

HIV-1 RNA Detection and Quantification, Plasma

Test ID: HIVQN

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 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. |

| New Test Classification |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 James Conn, Laboratory Resource Coordinator at 800-533-1710.