Lab Dept: Microbiology/Virology

Test Name: HIV-1 RNA Detection and Quantification, Plasma

General Information

Lab Order Codes:	HIVP
Synonyms:	HIV Monitor Test, RT-PCR; HIV-1 PCR; HIV-1 Quantitation, PCR; HIV-1 RNA, Viral Load; Human Immunodeficiency Virus, PCR; PCR, HIV-1 Quantitation; Quantitation, HIV Monitor Test RT-PCR; Viral Load, HIV-1 RNA; HIV-1 Quantitation Ultra Sensitive
CPT Codes:	87536 – HIV-1, quantification
Test Includes:	Detection of HIV-1 RNA either as undetected or reported in copies/mL.

Logistics

Test Indications:	Diagnosis of HIV-1 infection in individuals with acute or early HIV-1 infection. Diagnosis of HIV-1 infection in infants of <2 years of age born to HIV-1 infected mothers. Quantifying HIV-1 RNA levels (viral load) in HIV-1 infected individuals: ● Before initiating anti-HIV-1 drug therapy (baseline viral load) ● Who mnay have developed HIV-1 drug resistance while on anti-HIV-1 therapy ● Who may be non-compliant with anti-HIV-1 drug therapy Monitoring HIV-1 disease progression while on or off antiretroviral drug therapy.
Lab Testing Sections:	Microbiology/Virology - Sendouts
Referred to:	Mayo Medical Laboratories (MML Test: HIVQN)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	1 – 3 days, test set up Monday - Saturday
Special Instructions:	Specimen should be centrifuged and separated from cells within 2 hours of collection.

Specimen

Specimen Type:	Blood
Container:	Lavender top (EDTA) tube
Draw Volume:	4.5 mL (Minimum: 2.4 mL) blood
Processed Volume:	1.5 mL (Minimum: 0.8 mL) plasma
Collection:	Routine blood collection
Special Processing:	Lab Staff: Aseptically centrifuge the specimen, remove plasma aliquot and place in a screw-capped plastic vial within 2 hours of collection. Freeze immediately. Store and ship at frozen temperatures. Avoid specimen to specimen contamination. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Avoid freeze/thaw cycles; prolonged ambient temperature exposure; obvious microbial contamination; specimen to specimen contamination; incorrect anticoagulant, mislabeled or unlabeled specimens; specimens other than EDTA

Interpretive

Reference Range: Undetected

If detected, results are reported in copies/mL.

Interpretation: This assay has a plasma HIV-1 RNA quantification result range of 20 copies/mL to 10,000,000 copies/mL.

An “undetected” result indicates that the assay was unable to detect HIV-1 RNA with the plasma specimen.

A result of <20 copies/mL indicates that HIV-1 RNA is detected, but the level present is less than the lower quantification limit of the 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 the assay. However, the clinical implications of a viral load <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, less than 3 weeks from time of infection), or absence of HIV-1 infection (ie, false-positive).

A result of >10,000,000 copies/mL with the result comment of “HIV-1 RNA level is >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 United States Department of Health and Human Services Panel on

Antiretroviral Guidelines for Adults and Adolescents defines virologic failure as a confirmed viral load of >200 copies/mL, which eliminates most cases of viremia resulting from isolated blips or assay variability. Confirmed viral load rebound (ie, >200 copies/mL0 on 2 separate tests obtained at least 2-4 weeks apart should prompt a careful evaluation of patient's tolerance of current drug therapy, drug-drug interactions, and patient adherence.

Critical Values: N/A

Limitations: This test is not licensed by the Food and Drug Administration (FDA) as a screening test for HIV-1 infections 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 US Working Group on Antiretroviral Therapy and Medical Management of molecular-based assays to detect HIV-1 RNA or proviral DNA for the diagnosis of HIV infection in infants and <18 month 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 HIV-1-infected patients. 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, <100-fold (<2 log) change in plasma HIV-1 viral load should not be considered as significant change.

Viral load results of <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 falsely lower the plasma viral load results.

Although this commercial viral load assay is optimized for quantification of plasma viral load in HIV-1 infection due to HIV-1 group 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 strains or 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.

Methodology: Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

PCR is utilized pursuant to a license agreement with Roche Molecular Systems, Inc.

References:

Mayo Medical Laboratory May 2018

Updates:

4/21/2004: Test moved from Fairview University Diagnostic Laboratories forward to ARUP to Mayo Medical Laboratories.
8/10/2004: Ultra Sensitive was added to the test name.
8/19/2008: Ultra Sensitive removed from test name as per Mayo.
7/14/2009: Minimum volume of 1.2 mL plasma removed due to short sampling/QNS specimens. Instrument change at Mayo (COBAS AmpliPrep/COBAS TaqMan HIV-1)
5/4/2010: Minimum volume of 1.2 mL plasma reinstated.
1/3/2011: Minimum volume removed due to test cancellations.
6/26/2015: Updated PCR method at MML.
5/3/2018: Updated volume per MML.
10/20/22: Updated name per MML.