

Performance Evaluation of The GeneXpert HIV-1 Quant Assay For Detection of HIV-1 in Plasma

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Introduction

The HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems is designed for the rapid quantitation of HIV-1 in human plasma with an analytical range of 40 to 10,000,000 copies/mL for HIV-1 Group M subtypes A, C, D, AE, F, G, H, AB, AG, J, K and Groups N and O. Testing is performed in single-use disposable GeneXpert cartridges that hold the real-time reverse transcriptase polymerase chain reaction (RT-PCR) reagents and host the RT-PCR processes. This study assessed the performance of the system in routine plasma.



HIV-1 TaqMan v2 vs. GeneXpert (n=114)





Method



Bland-Altman graph for results between Not Detected-5000 c/mL. (n=64)



Bland-Altman graph for results between Not Detected-1000 c/mL. (n=39)

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<mark>ح 500 م</mark>	Bias	-58.19
	SD of bias	185.7

Results/Outcomes

Overall the HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems correlated with the routine analytical platform ($r^2 = 0.9333$)

Samples with valid results ranged:

- undetectable (16, 8.8%)
- below the benchmark test lower limit of detection (<20 copies/mL) (10, 7.9%)
- low range (20 5,000 copies/mL) (43, 33.1%)
- medium (5,000 50,000 copies/mL) (24, 18.5%)

To date, a total of 130 plasma samples have been tested over the analytical range and compared to a benchmark real-time PCR system – the Roche COBAS AmpliPrep/COBAS TaqMan system (CAP/CTM)

Seventy four samples (56.9%) were of a known subtype comprising of subtype B (37.6%), AE (7.7%), C (4.6%), AG (1.5%) and mixed (4.6%).

Additional samples consisting of an external quality control samples run over multiple days, and samples with HIV-1 RNA not detected or below the lower limit of the assay were also tested to assess performance.

HIV-1 RNA result (cpy/mL)	Number of samples
Low range (Not Detected - 5,000)	68
Medium range (5,001 – 50,000)	35
High range (>50,000)	27

• high range (>50,000 copies/mL) (29, 22.3%)

Thirteen samples (10%) were invalid as a result of insufficient sample (<1 mL).

Samples in the lower analytical range of <1,000 copies/mL showed little variance when compared to Roche CAP/CTM using Bland Altman analysis.

Reproducibility was assessed in the high, medium and low range with-in 1-2 SD of the mean.

Sixteen replicates of a commercial external quality control sample, Acrometrix HIV-1 Low Control, showed very good reproducibility.







Conclusions

HIV subtype distribution. (n=130)



The HIV-1 Quant Assay performed on the GeneXpert® Instrument Systems correlated with a commonly used HIV RNA test in plasma and offered significant workflow advantages.

Time to result is approximately 90 minutes.

Sample required is 1 mL plasma.

The system has a small footprint and requires no further consumables other than the singleuse test cartridges.

Further studies are planned to fully assess the assay performance.