



CPAL

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HIV-1 Viral Load Assay Change (Dual Target Probes)

Contact:

Dr. Jeffrey Wisotzkey, 717-851-1422
Technical Director, CPAL

Jill Johns, MT(ASCP), SH, QCYM, 717-851-4320
Operations Manager, CPAL

Effective Date: December 6, 2010

New reference Range: <20 copies/mL

Summary: Effective December 6, 2010 CPAL will institute the next generation of HIV-1 viral load assay using real-time PCR. Recently, the recognition of increasing genetic diversity of HIV has highlighted the need to further evolve the design of next-generation real-time amplification tests. In order to address the risk of mutational escape, a novel PCR design (the dual target approach) was implemented resulting in co-amplification of two target regions of HIV-1. The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test, v2.0 is an in vitro nucleic amplification test that quantitates all major subtypes of HIV-1 Group M and HIV-1 Group O. Three primers and one probe from the HIV-1 Long Terminal (LTR) as well as four primers and one probe in the gag region target and amplify the two HIV-1 regions. Both the gag and the LTR region are phylogenetically highly conserved to ensure broad subtype coverage.

NOTE 1: The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test, v2.0 exhibits a higher level of sensitivity compared with the previous versions of the assay (The COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1) reporting values ≥ 20 cop/mL that were undetectable or below the limit of quantitation in these methods.

NOTE 2: Upon implementation of this assay and in concert with the implementation of the new Laboratory Information System (LIS) at CPAL, ordering institutions are reminded that graphical representations of the individual patient viral load histories can no longer be provided to our clients. Individual patient data should be evaluated using alternative mechanisms (ie individual institutional LIS software) as appropriate.

Correlation studies were conducted to verify the performance of the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test, v2.0, as compared to the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HIV-1 Test. Numerous studies were performed on samples and standards obtained from a variety of sources. One such study, head to head specimen comparison data (summary), is presented below for illustration.

