

affigene® HSV 1/2 tracer 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 Herpes Simplex viruses (HSV) 1 and 2 was sent out in 2005 to 130 participants. 140 datasets were submitted back to QCMD. Of these 26 were analysed with commercial real-time PCR assays. Two data sets were analysed at SMD using affigene® HSV 1/2 tracer.

Material and methods

The QCMD HSV panel 2005 consisted of twelve samples, with varying HSV-1 or HSV-2 concentration. The concentration was unknown to the operator at the time of analysis. The QCMD panel was prepared at two occasion using affigene® DNA extraction. Subsequently, the samples were analysed by real-time PCR using affigene® HSV 1/2 tracer on the Mx3000P instrument (Stratagene, La Jolla, CA). The samples were analysed based on the qualitative results.

Results and discussion

Of the twelve blinded samples, three were expected to be negative HSV samples. The other samples ranged from 580 copies/ml to 5.8×10^6 copies/ml of either HSV-1 or HSV-2. For the qualitative performance of the panel QCMD used a scoring system where a correct result gave 2 points and all other results gave 0 points. A maximum score of 24 points was attainable. One of the two affigene® HSV 1/2 tracer data sets scored the total of 24 points. Whereas the scoring for the other data set was 22. In the latter case one of the samples (no 9) was detected as a mix of HSV-1 and HSV-2. However, the Ct-value for HSV-1 was late (>40). The expected status of this sample was HSV-2. The mean scoring for the 26 data sets that were analysed with commercial real-time PCR assays was 21.3 (see table 1).

Scoring mean commercial real-time PCR assays (n=26)	Scoring affigene® HSV 1/2 tracer (n=2)	Max scoring
21.3	23	24

Table 1

The table describes the mean scoring for the reported results of all commercial real-time PCR assays used in the QCMD HSV panel 2005 as well as the scoring for the two data sets analysed with affigene® HSV 1/2 tracer. The maximum scoring is also shown.

Conclusion

- The affigene® HSV 1/2 tracer assay performed well in the QCMD HSV proficiency panel 2005.
- The qualitative performance of the assay shows a mean score of 23 where one sample is one data set was detected with low levels of HSV-1, as well as HSV-2, in an expected pure HSV-2 sample.