
Lab Dept: Microbiology/Virology

Test Name: HIV-1 RNA QUANTIFICATION W/REFLEX TO HIV-1 GENOTYPIC DRUG RESISTANCE

General Information

Lab Order Codes: HIVQG

Synonyms: HIV-1 RNA Quantification PCR

CPT Codes: 87536 – HIV-1, quantification, includes reverse transcription
87901 – HIV-1 genotypic drug resistance (if appropriate)

Test Includes: HIV-1 reported as undetected or detected levels will be reported in copies/mL. If the RNA titer is > or =500 copies/mL, then HIV-1 genotypic drug resistance mutations will be determined at an additional charge.

Logistics

Test Indications: Detecting and quantifying plasma HIV-1 RNA levels (viral load) in HIV-1 infected patients, followed by genotypic determination of viral resistance to anti-HIV drugs. Guiding initiation or change of antiretroviral regimens.

This test can be used for detection and diagnosis of HIV-1 infections, including in children <18 months of age when serologic tests are not useful (due to presence of maternal HIV antibodies).

Lab Testing Sections: Microbiology/Virology – Sendouts

Referred to: Mayo Medical Laboratories (Test: HIRGT)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 3 - 10 days

Special Instructions: Specimen must be centrifuged within 2 hours of collection.

Specimen

Specimen Type: Blood

Container: Lavender top (EDTA) tube

Draw Volume:	10.8 mL (Minimum: 6 mL) blood
Processed Volume:	3.6 mL (Minimum: 2 mL) plasma
Collection:	Routine venipuncture, invert tube several times to mix so no clots form. Send to Children's laboratory as soon as possible for shipping to the reference lab facility.
Special Processing:	Lab Staff: Centrifuge specimen. Remove plasma aliquot within 2 hours of collection. Store and ship at frozen temperatures on dry ice. Forward promptly.
Patient Preparation:	None
Sample Rejection:	Mislabeled or unlabeled specimens; sample collected in ACD yellow tube

Interpretive

Reference Range: Undetected

Interpretation:

HIV-1 detection and quantification: This assay has a plasma HIV-1 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 within the plasma specimen.

A result of <20 IU/mL indicates that HIV-1 RNA is detected, but the level present is less than the lower quantification limit of this assay. Due to 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, clinical implications of a viral load present (eg, in the range of 1-19 copies/mL), very early HIV-1 infection (ie, <3 weeks from the time of infection), or absence of HIV-1 infection (ie, false-positive).

A result of >10,000,000 with a 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 US 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/mL) on two separate tests obtained 2-4 weeks apart should prompt a careful evaluation of patient's tolerance of current drug therapy, drug-to-drug interactions, and patient adherence.

If the viral load is \geq 500 copies/mL, genotypic anti-HIV-1 drug resistance

mutation analysis is performed automatically at an additional charge. Sequence data of the patient's viral strain is compared with those in a database of known drug resistance mutations. Results are provided that highlight those codon changes associated with specific drug resistance. These mutations are categorized and reported.

Critical Values: N/A

Limitations: The HIV-RNA detection and quantification assay is not licensed by the 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 US Working Group of 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 <18 months of age and born to HIV-infected mother.

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) changes in plasma HIV-1 viral load should not be considered to be significant changes.

Viral load results <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 (≥ 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.

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

References: [Mayo Medical Laboratories Web Page](#) May 2018

Updates: 5/3/2018: Updated volume and processing information.