MAYO CLINIC LABORATORIES

Test Definition: PSHIV

HIV-1 RNA Patient Source, Plasma

Overview

Useful For

Detection and diagnosis of HIV-1 infection in an acutely or early infected individual (including infants of <2 years of age) who is the source of blood or body fluid in an occupational exposure event

Testing Algorithm

For information see HIV Testing Algorithm (Fourth-Generation Screening Assay) for Occupational Exposure Events.

Special Instructions

- HIV Testing Algorithm (Fourth-Generation Screening Assay) for Occupational Exposure Events

Method Name

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

NY State Available

No

Specimen

Specimen Type

Plasma EDTA

Shipping Instructions

Ship specimen frozen on dry ice. If shipment will be delayed for more than 24 hours, freeze plasma specimen at -20 to -80 degrees C until shipment 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
Collection Instructions:
1. Centrifuge blood collection tube and aliquot plasma into plastic vial per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Freeze aliquoted plasma for shipment.

Specimen Minimum Volume

0.8 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Frozen (preferred)	84 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 its morphology, overall genomic structure, and ability to cause AIDS.

Multiple clinical studies of plasma HIV-1 viral load (expressed as HIV-1 RNA copies/mL of plasma) have shown a clear relationship of HIV-1 RNA copy number to stage of HIV-1 disease and efficacy of anti-HIV-1 therapy. Quantitative HIV-1 RNA level in plasma (ie, HIV-1 viral load) is an important surrogate marker in assessing the risk of disease progression and monitoring response to anti-HIV-1 drug therapy in the routine medical care of individuals living with HIV-1.

HIV serologic tests may be unreliable for infants born to HIV-infected mothers. In infants up to 2 years of age, positive serologic test results can be due to the presence of maternal HIV antibodies. Therefore, the US Department of Health and Human Services Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children recommends the use of HIV RNA or proviral DNA tests for the detection of HIV infection in infants born to HIV-infected mothers.

Reference Values

Undetected

Interpretation

This assay has a plasma HIV-1 RNA quantification result range of 20 to 10,000,000 copies/mL (1.30-7.00 log copies/mL).

An "Undetected" result indicates that the assay was unable to detect HIV-1 RNA in the plasma specimen tested.

A result of "less than 20 copies/mL" indicates that HIV-1 RNA is detected, but the level present is less than the lower quantification limit of this assay. Due to the increased sensitivity of this assay, patients with previously low or undetectable HIV-1 viral load may show increased or detectable viral load with this assay. However, the clinical

implications of a viral load below 20 copies/mL remain unclear. Possible causes of such a result include very low plasma HIV-1 viral load present (eg, in the range of 1-19 copies/mL), very early HIV-1 infection (ie, <3 weeks from time of infection), or absence of HIV-1 infection (ie, false-positive).

A result of "greater than 10,000,000 copies/mL" with the result comment of "HIV-1 RNA level is greater than 10,000,000 copies/mL (>7.00 log copies/mL). This assay cannot accurately quantify HIV-1 RNA above this level" indicates that HIV-1 RNA is detected, but the level present is above the upper quantification limit of this assay.

For the purpose of monitoring patient's response to antiretroviral therapy, the US Department of Health and Human Services Panel on Antiretroviral Guidelines for Adults and Adolescents defines virologic failure as a confirmed viral load above 200 copies/mL, which eliminates most cases of viremia resulting from isolated blips or assay variability. Confirmed viral load rebound (ie, >200 copies/mL) on 2 separate tests obtained at least 2 to 4 weeks apart should prompt a careful evaluation of patient's tolerance of current drug therapy, drug-drug interactions, and patient adherence.

Cautions

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

Although this quantitative HIV-1 RNA test is not FDA-approved for diagnostic purposes, the U.S. Department of Health and Human Services Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children recommends the use of molecular-based assays to detect HIV-1 RNA or proviral DNA for the diagnosis of HIV infection in infants under 2 years of age and born to HIV-infected mothers.

