



affigene® HBV treader in QCMD proficiency program

Background

Quality Control for Molecular Diagnostics (QCMD) specialises in the standardisation and Quality Control for molecular diagnostics and genomic technologies. A proficiency panel for Hepatitis B virus (HBV) was sent out in early 2005 to 116 participants. 122 datasets were submitted of which 39 were analysed with commercial real-time PCR assays, and of these, six were analysed using affigene® HBV treader.

Material and methods

The QCMD HBV panel 2005 consisted of eight samples, with varying HBV viral concentration. The concentration was unknown to the operator at the time of analysis.

The QCMD panel was prepared at six occasions using affigene® DNA extraction. Subsequently, the samples were analysed by real-time PCR using affigene® HBV treader on the Mx3000P instrument (Stratagene, La Jolla, CA).

Viral loads were calculated utilising the affigene® analysis software.

Results and discussion

Of the eight blinded samples, one was expected to be a negative HBV sample. The other samples ranged from 10^3 copies/ml to 10^6 copies/ml.

For the qualitative performance of the panel QCMD used a scoring system where a correct result gives 2 points and all other results give 0 points. A maximum score of 16 points was attainable. The scoring for each of the six affigene® HBV treader data sets was 16.

The mean scoring for the 39 data sets analysed with commercial real-time PCR assays was 15.54.

Scoring mean commercial real-time PCR assays (n=39)	Scoring affigene® HBV treader (n=6)	Max scoring
15.54	16	16

Table 1

The table describes the mean scoring for the reported results of all commercial real-time PCR assays used in the QCMD CMV panel 2005 as well as the scoring for the two data sets analysed with affigene® CMV treader. The maximum scoring is also shown.

Figure 1 displays the quantitative results of the HBV proficiency panel. The viral load is plotted versus QCMD sample number. The figure shows the expected viral load, the reported mean of viral loads reported from the 39 data sets analysed with commercial real-time PCR assays and the results from the six affigene® HBV treader data sets. The samples in all six data sets analysed with affigene® HBV treader were within 0.5 log-values from expected viral load except for two data sets where sample 5 was quantified between 0.52 and 0.66 log-values too high and sample 6 that was quantified between 0.52 and 0.60 log-values too high compared to expected viral load. The reported range of viral load was shown as ± 1 SD of the mean for all data sets analysed with commercial real-time assays. All samples in the six data sets from affigene® HBV treader were within this range. The imprecision of the measurements using the affigene® HBV treader assay was defined by the standard deviation of the six data sets. The imprecision was below 0.25 log-values for all samples except sample 6 which had an SD of 0.35.

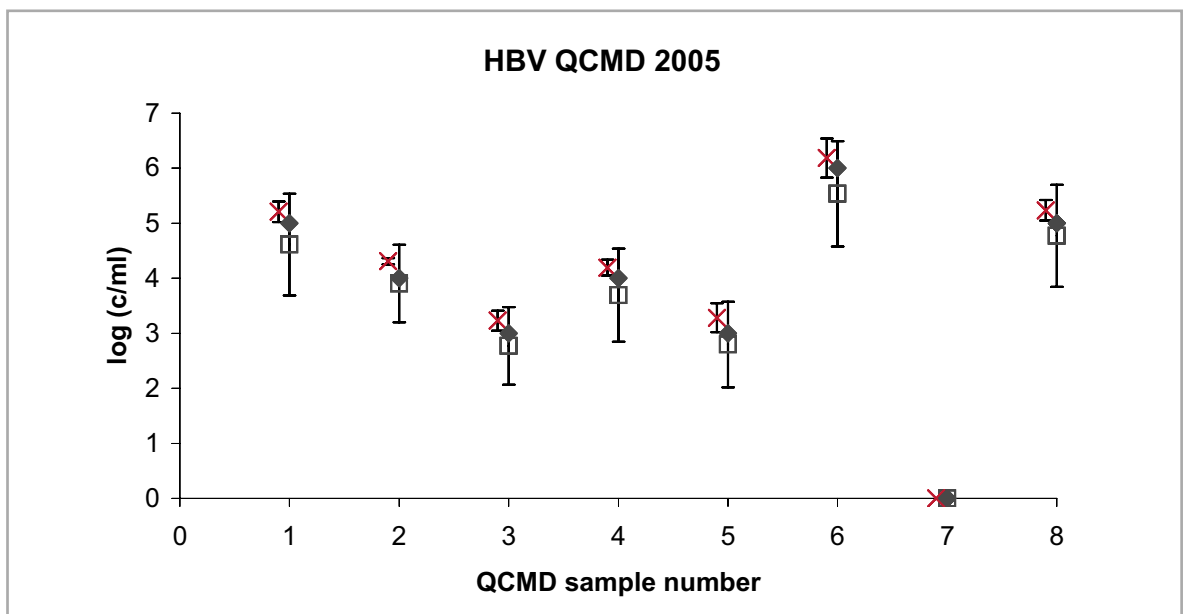


Figure 1. Results of the 2005 QCMD HBV panel.

The expected viral load is displayed as a closed box (◆). The reported mean viral load from 39 data sets analysed with commercial real-time PCR assays is shown as an open box (□) with error bars (shown as ± 1 SD of the log mean of all 39 data sets). The six affigene® HBV treader data sets are displayed as the mean (×) with error bars (shown as ± 1 SD of the log mean of 6 data sets).

Conclusion

- The affigene® HBV treader assay performed well in the QCMD HBV proficiency panel 2005.
- The qualitative performance of the assay show the highest possible score for all of the six data sets, meaning 100% correlation to the qualitative result.
- The quantitation was almost always within 0.5 log-values from expected viral load
- The results from all data sets were within ± 1 SD of the reported range of viral loads.
- The imprecision of the assay, for all but one sample, was less than 0.25 SD.