

TEST CHANGE

Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, CSF 3000872 HIVCSF ONT

Effective Date: October 21, 2024

3000872, HIVCSF QNT	
Specimen Requirements:	
Patient Preparation:	
Collect:	Cerebral spinal fluid.
Specimen Preparation:	Transfer 2 mL CSF to an ARUP <u>standard transport tube (ARUP supply #15824)</u> . Available online through eSupply using ARUP <u>Connect(TM)</u> or contact ARUP Client Services at 800-522-2787 (Minimum volumeStandard Transport Tube and freeze. (Min: 0.78 mL)
Transport Temperature:	Frozen
Unacceptable Conditions:	Plasma (refer to Human Immunodeficiency Virus 1 (HIV-1) by Quantitative NAAT, Plasma, ARUP test code 3000867).
Remarks:	
Stability:	Ambient: <u>24 hours (Critical: Ship FROZEN)</u> ; <u>Unacceptable</u> ; Refrigerated: 5 days; Frozen: <u>30 days 1 month</u>
Methodology:	Quantitative Polymerase Chain Reaction (PCR) Transcription-Mediated Amplification
Performed:	Sun-Sat
Reported:	1-4 days
Note:	The limit of quantification for this RNA assay is 1.747 log copies/mL (5030 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. Not Quantified." — 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 Codes:	87536
New York DOH Approval Status:	This test is New York DOH approved.



Normal range for this assay is "Not Detected".

The quantitative range of this $\underline{\text{test}}_{\text{assay}}$ is $1.\underline{70}_{\text{47}}$ -7.00 log copies/mL ($\underline{50}_{\text{30}}$ -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 <u>test</u> Care should be taken in the interpretation of any single viral load determination.

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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 <u>reentry protocols</u>, <u>or for screening human cells</u>, <u>tissues</u>, <u>and cellular- or tissue-based products (HCT/P)</u>. <u>re-entry protocols</u>, <u>or for screening Human Cell</u>, <u>Tissues and Cellular Tissue-Based Products (HCT/P)</u>.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Reference Interval:

Not detected