CPAL
Central **P**ennsylvania **A**lliance **L**aboratory

Technical Bulletin
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HIV-1 Real Time PCR Viral Load Assay

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Effective Date:
November 3, 2008
Mnemonic:
HIV VL
Performed:
Monday, Wednesday, Friday (days)
Specimen:
2mL K2/K3 EDTA Plasma Frozen Aliquot
(Separate plasma within 4 hours, freeze within 48hr)

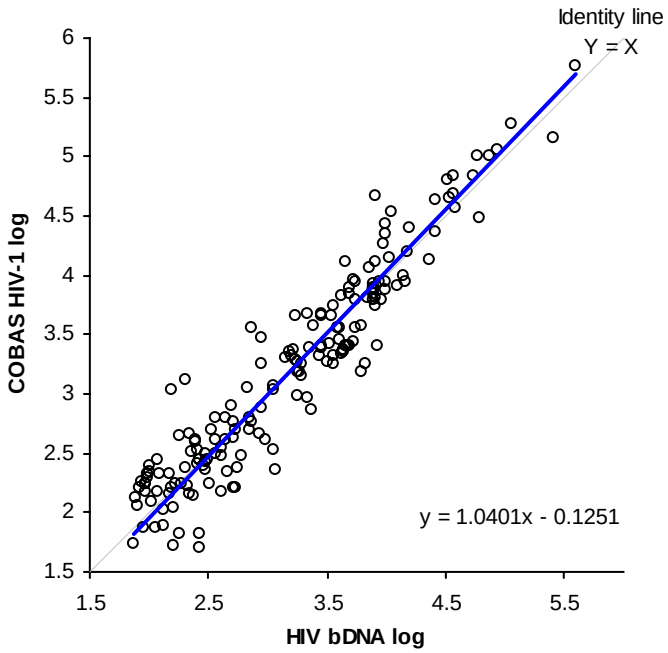
Summary:
Effective November 3, 2008 HIV-1 Viral Load testing will be performed at CPAL using Real-Time quantitative PCR.

CPAL has installed and verified the performance characteristics of the Roche Molecular Systems, Inc. COBAS® AmpliPrep®/COBAS® TaqMan® HIV-1 Test. This assay replaces the HIV-1 bDNA quantitative viral load assay and can quantitate HIV-1 RNA over the range of **48 to 5,000,000 copies/mL**. The assay is able to quantitate viral loads from each HIV-1 group M subtype A through H. (*The performance of the COBAS® AmpliPrep®/COBAS® TaqMan® HIV-1 Test has not been evaluated with specimens containing HIV-1 groups O and N, nor with specimens containing HIV-2*).

Verification studies included analysis of assay performance for 241 comparative specimens (bDNA vs Real Time PCR) and Acrometrix, Inc. ValiQuant Validation HIV-1 Panel. The reportable range of the assay was verified up to 5,000,000 copies/mL.

Deming regression analysis for the comparative specimens is presented below. This assay has been demonstrated to correlate very well with other versions of Roche HIV-1 Viral Load

assays (COBAS® AMPLICOR® HIV-1 MONITOR Test v1.5 and the COBAS® AmpliPrep/COBAS® AMPLICOR HIV-1 MONITOR Test v1.5) and also with the Versant HIV-1 RNA 3.0 Assay (bDNA). Correlation studies performed at CPAL verified that the assay performs as expected. An R^2 correlation coefficient of 0.8994 was obtained over an assay range of 1.875 to 5.60 Log10 HIV-1 RNA copies/mL. The slope of the regression line is 1.0401 (see below).



Notes:

1. Performance characteristics (as described in the Package Insert and verified at CPAL) of the Roche Molecular Systems, Inc. COBAS® AmpliPrep®/COBAS® TaqMan® HIV-1 Test have demonstrated that there is no need to re-baseline or recalibrate previously tested patients. This claim is supported by the manufacturer (see seperate letter from Michael Samozuk, MD, Chief Medical Officer and Tadd Lazarus MD, Medical Director, Roche Diagnostics Corporation) based on the correlation studies described in the Package Insert for the assay.
2. 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.
3. 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.