ARUP LABORATORIES

Quarterly HOTLINE: Effective November 12, 2018

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

Methodology: Quantitative Transcription-Mediated Amplification
Performed: Sun-Sat
Reported: 1-4 days

Specimen Required: Collect: Lavender (EDTA), Pink (K_2EDTA), 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 and freeze. (Min: 0.8 mL)
Storage/Transport Temperature: Frozen.
Unacceptable Conditions: Serum. CSF (refer to Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, CSF, ARUP test code 3000872). Heparinized specimens.
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 3 months

Reference Interval: Not detected

Interpretive Data: Normal range for this assay is "Not Detected".
The quantitative range of this assay is 1.47-7.00 log copies/mL (30-10,000,000 copies/mL).

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 assay. Care should be taken in the interpretation of any single viral load determination.
The clinical significance of changes in HIV-1 RNA 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 re-entry protocols, or for screening Human Cell, Tissues and Cellular Tissue-Based Products (HCT/P).

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 µL 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.

CPT Code(s): 87536

New York DOH Approved.

HOTLINE NOTE: Refer to the Test Mix Addendum for interface build information.