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Paper Poster Session

Novel diagnostics for viral hepatitis

Xpert® HCV viral load RT-PCR assay (Cepheid) for urgent sample hepatitis C virus quantification

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Background: Hepatitis C virus (HCV) RNA detection and quantification are the key diagnostic tools for the management of hepatitis C. Lately, Cepheid launched a HCV viral load *in vitro* monitoring assay for HCV-infected individuals undergoing antiviral therapy.

With a time to results of 105 minutes and a limit of detection of 4 IU/ml for HCV genotypes 1-6, this assay appears well suited for application in laboratory routine analyses not only for routine sample but also urgent specimens HCV screening, although not validated for it. Therefore, we evaluated this assay following the quality requirements (NF EN ISO 15189).

Material/methods: HCV viral load was evaluated by RT-PCR on GeneXpert® (Cepheid, Sunnyvale) and Cobas AmpliPrep®/Cobas TaqMan® HCV test (CAP/CTM, V 2.0 Roche Diagnostics, Indianapolis) using 20 pure or diluted plasma specimens from HCV infected individuals.

The precision of the assay was assessed through the repeatability (15 replicates of plasma pool with low and high HCV viral load and one lot of reagents) and the reproducibility (19 replicates by two operators and two different lots of reagents tested once per day). Inter units variability was rated using the results of repeatability. The coefficients of variation of log-normal distribution (lognormal CV %) were calculated for log-transformed data.

Xpert HCV Viral Load was compared to CAP/CTM HCV test for his ability to quantify HCV RNA in clinical specimens. Data were analysed using linear regression and Bland-Altman difference plot.

Results: In our study, data analysis of the repeatability demonstrated an excellent precision of Xpert HCV assay on both pool plasma specimens with an average viral load of 5.44 and 2.63 log UI/ml and lognormal CV of 28.1% and 30.6% respectively. The percentage of lognormal CV for the reproducibility was 25.7%. Inter-units variability for 2 samples was low with lognormal CV of 20.9 % and 27.4%.

Moreover, we found a good correlation between the Xpert HCV Viral Load and CAP/CTM HCV test with correlation coefficient, $r=0.984$. Linear regression analyses give an equation $y= 0.9935x -0.2894$ and $R^2= 0.967$ for the HCV viral load level of $1.0E+01$ to $6.04E+06$ IU/ml ($1.0 - 6.78$ log UI/m). The median difference on Bland Altman difference plot between Xpert HCV Viral Load and CAP/CTM HCV

assay was of -0.31 log IU/ml. Overall, we observe a good concordance between this HCV viral load quantification assay that yielded comparable results.

Conclusions: In conclusion, Cepheid's new Xpert HCV Viral Load assay demonstrates excellent performances for the management and measurement of HCV viremia in clinical specimens as well as urgent sample HCV testing. Taken the advantages of arbitrary access and prompt results, this assay seems ideally appropriate for urgent samples and daily routine analysis.