A single HIV-1 viral load test result should not be used as the sole criterion in guiding therapeutic decisions and intervention in the clinical care of individuals living with HIV-1. Viral load results should be correlated with patient symptoms, clinical presentation, and CD4 cell count. Due to the inherent variability in the assay, physiologic variation, and concurrent illnesses in the infected patients, less than 100-fold (<2 log) changes in plasma HIV-1 viral load should not be considered significant changes.

Viral load results of less than 20 copies/mL do not necessarily indicate absence of HIV-1 viral replication. Inhibitory substances may be present in the plasma specimen, leading to negative or falsely low HIV-1 RNA results. Improper specimen collection or storage may lead to negative or falsely lower plasma viral load results.

Although this commercial HIV-1 viral load assay is optimized for quantification of plasma viral load in HIV-1 infection due to HIV-1 groups M (subtypes A to H) and O strains, results generated from HIV-1 group O strains may be discordant (> or = 0.5 log copies/mL) with those obtained from other commercially available HIV-1 viral load assays. The assay is not reliable for quantifying plasma viral loads in infection caused by HIV-1 group N and HIV-2 strains.

ACD plasma specimens are not optimal for HIV-1 viral load testing because such plasma specimens show HIV-1 RNA levels that are approximately 15% lower than those collected in tubes containing EDTA. Plasma specimens stored frozen in plasma preparation tubes (PPT) are not suitable for HIV-1 viral load testing due to falsely high viral load results from release of intracellular HIV-1 nucleic acids (DNA and RNA) during the freezing process.

Clinical Reference

1. Kuhar DT, Henderson DK, Struble KA, et al. Updated U.S. Public Health Service Guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis. Atlanta, GA: U.S. Department of

Health and Human Services, CDC; 2013. Updated May 23, 2018. Accessed September 29, 2023. Available at http://stacks.cdc.gov/view/cdc/20711
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 September 29, 2023. Available at http://stacks.cdc.gov/view/cdc/23447
3. Gunthard HF, Saag MS, Benson CA, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2016 recommendations of the International Antiviral Society-USA Panel. JAMA. 2016;316(2):191-210. Available at https://jamanetwork.com/journals/jama/fullarticle/2533073
4. Panel on Antiretroviral Guidelines for Adults and Adolescents: Guidelines for the use of antiretroviral agents in adults and adolescents with HIV. U.S. Department of Health and Human Services. Updated September 1, 2022. Accessed September 29, 2023. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf

Performance

Method Description

The cobas HIV-1 assay is a US Food and Drug Administration-approved, in vitro nucleic acid amplification test for the quantification of HIV-1 RNA in human plasma using the cobas 6800 System or cobas 8800 System for fully automated viral nucleic acid extraction (generic silica-based capture technique) and automated amplification and detection of the viral nucleic acid sequence. This polymerase chain reaction (PCR) assay amplifies sequences within the *gag* gene and long terminal repeat (LTR) region of the HIV-1 genome and generates amplification products that are detected and quantified in real-time with 2 sequence-specific TaqMan probes. A non-HIV armored RNA quantitation standard (RNA-QS) is introduced into each specimen during sample preparation to serve as internal control for nucleic acid extraction and PCR amplification and detection processes. Fluorescent reporter dye-labeled TaqMan probes hybridized to the complementary HIV-1 target sequences and RNA-QS sequence undergo hydrolysis during PCR amplification step to generate fluorescent signal detected in 2 different dye channels. Concentration of the HIV-1 RNA in a patient's plasma sample is determined by a ratio of the intensity of the fluorescent dye from the cleaved HIV-1 target sequence probes and that from the RNA-QS target probe detected throughout the PCR process.(Package insert: cobas HIV-1-Quantitative nucleic acid test for use on the cobas 6800/8800 Systems; Roche Molecular Systems, Inc; Doc rev. 2.0, 12/2020)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

60 days

Performing Laboratory Location

Jacksonville

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 modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

87536

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PSHIV	HIV-1 RNA Pt Source, P	70241-5

Result ID	Test Result Name	Result LOINC® Value
65819	HIV-1 RNA Pt Source, P	70241-5