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Paper Poster Session

Novel diagnostics for viral hepatitis

Comparison of the recently launched Hologic Aptima HCV Quant Dx assay with the established Abbott RealTime HCV assay in viral load measurement

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Background: Hologic's Aptima HCV Quant Dx assay is a HCV RNA quantitative assay based on real-time Transcription Mediated Amplification (TMA) that runs on the fully automated Panther system with random access. A comparison with the Abbott m2000 RealTime assay was performed. Special focus with clinical samples was put on linearity, reproducibility, viremia near the limit of detection, different genotypes, and in monitoring of treatment efficacy.

Material/methods: Fresh (n=173), frozen (n=130; from 30 patients therapy monitoring) and diluted (n=450) patient samples spread over the clinical relevant range were tested. Analytical sensitivity of the Aptima assay was assessed using dilutions of the AcroMetrix HCV standard (SKU963003) run in replicates of at least 10/dilution. Linearity of both assays was tested by dilution series of patient samples with HCV genotypes 1b, 3a and 4p from 6.78 to 2.78 log IU/mL in replicates of 5. Intra- and inter-assay variation was calculated by testing 30/20 samples in three dilution steps of genotypes 1a, 1b, 4a/3a, respectively.

Results: Aptima HCV Quant Dx assay showed excellent performance in high throughput routine, with a lower limit of quantification (LLOQ) of 10 IU/mL and a lower limit of detection (LLOD) of 4.3 IU/mL (plasma). Regression models demonstrated high concordance between the two assays for all genotypes. In the correlation analyses for all tested samples (1a I/II, 1b, 2, 3, 4, 5 and 6) the slope was 1.14 with an intercept of 0.34 and R² of 0.98. Bland Altman plots (Aptima minus RealTime) showed a mean difference of 0.322 with a trend to higher-quantification in the upper viral load range and lower quantification in the low end for the Aptima compared to RealTime. Linearity was proofed by serial dilution from 6.23log IU/mL to 2.23log IU/mL also with higher results for Aptima in the upper range. Intra- and inter-assay variation was low and comparable to RealTime with intra-assay %CV ranging from 2.5% for samples with a viral load of 3.0log IU/mL to 9.6% with 1.4log IU/mL. In monitoring of treatment efficacy at weeks 4, 8, 12 and SVR 12 of 30 DAA treated patients Aptima showed less often detectable results than RealTime in patients with successful treatment outcome.

Conclusions: The Aptima HCV Quant Dx assay showed good correlation with RealTime with higher sensitivity, linearity and accuracy for all tested HCV genotypes. The higher sensitivity of the Aptima assay could be drawn by the target capture technology used in RNA isolation. The phenomenon of higher results compared to RealTime in the upper end of viral loads was shown for Roche HPS/CTM as well (Cloherty et al. 2014). With random access and time to first result of about 150 minutes this assay is a major improvement in the viral load monitoring of HCV infection.