Abstract

Background:
The Hologic Aptima HCV Quant Dx Assay is a fully automated quantitative assay being developed on the Panther system, and is based on real-time Transcription-Mediated Amplification (TMA) technology. This assay is intended for detecting and monitoring hepatitis C virus (HCV) in plasma and serum specimens.

Methods:
A cohort of 490 clinical specimens from University of Athens Medical School was tested using the Aptima HCV Quant Dx Assay (Hologic assay), the COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 (Roche assay) and the Abbott RealTime HCV Assay (Abbott assay). The specimens included HCV genotypes 1, 2, 3, and 4, and ranged in concentration from 16IU/mL (1.20 log IU/mL) to 26.4 million IU/mL (7.42 log IU/mL) as measured by the Roche assay. Analytical sensitivity of the Aptima assay was assessed using dilutions of the 2nd WHO Standard (NIBSC 09/275) run in replicates of at least 100 per dilution on multiple Panther systems. Linearity of the Aptima assay was tested by dilution HCV 1a armored RNA from 10 to 100,000,000 IU/mL and testing in replicates of 5 on a single Panther system.

Results:
For the purposes of the clinical specimen correlation to the Abbott assay, a lower limit of quantitation for the Aptima assay of 12 IU/mL (1.08 log IU/mL) was used. Due to specimen volume constraints only 412 specimens could be tested using the Abbott assay from which 404 gave results above 12 IU/mL (1.08 log IU/mL). The slope was 1.05 (Aptima vs Abbott) with an intercept of 0.07 and an R2 of 0.97.

For the purposes of the clinical specimen correlation to the Roche assay, a lower limit of quantitation for the Aptima assay of 15 IU/mL (1.18 log IU/mL) was used. Four hundred and twenty-four (424) specimens gave results quantifiable for both Aptima and Roche assays. The slope was 1.07 (Aptima vs. Roche) with an intercept of -0.34 and an R2 of 0.97.

The analytical sensitivity (limit of detection) of the Aptima assay as measured by the dilutions of the WHO 2nd standard was 4.3 IU/mL for plasma and 3.9 IU/mL for serum using probit analysis and a 95% positivity rate. The Aptima assay was shown to be linear over the range of 10 to 100,000,000 IU/mL.

Conclusions:
The Aptima HCV Quant Dx Assay gave comparable viral load results when compared to the Roche COBAS AmpliPrep/COBAS TaqMan HCV Test, v2.0 and Abbott RealTime HCV Assay. The performance of the Aptima assay makes it an excellent candidate for the detection and monitoring of HCV.