MAYO CLINIC
Mayo Medical Laboratories

METHOD CHANGE
NOTIFICATION DATE: January 14, 2011
EFFECTIVE DATE: February 1, 2011

HIV-1 RNA Quantification, Plasma #81958

EXPLANATION: Effective February 1, 2011, this test will be performed using the FDA-approved Cobas AmpliPrep/Cobas TaqMan HIV-1 Test, version 2.0 from Roche Molecular Systems, Inc., Branchburg, NJ. This updated version of the real-time PCR assay will have improved ability to detect and quantify HIV-1 group M and O strains in plasma specimens from HIV-1-infected patients, with a wider quantification range (20 to 10,000,000 copies/mL) than the previous version of the assay (48 to 10,000,000 copies/mL).

IMPACT ON PATIENT CARE: Due to the increased sensitivity of this updated version of the assay, patients with previously low or undetectable HIV-1 viral load may show increased or detectable viral load with this assay. However, the clinical implications of a viral load below 50 copies/mL remain unclear.

For the purpose of patient monitoring, the U.S. Dept. of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents defines virologic failure as a confirmed viral load of >200 copies/mL, which eliminates most cases of viremia resulting from isolated blips or assay variability. Confirmed viral load rebound (ie, >200 copies/mL) on 2 separate tests obtained at least 2 to 4 weeks apart should prompt a careful evaluation of patient's tolerance of current drug therapy, drug-drug interactions, and patient adherence.

References:

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 10, 2011; 1–166. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.
2. Thompson MA, Aberg JA, Cahn P, et al. Antiretroviral treatment of adult HIV infection: 2010 recommendations of the International AIDS Society-USA panel. *J Am Med Assoc* 2010;304:321-333

NOTE: 1. There will be no change to specimen requirements, list fee, or CPT codes.
2. This will not require file definition changes to the test set-up.
3. This test is also part of MML unit code #89402.

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager
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