Evaluation of the Hologic Aptima HIV-1 Quant Dx Assay With HIV-1 Subtypes

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Background: An important consideration in selection of HIV-1 viral load assays is the ability to detect and accurately quantify the diversity of current HIV-1 subtypes. In this study, we evaluated the quantitation of HIV-1 subtypes by a new Hologic Aptima HIV-1 Quant Dx Assay, which is currently in development, on the fully automated PANTHER System and compared it to that of the Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 v2.0 and the Abbott m2000 RealTime HIV-1 Assays.

Methodology: Assay performance to include precision, linear dynamic range, and lower limit of detection (LLOD) was evaluated using well-characterized panels of cultured virus spiked into HIV negative plasma. LLOD was determined by testing thirty replicates each of 2-fold serial dilutions of cultured subtype B virus at 100 to 1.5 copies/ml. Subtype sensitivity was evaluated on 62 previously subtyped plasma samples from Uganda, Kenya, Tanzania and Thailand and 171 HIV-1 isolates from 35 different countries. Samples diluted to ~1E5 copies/ml were tested using the Hologic Aptima, Roche TaqMan, and Abbott m2000 quantitative HIV-1 RNA assays.

Results: The Aptima assay demonstrated good linearity from 1E2 to 1E7 copies/ml, with R² values >0.992 for all subtypes. Assay accuracy was within 0.15 log of the target value of the secondary HIV-1 WHO standard. Probit analysis of serial dilutions of cultured HIV-1 established a LLOD of 3.1 copies/ml (50%) and 15 copies/ml (95%), with a precision of 10.4% at 100 copies/ml. Quantitation of HIV-1 subtypes by the Hologic assay agreed closely with those by the Roche and Abbott assays, and were within 0.5 logs in 94.8% and 84.9% of the samples, respectively; the remainder within 1 log of the Hologic measurement.

Conclusions: The Hologic Aptima HIV-1 Quant Dx Assay demonstrated excellent specificity, precision, sensitivity, and linear dynamic range. The assay was capable of accurate quantitation of all major HIV-1 subtypes including subtypes A, B, C, D, F, G, H, O, CRF01_AE, CRF02_AG and complex mixtures, with results comparable to that of the Roche TaqMan v2.0 and Abbott m2000 quantitative HIV-1 RNA assays. The fully automated assay is easy to perform, and results for at least 275 samples can be obtained within an 8 hour shift.