

HOTLINE: Effective May 17, 2021

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**New Test**      **3003760**      **Human Immunodeficiency Virus 1 (HIV-1) by Qualitative NAAT**      **HIV1QUAL**

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

**Specimen Required:** Collect: Lavender (EDTA), Pink (K<sub>2</sub>EDTA), 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: Heparinized specimens.  
Stability (collection to initiation of testing): After separation from cells: Ambient: Unacceptable; Refrigerated: 72 hours; Frozen: 90 days

**Reference Interval:** Not detected

**Interpretive Data:**

This test detects human immunodeficiency virus type 1 (HIV-1) RNA from Group M, N and O subtypes; it does not detect HIV-1 proviral DNA. 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. The diagnosis of HIV-1 infection should not be made based solely on a single HIV-1 test result. Diagnosis requires repeat and confirmatory testing as recommended by U.S. Health and Human Services Guidelines. 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).**

**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.