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 mpnths 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 (Test: HIVP)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	3 - 5 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 and other diagnostic laboratory tests prior to establishing a diagnosis. Undetected results should e 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 fo r 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 (August 2016)
Updates:	N/A