GENETIC ASSAYS
A Molecular Diagnostics Laboratory

HIV HIV-1 RNA by TMA - Quantitative

GA Test Code	**875TQ**
Method	***FDA-approved*** Hologic Aptima® HIV-1 Quant assay, using transcription-mediated amplification (TMA)
Specimens	**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. **Plasma - PPT**: 2.0 mL (1.0 mL), centrifuged, room temp or refrigerated *(do not freeze in PPT)*. 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). **CSF**: 1.0 mL (0.2 mL), refrigerated (up to 7 days) or frozen (2 months).
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 (< 12 copies/mL)
Quantitative Range	30 to 10,000,000 HIV-1 RNA copies/mL
Turnaround Time	1-4 Days
CPT Code	87536

Description

The Aptima HIV-1 Quant assay is an *in vitro* nucleic acid amplification test that uses transcription-mediated amplification (TMA) for the quantitation of Human Immunodeficiency Virus type 1 (HIV-1) RNA in human plasma from HIV-1 infected individuals. The assay quantitates HIV-1 RNA groups M, N, and O over the range of 30 to 10,000,000 copies/mL.
The Aptima HIV-1 Quant assay, through TMA, utilizes multiple, long primers that target several regions of the HIV-1 genome in order to compensate for the high mutation rate of HIV-1. The assay includes dual-target amplification and detection systems, targeting two regions of the HIV-1 genome (pol and LTR) independently. The assay software does not average the signals from the two systems. The dual target system is designed to increase the chances of accurately detecting and quantitating samples.

Clinical Utility

The Aptima HIV-1 Quant assay is intended for use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels. The 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.