HIV-1 Quantitation (Viral Load Testing)

Test Information

HIV-1 quantitation is the measure of the number of viral RNA genomes present per ml. of circulating plasma. The test is intended to be utilized to measure viral load in patients diagnosed with HIV infection. Viral load measurements may be used for several clinical applications including: prognostic assessment of newly diagnosed patients, consideration of when to initiate antiviral therapy, and criteria for changing therapy. The test is not intended as a screen or confirmatory test for HIV infection.

There have been several articles showing a correlation of high viral loads with increased risk of a more rapid progression to AIDS (Mellors 1995, O’Brien, Mellors 1996). Other publications have shown that a decrease in viral load is a predictor of treatment efficacy and present guidelines for utilization of viral load testing (Carpenter and Saag). Measurement of viral load is currently recommended at the time of diagnosis of HIV infection and every 3 to 4 months thereafter in untreated patients. For monitoring response to antiretroviral therapy the recommendations are: 1) Baseline (2 samples 2 to 4 weeks apart). 2) Post therapy (1 sample 3 to 4 weeks after initiation of changing therapy. 3) Long term (one sample every 3 to 4 months to determine if response to therapy is persisting.

Test Performance

The Roche Amplicor HIV-1 Monitor test is a nucleic acid amplification assay based on PCR (polymerase chain reaction). HIV-1 RNA is reverse-transcribed to DNA and the DNA is amplified, along with a control sequence, utilizing a PCR reaction. The quantity of HIV-1 RNA sequences is calculated by comparing the amplification of patient sample to the control sequences. Overall sensitivity of the Roche Amplicor HIV-1 test is 400 copies/ml with the linear range being between 400 and 750,000 HIV-1 RNA copies/ml. Sensitivity of the ultrasensitive modification of the test is 50 copies with a linear range from 50 to 50,000 copies/ml. Patient biological variation is 0.3 log_{10} and test variation is 0.2 log_{10}. Since this variation is additive, a change in virus level must be a minimum of 3-fold (0.5 log_{10}) to be considered significant.

Which Test to Order

For initial analysis of a patient order a standard test. After the initial test, order an ultrasensitive test if there is reason to believe that the patient’s viral load will be less than 400 copies/ml. The usual reasons are the following:
1) Patient has had a previous result ≤ 400 copies/ml.
2) Patient has had a previous result of ≤ 4000 copies/ml, their viral load has been dropping and the patient is on effective treatment.

The linear range of the two tests overlap over a wide range. There is no advantage to ordering an ultrasensitive test for patients whose viral load is over 400 copies/ml. Both tests have equal accuracy, however the standard test is faster and less time consuming for the laboratory to perform. If a standard test result is <400 copies/ml and there is sufficient specimen, an ultrasensitive retest may be subsequently performed. Call the laboratory directly to request this.

To order the appropriate test check the corresponding box on the voucher or laboratory form. Write in test description and test number on old laboratory slips.

Interpretation of Results

Below assay cutoff:
Standard assay: “HIV-1 RNA QUANTITATION: HIV-1 RNA NOT DETECTED. LESS THAN 400 COPIES/ML.”
Ultrasensitive: “HIV-1 RNA ULTRA-SENSITIVE QUANTITATION: HIV-1 RNA NOT DETECTED: LESS THAN 50 COPIES/ML.”
In assay linear range:
Standard: “HIV-1 RNA QUANTITATION: HIV-1 RNA DETECTED: COPIES/ML = _______”
Ultra-sensitive: “HIV-1 RNA ULTRA-SENSITIVE QUANTITATION: HIV-1 RNA DETECTED: COPIES/ML = _______”

Above linear range:
Standard assay: “HIV-1 RNA QUANTITATION: HIV-1 RNA DETECTED: COPIES/ML: >750,000”
Ultra-sensitive assay: “HIV-1 RNA ULTRA-SENSITIVE QUANTITATION: HIV-1 RNA DETECTED: COPIES/ML: >50,000”

Test order information

Name: HIV-1 RNA Quantitation Test Number: VH72
Test number: HIV-1 RNA Ultrasensitive Quantitation Test Number: VH72A
Normal value: HIV-1 RNA not detected
Specimen requirement: Blood in EDTA (lavender top tube), 3 ml minimum.
Specimen transport: Store whole blood at 2-25°C. Lab must receive specimen and complete processing within 6 hours.
Specimen Processing: Separate plasma from whole blood within 6 hours of collection. Centrifuge at 800-1600 x G for 20 minutes at room temperature. Transfer plasma to a sterile polypropylene tube and freeze at -20 to -80°C.
Turnaround time: 5 working days

References