

HOTLINE: Effective May 20, 2019

New Test	3001474	Human Immunodeficiency Virus 1 (HIV-1) Qualitative by NAAT, Whole Blood	HIV QUAL
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Methodology: Qualitative Transcription Mediated Amplification
Performed: Tue-Sat
Reported: 2-5 days

Specimen Required: Collect: Lavender (EDTA) or Pink (K₂EDTA).
Specimen Preparation: Transport 1 mL whole blood. (Min: 0.4 mL)
Storage/Transport Temperature: Refrigerated.
Unacceptable Conditions: Heparinized specimens.
Stability (collection to initiation of testing): Ambient: Unacceptable; Refrigerated: 1 week; Frozen: 1 week

Reference Interval: Not detected

Interpretive Data: This test detects human immunodeficiency virus type 1 (HIV-1) RNA from Group M, N and O subtypes. A result of "Not Detected" does not rule out HIV-1 RNA concentrations below the limit of detection of the assay or the presence of inhibitors in the patient specimen. This assay may not detect HIV infection in infants during the first months of life. The diagnosis of HIV-1 infection should be made based on clinical presentation and results from additional diagnostic tests. Diagnosis should not be made based solely on a single HIV-1 test. Improper specimen handling can cause false negatives or contamination.

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).

See Compliance Statement B: www.aruplab.com/CS

Note: Assay detects HIV-1 virus RNA. Proviral DNA will not be detected.

CPT Code(s): 87535

New York DOH Approved.

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