

HIV

HIV-1 RNA by PCR - Quantitative

GA Test Code	875TQ
Method	<i>FDA-Approved</i> Abbott RealTime <i>in vitro</i> Reverse Transcription - Quantitative Real-Time Polymerase Chain Reaction (RT-qPCR)
Specimens	<p>Plasma - EDTA or ACD: 2.0 mL (1.0 mL), separated and frozen. Freshly drawn whole blood may be held at room temp for up to 6 hours or refrigerated for up to 24 hours, prior to centrifugation. After centrifugation, remove plasma from cells. Plasma specimens may be stored at room temp for up to 24 hours or refrigerated for up to 5 days. If longer storage is required, plasma specimens must be stored frozen. Ship specimen frozen on dry ice.</p> <p>Plasma - PPT: 2.0 mL (1.0 mL), centrifuged, room temp or refrigerated (<i>do not freeze in PPT</i>). PPT can be stored at room temp up to 48 hours or refrigerated up to 72 hours. If longer storage is required, transfer plasma to separate tube before freezing (stable up to 2 months).</p> <p>CSF: 1.0 mL (0.2 mL), refrigerated (up to 7 days) or frozen (2 months).</p>
Causes for Rejection	Quantity not sufficient (QNS) for analysis; plasma frozen in PPT; time and/or temperature instructions not followed as specified; blood collected in heparin.
Reference Range	Not Detected (< 40 copies/mL)
Quantitative Range	40 to 10,000,000 HIV-1 RNA copies/mL
Turnaround Time	1-4 Days
CPT Code	87536

Description

The Abbott RealTime HIV-1 assay is an FDA-approved *in vitro* reverse transcription-polymerase chain reaction (RT-PCR) assay for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) in human plasma from HIV-1 infected individuals.

Clinical Utility

The assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in assessing viral response to antiretroviral treatment as measured by changes in plasma HIV-1 RNA levels. It is the only test of its kind validated to detect and quantitate the common strains of HIV-1 as well as all known genetic variations of the virus, including group O, group N, and non-B subtypes. The test targets the highly conserved pol integrase region of the HIV-1 genome, giving the test its unique ability to detect and measure all known genetic variations of the virus. The assay also correlates well with other viral load tests, suggesting that it is not necessary to reestablish a baseline viral load for patients when changing to this test. This assay is not intended to be used as a donor-screening test for HIV-1 or as a diagnostic test to confirm the presence of HIV-1 infection. A specimen with a result of "No HIV-1 RNA Detected" cannot be presumed to be negative for HIV-1 RNA. As with any diagnostic test, results should be interpreted in conjunction with other clinical and lab findings.

Abbott Molecular Inc. Abbott RealTime HIV-1 Package Insert, List Number 6L18, 51-602146/R2, 2007.

Reuters. Abbott gets US FDA nod for RealTime HIV-1 viral load test, Aug 9, 2007.

Genetic Assays, Inc.