	25835-0
616345	HIV-2 RNA	69353-1