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Paper Poster Session III

HIV/AIDS

"Performance of the Cepheid Xpert® HIV-1 VL compared to the Abbott RealTime HIV-1 viral load measurement"

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Background:
The GeneXpert® platform is well established for performing different molecular diagnostics assays. The ease of usage, the random access capability and the rapid turn-around time make the platform very interesting for a broad spectrum of applications. We compared the newly developed Xpert® HIV-1 VL assay to the broadly used Abbott m2000 RealTime HIV-1 viral load assay. Special focus was put on reproducibility of results in the low viral load range and linearity in HIV-1 subtype B and non-subtype B viruses.

Methods:
Fresh (n=100) and diluted (n=225) patient samples spread over the clinical relevant range of viral load with a focus on low viremia were tested. The Xpert® HIV-1 VL uses the same cartridge format as the other assays on the GeneXpert® platform.

Fresh samples from daily clinical routine were tested in direct comparison to the Abbott m2000 RealTime HIV-1 viral load assay. Three high viral load samples from different HIV-1 subtypes (B, CRF01_AE, CRF02_AG) were diluted to following target concentrations: 100000 cop./ml, 10000 cop./ml, 1000 cop./ml, 500 cop./ml, 250 cop./ml, 125 cop./ml, 63 cop./ml, 31 cop./ml and 15 cop./ml. Each dilution step was tested in 5 replicates. To better assess reproducibility in the low ranges, dilutions with 250 cop./ml, 125 cop./ml, 63 cop./ml were tested in 10 replicates with the Xpert® HIV-1 VL and the Abbott m2000 RealTime HIV-1
Results:79 of the fresh samples were below the detection limit of 40 cop./ml in the Xpert® HIV-1 VL and 82 of the samples were below the detection limit of 40 cop./ml in the Abbott m2000 RealTime HIV-1. While only 11 of those samples showed a detection signal with RealTime HIV-1, 22 samples showed a detection signal with the Xpert® HIV-1 VL leading to an overall concordance of 77%.

Intra- and inter-assay variation was low and comparable to RealTi*m*e with intra-assay %CV ranging from 2.5% for samples with a viral load of 2.4 log cps/ml to 7.8% with 1.8 log cps/ml.

Linearity on the diluted samples could be show by using a simple linear regression model with a slope of 0.99, intercept of 0.07 and a coefficient of determination (R^2) of 0.99.

Conclusions:
A high correlation between the Abbott m2000 RealTime HIV-1 and the Xpert® HIV-1 VL could be shown. The higher detection rate below detection limit might hint to a higher sensitivity of the Xpert® HIV-1 VL. The assay showed excellent linearity and robust reproducibility.

The random access capability and the rapid time to result of only 90 minutes make the GeneXpert® platform and the Xpert® HIV-1 VL a valuable tool in clinical routine, especially for urgent samples.