MAYO CLINIC LABORATORIES

TEST CHANGE

Notification Date: February 20, 2024
Effective Date: February 28, 2024

HIV-1 RNA Detection and Quantification, Plasma

Test ID: HIVQN; performed at Mayo Clinic Laboratories Florida.

Explanation:

Due to the availability of new testing options for detection of HIV-1 and/or HIV-2 to confirm the presence of HIV infection, this test will now be performed only as an FDA-approved assay for quantification of HIV-1 RNA in plasma for individuals with known or confirmed HIV-1 infection.

Current Test Classification	New Test Classification
This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.	This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

If confirmatory molecular HIV testing is needed, please select the alternative qualitative nucleic acid test below:

Recommended Alternative Test:

HIV-1/HIV-2 RNA Detection, Plasma

Test ID: HIP12

Methodology:

Real-Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

Reference Values:

Undetected

Questions

Contact Bonnie Meyers, Laboratory Resource Coordinator at 800-533-1710.