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SaludMadrid

Instituto de Investigación Hospital 12 de Octubre

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Poster 571

Evaluation of the Aptima HIV-1 Quant Dx Assay for Monitoring of HIV-1 Viral Load by Transcription Mediated Amplification

Mónica García-Álvarez, Sagrario Zurita, Francisca Gutiérrez, Paula Aranguren, Samanta Aparicio and Rafael Delgado

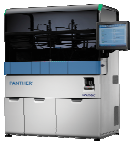
Molecular Microbiology Department. Hospital Universitario 12 de Octubre. Madrid. Spain

Background: Viral load monitoring of HIV-1 is critical for effective HIV-infection management. This has led to the development of HIV-1 quantitative assays to evaluate HIV disease prognosis and monitor the effectiveness of antiretroviral therapy. The Aptima HIV-1 Quant Dx is a quantitative assay based on real-time transcription mediated amplification (TMA) and detection, run on the fully automated and random access Panther System instrument (Hologic). The objective of this study was to evaluate correlation, linearity, reproducibility and performance characteristics of the Aptima HIV-1 Quant Dx Assay (Aptima) in comparison to the reference method, Roche cobas 6800 System (c6800).

Methods: For clinical reactivity correlation, 120 retrospective and 300 prospective collected plasma samples were tested in parallel in Aptima in side-by-side testing to the reference method cobas® HIV-1 6800. Linearity and reproducibility were assessed by replicate testing of serial dilutions of well-characterized clinical samples (5 replicates of seven dilution levels spanning the assay dynamic range), and an external proficiency panel (AcroMetrix™ HIV-1 panel). Subtype reactivity was addressed in Aptima by testing an external genotype panel (SeraCare HIV-1 Genotype). A workflow study was conducted to define the performance characteristics: protocols were designed to test different laboratory workflows when running HIV, HCV and HBV viral load assays on 3 different molecular diagnostics instruments (c6800, Veris and Panther).



Beckman DNx VERIS



Hologic Panther System



Roche cobas 6800

Contact information:
mgalvarez.imas12@h12o.es

Analytical Reactivity:

Correlation between Aptima and c6800 assays in a set of 100 clinical samples within the linear range of both techniques was 0.965 (**Fig 1**). The Bland-Altman mean difference estimate between the two methods was 0.24 Log cp/mL (**Fig 2**). Both systems demonstrated linearity over the dilution range (**Fig 3**). The intra-assay variability was 1.24% for c6800 and 1.76% for Aptima, and the mean coefficient of variation inter-assay was 1.52%. Specificity for Aptima on negative samples was 100%. Aptima allowed detection and quantification of all HIV-1 subtypes tested (**Fig 4**). Panther system allowed rapid and fully automated testings: average time to first result was 161 minutes and turn around time was the shortest at different scenarios (**Fig 5-7**).

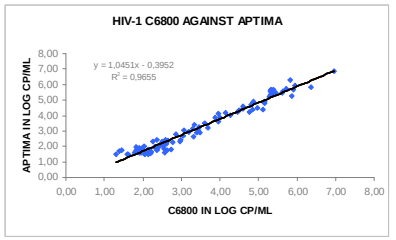


Figure 1. Linear correlation between c6800 and Aptima

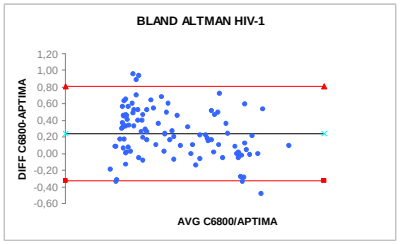


Figure 2. Bland Altman analysis c6800 vs Aptima

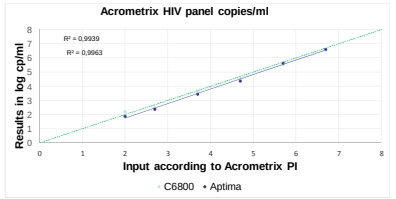


Figure 3. HIV-1 Linearity for c6800 and Aptima

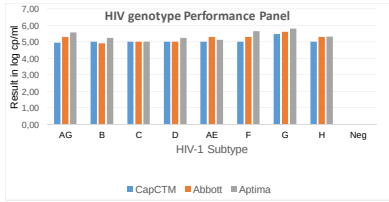


Figure 4. HIV-1 Genotype reactivity for Aptima

Workflow Study:

Figure 5: Scenario #1: Timeline for 101 Patients run in Batch Mode
59 HCV samples, 34 HIV samples, 8 HBV samples

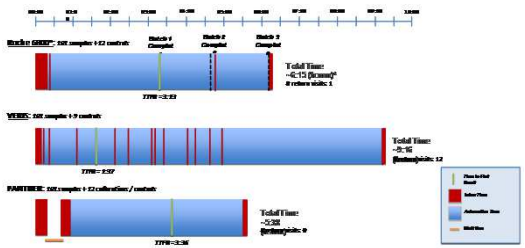


Figure 6: Scenario #2: Timeline for 82 Patients run Continuous Mode
24 HCV samples, 40 HIV samples, 18 HBV samples

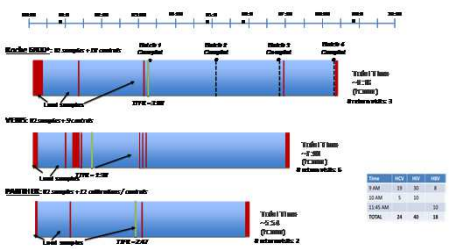
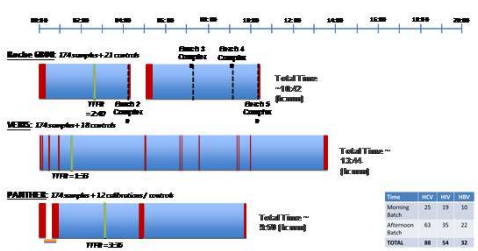


Figure 7: Scenario #3: Timeline for 174 Total Patients (Morning and Afternoon Deliveries)
88 HCV samples, 54 HIV samples, 32 HBV samples



Conclusions: The Aptima HIV-1 Quant Dx is a sensitive and reproducibility assay for monitoring of HIV-1 viral load. Random access, large capacity and improved time to result make the Aptima HIV-1 Quant Dx Assay run on the Panther System a good candidate for measuring viral load in HIV-1 infected patients.