



NOTICE

Date: August 16, 2009

CORRECTION: Specimen Requirement

Dear Valued Clients:

Foundation Laboratory is pleased to announce that effective August 24, 2009 all HIV-1 viral load tests will be performed using the FDA-approved Roche COBAS® AmpliPrep/COBAS® TaqMan® replacing HIV-1 viral load manufactured by Siemens.

The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is a fully automated sample preparation, amplification and detection test that utilizes real-time PCR and fluorescence resonance energy transfer (FRET) to quantify Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human plasma. This test is intended for use in conjunction with clinical presentation and other laboratory markers of disease progress for the clinical management of HIV-1 infected patients. The test can be used to assess patient prognosis by measuring the baseline HIV-1 RNA level or to monitor the effects of antiretroviral therapy by measuring changes in EDTA plasma HIV-1 RNA levels during the course of antiretroviral treatment.

Regardless of how long ago the patient was diagnosed or the duration of treatment, the new dynamic range of this test delivers standard of care sensitivity (50 copies/mL) and quantification between 48 copies and 10,000,000 copies. This method increases the probability of detection and expands the coverage by targeting two highly conserved regions of the HIV-1 genome to compensate for the possibility of mutations or mismatches. The COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test is not intended for use as a screening test for the presence of HIV-1 in blood or blood products or as a diagnostic test to confirm the presence of HIV-1 infection.

The specimen requirement:

- Three (3) to four (4) mL of plasma specimens.
- Blood should be collected EDTA (lavender top) as the anticoagulant.
- **Sample collected in PPT tubes cannot be used for this test and have to be rejected.**

For supplies and other needs please make sure to contact your Foundation Laboratory representative.

Sincerely;

J. Kermani, MSMT (ASCP, NCA), Ph.D.
Director of Technical Operations