
Lab Dept: Microbiology/Virology

Test Name: HIV-1 DNA/RNA QUALITATIVE PCR

General Information

Lab Order Codes: HIVDR

Synonyms: HIV-1 DNA/RNA by PCR, Qualitative

CPT Codes: 87535 – HIV-1, amplified probe technique

Test Includes: HIV-1 reported as detected or undetected.

Logistics

Test Indications: Virologic detection of HIV-1 infection in infants <18 months of age (an age group for which serologic tests are unreliable) born to HIV-1 infected mothers.

Early detection of HIV-1 infection in children and adults who may be receiving combination antiretroviral prophylaxis or pre-emptive treatment.

Determining eradication of HIV-1 in individuals receiving combination highly active anti-retroviral therapies.

Lab Testing Sections: Microbiology/Virology – Sendouts

Referred to: Mayo Medical Laboratories (MML Test: HIVP)

Phone Numbers: MIN Lab: 612-813-6280

STP Lab: 651-220-6550

Test Availability: Daily, 24 hours

Turnaround Time: 1 - 10 days, test set performed Monday - Thursday.

Special Instructions: N/A

Specimen

Specimen Type: Whole blood

Container: Lavender top (EDTA) tube

Draw Volume: 3 mL (Minimum: 1.5 mL) blood

| | |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Processed Volume: | 1 mL (Minimum: 0.5 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 6 hours of collection. Store and ship at frozen temperatures. Forward promptly. |
| Patient Preparation: | None |
| Sample Rejection: | Mislabeled or unlabeled specimens |

Interpretive

Reference Range: Undetected

Interpretation: A detected result is consistent with HIV infection (see Limitations). Per CDC and USPHS recommendations, a second specimen should be collected from any patient with first-time detectable HIV-1 DNA or RNA result and tested to verify the diagnosis of HIV-1 infection.

An undetected result indicates that neither HIV-1 DNA nor RNA is detected in the specimen (see Limitations). Repeat testing in 1-2 months is recommended for those at risk of HIV-1 infection. The lower limits of detection (based on 95% detection rate) of this assay

An inconclusive result indicates that the absence or presence of HIV-1 DNA or RNA could not be determined with certainty after repeat testing of the clinical specimens in the laboratory, possibly due to PCR inhibition. Submission of a new specimen for testing is recommended.

Critical Values: N/A

Limitations: This assay should not be used as a screening test or primary diagnostic test for HIV-1 infection, except in infants <18 months of age born to HIV-1 infected mothers.

This assay is optimized for the detection of group M subtypes (A to H), N and O, but it may not detect all HIV-1 group N or O strains.

Diagnosis of HIV-1 infection should not rely solely upon a Detected result for HIV-1 DNA and/or RNA. Such a result should be considered in conjunction with a patient's clinical presentation, physical findings and other diagnostic laboratory tests prior to establishing a diagnosis. Undetected results should be interpreted with caution, considering the patient's risk factors for HIV-1 infection, the analytical sensitivity of the assay, and the group of the infecting HIV-1 strain. Follow up testing is recommended for high-risk patients with initially Undetected test results.

Undetected result together with repeatedly positive HIV-1 antibody supplemental test results may be observed in HIV-2 infected individuals.

For such patients with risk factors for HIV-2 infection, specific testing for HIV-2 antibodies (serologic) and HIV-2 DNA and/or RNA is recommended.

Methodology: Polymerase Chain Reaction (PCR)

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

Updates: 1/26/2018: Update TAT.