

TEST CHANGE

Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, Plasma 3000867, HIV QNT

Specimen Requirements:

Patient Preparation:

Collect: Lavender (EDTA), pink (K2EDTA), yellow (ACD), or plasma

preparation tube (PPT).

Specimen Preparation: Separate from cells within 24 hours of collection. Transfer 2 mL

plasma to an ARUP standard transport tube (ARUP supply #15824). Available online through eSupply using ARUP

Connect(TM) or contact ARUP Client Services at 800-522-2787.

Effective Date: October 21, 2024

(Minimum volume: 1.3mL) and freeze. (Min: 0.8 mL)

Transport Temperature: Frozen.

Unacceptable Conditions: Serum. CSF (refer to Human Immunodeficiency Virus 1 (HIV-1)

by Quantitative NAAT, CSF, ARUP test code 30178153000872).

Heparinized specimens.

Remarks:

Stability: After separation from cells: Ambient: 24 hours (Critical: Ship

FROZEN); Refrigerated: 6 days 72 hours; Frozen: 3 months

Methodology: Quantitative Polymerase Chain Reaction (PCR Transcription-

Mediated Amplification (TMA)

Performed: Sun-Sat

Reported: 1-4 days

Note: The limit of quantification for this assay is 1.3 log copies/mL

(20 copies/mL). If the assay DETECTED the presence of the virus but was not able to accurately quantify, the test will be

reported as "Not Quantified, Detected."

CPT Codes: 87536

New York DOH Approval Status: This test is New York DOH approved.

Interpretive Data:

Normal range for this assay is "Not Detected."

The quantitative range of this assay is 1.3047-7.00 log copies/mL (2030-10,000,000 copies/mL).



A result

An interpretation of "Not Detected" does not rule out the presence of inhibitors or HIV-1 RNA concentration below the level of detection of the <u>testassay</u>. Care should be taken in the interpretation of any single viral load determination.

Effective Date: October 21, 2024

This test is intended for use in conjunction with The clinical presentation and other laboratory markers for the clinical management significance of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment. concentration has not been fully established; however, a change of 0.5 log copies/mL may be significant.

This assay should not be used for blood donor screening, associated reentry protocols, or for screening human <u>cells</u>, <u>tissues</u>, <u>and cellular- or tissue-based products (HCT/P)</u>. <u>cell, tissues and cellular tissue-based products (HCT/P)</u>.

Note: The limit of quantification for this RNA assay is 1.47 log copies/mL (30 copies/mL). If the assay DETECTED the presence of the virus but was not able to accurately quantify the viral load, the test result will be reported as "<; 30 Detected."

Specimens received with less than minimum volume for testing will automatically be run with a dilution according to the guidelines below:

Specimens with 240-700 uL will be diluted resulting in a modification of the quantitative range of the assay to 1.95-7.48 log copies/mL (90-30,000,000 copies/mL).

This test is intended for use in conjunction with clinical presentation and other laboratory markers as an indicator of disease prognosis. This test is also used as an aid in assessing viral response to antiretroviral treatment as measured by changes in HIV-1 RNA concentration.

Reference Interval:

Not detected.