

Performance of the Aptima® HIV-1 Quant Dx Assay on the Panther System

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Abstract : The Aptima® HIV-1 Quant Dx Assay is a fully automated assay on the Panther system. It is based on Transcription-Mediated Amplification and real time detection technologies. This assay is intended for monitoring HIV-1 viral load in plasma specimens and for the detection of HIV-1 in plasma and serum specimens. Nine-hundred and seventy nine specimens selected at random from routine testing at St Thomas' Hospital, London were anonymised and used to compare the performance of the Aptima HIV-1 Quant Dx assay and Roche COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test, v2.0. Two-hundred and thirty four specimens gave quantitative HIV-1 viral load results in both assays. The quantitative results reported by the Aptima Assay were comparable those reported by the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0 with a linear regression slope of 1.04 and an intercept on -0.097. The Aptima assay detected HIV-1 in more samples than the Roche assay. This was not due to lack of specificity of the Aptima assay because this assay gave 99.83% specificity on testing plasma specimens from 600 HIV-1 negative individuals. To understand the reason for this higher detection rate a side-by-side comparison of low level panels made from the HIV-1 3rd international standard (NIBSC10/152) and clinical samples of various subtypes were tested in both assays. The Aptima assay was more sensitive than the Roche assay. The good sensitivity, specificity and agreement with other commercial assays make the HIV-1 Quant Dx Assay appropriate for both viral load monitoring and detection of HIV-1 infections.

Keywords : HIV viral load, Aptima, Roche, Panther system

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