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

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Background

About 185 million people worldwide i.e. approximately 3% of the world's population have been infected with Hepatitis C virus (HCV)[1]. HCV RNA detection and quantification are the key diagnostic tools for the management of hepatitis C.

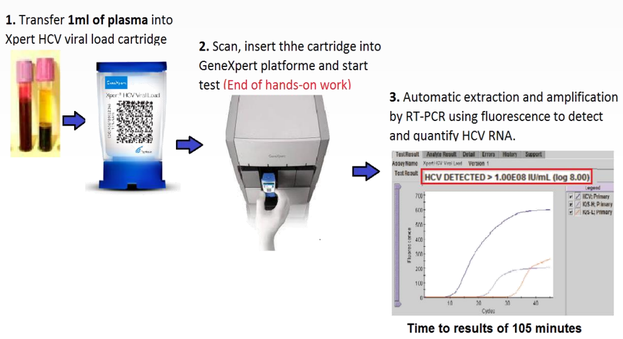
In 2014, Cepheid launched an on-demand HCV viral load assay for the monitoring of HCV infected patients undergoing an antiviral therapy.

With a time to result of 105 minutes and a limit of detection of 4 IU/ml for HCV genotypes 1-6, this technique appears well suited for both laboratory routine and urgent specimens for HCV screening.

Objectif

Evaluate and validate the analytical performances of **Xpert HCV viral load RT-PCR assay for HCV quantification on urgent samples** following the quality requirements (NF EN ISO 15189).

Materials & Methods



GeneXpert HCV viral load workflow

Assay accuracy was assessed through the:

- Repeatability (pooled plasma of low and high HCV viral load)
- Reproducibility (two operators and two different reagents lots tested once per day)
- Inter units variability

Correlation study:

Xpert HCV Viral Load results has been compared to Cobas AmpliPrep®/Cobas TaqMan® HCV test (CAP/CTM, Roche) using 20 raw or diluted plasma clinical specimens. Data were analysed by linear regression and Bland-Altman difference plot.

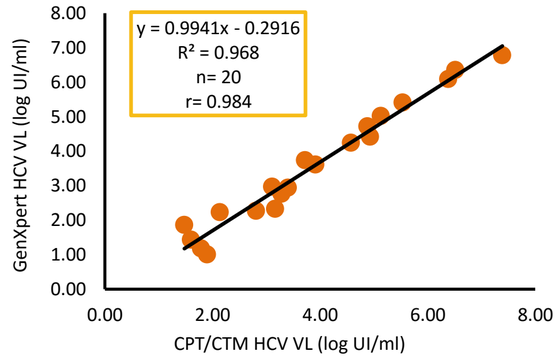
Results

- Data analysis show an excellent precision of Xpert HCV assay for the pooled plasma specimens. Coefficients of variation of log-normal distribution (lognormal CV %) were calculated form log-transformed data.

$$CV(of\ the\ lognormal\ dist) = \sqrt{10^{\ln(10)\cdot\sigma^2} - 1}$$

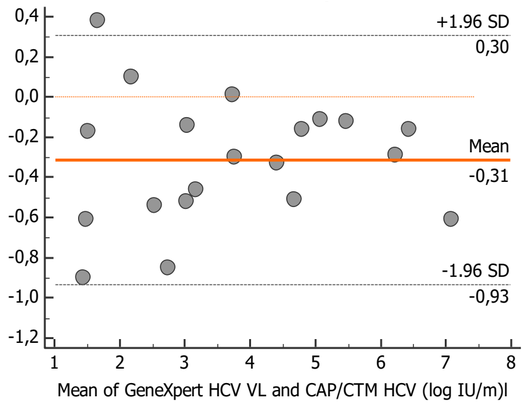
- Comparison of HIV-1 viral load of Xpert to CAP/CTM Roche assay demostrated a sustainable correlation between the results of this two assays for the HCV viral load level of 1.0E+01 to 6.04E+06 IU/ml (1.0 – 6.78 log UI/m).

	Repeatability		Reproducibility	Inter-units variability	
	Low HCV viral load	Higt HCV viral load	Plasma pool	Low HCV viral load	Higt HCV viral load
Replicates (n)	15	15	19	15	14
Mean (log UI/ml)	2.63	5.44	2.62	5.44	2.66
Standard Deviation	0.12	0.13	0.11	0.117	0.09
CV (of lognormal distribution)	30.60%	28.10%	25.70%	27.40%	20.90%



- Good concordance between the two viral load quantification assay with median difference between Xpert HCV Viral Load and CAP/CTM HCV test of -0.31 log.

Bland Altman plot



Conclusions

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

Bibliography

1. Mohd Hanafiah K, et al. Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence. Hepatology 2013; 57(4): 1333-42.

2. Cepheid (www.**cepheid**.com)

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