

QUANTITATIVE HIV BY RT-PCR (QHIV-1)

Test Code: HIV-1

Use: The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 test, v2.0 quantifies HIV-1 viral RNA in HIV-1 M subtypes and HIV-1 group O.

Clinical Significance: The human immunodeficiency virus (HIV) is the etiologic agent of acquired immunodeficiency syndrome (AIDS) and is primarily transmitted by sexual contact, exposure to infected blood or blood products, or by an infected mother to her fetus. Once patients are infected with the virus, quantitative HIV-1 RNA measurement is a critical tool for disease management as well as the monitoring of antiretroviral therapy.

Methodology: The Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 test, v2.0 is based on three major processes: 1) specimen preparation to isolate HIV-1 RNA; 2) reverse transcription of the target RNA to generate complementary DNA (cDNA); and 3) simultaneous PCR amplification of target cDNA and detection of cleaved dual-labeled oligonucleotide detection probe specific to the target.

Normal Range: Not Detected

Reportable Range: 20 – 10,000,000 copies/mL of plasma

Interpretative Data:

Not Detected: Indicates that no HIV-1 viral nucleic acid was detected.

<20 cp/mL: Indicates that a small amount of viral nucleic acid was detected but is in quantities below the threshold for quantification.

>10,000,000 cp/ml: Indicates that the number of viral nucleic acid is above the upper limit of detection for this assay.

Assay Availability: HIV-1 assay is batched Monday – Friday, specific days are dependent on volume of tests.

Results Reported: 1 – 3 days

Specimen volume: Peripheral blood should be collected in a 6 ml Lavender top (EDTA) tube and sent to the laboratory immediately. A minimum of one milliliter of plasma is required to perform this test.

Storage: Send whole blood to the laboratory at room temperature. Samples may be stored at 2 – 6 °C for up to 24 hours prior to extraction. Longer storage requires that the plasma be separated from the cells under sterile conditions.

Causes for Rejection: Samples collected in heparin, or other non –approved collection tubes will be rejected. Samples received in the lab without proper identification will be rejected.

Laboratory Contact: For further information, please call the Molecular Diagnostics Laboratory at (501) 526-6439.