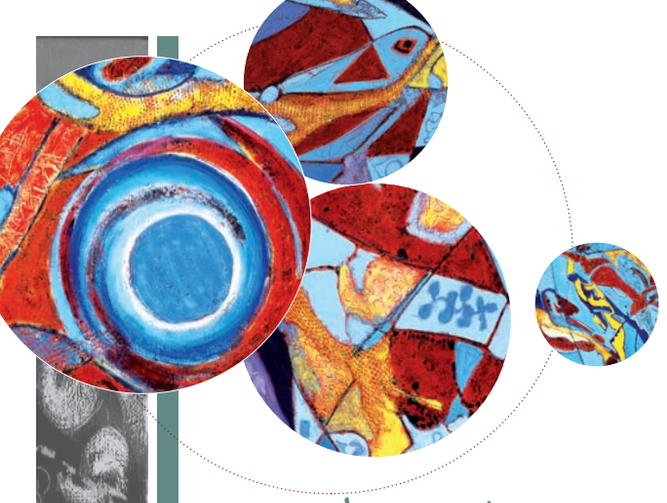

ARGENE

QCMD proficiency panels 2013

Herpes Simplex Viruses

Panel composition

This EQA panel for the detection of Herpesvirus 1/2 (HSV-1 and HSV-2) consisted of 4 samples containing various concentrations and strains of HSV-1, 4 samples containing various concentrations and strains of HSV-2, 1 sample of VZV and 1 negative sample.

Material and methods

The QCMD panel was prepared using NucliSENS® easyMAG® (bioMérieux) for sample extraction with Specific B protocol (200/50).
Subsequently, the samples were analysed by real-time PCR using the HSV1- and HSV2- specific premixes of **HSV1 HSV2 VZV R-gene®** (bioMérieux - ref.: 69-004B) on Dx Real Time System (Bio-Rad).

Results and discussion

	QCMD Results				HSV1 HSV2 VZV R-gene® Results	
Panel code	Sample Content	Sample Type*	Copies/mL	Log_{10} Copies/mL	Log_{10} Copies/mL	Delta Log_{10} Copies/mL)
HSVDNA 13-01	HSV-1 (95/1906)	Core	9,795	3.99	3.97	-0.02
HSVDNA 13-02	HSV-2 (MS)	Core	6,353	3.80	2.83	-0.97
HSVDNA 13-03	HSV-2 (09-015681)	Core	4,335	3.64	2.74	-0.90
HSVDNA 13-04	HSV-1 (MacIntyre)	Educational	189	2.28	2.16	-0.12
HSVDNA 13-05	HSV-2 (MS)	Educational	249	2.40	Negative	NA
HSVDNA 13-06	HSV Negative	Core	Negative	Negative	Negative	NA
HSVDNA 13-07	HSV-1 (MacIntyre)	Core	9,840	3.99	4.01	0.02
HSVDNA 13-08	HSV-1 (95/1906)	Core	490	2.69	2.72	0.03
HSVDNA 13-09	HSV-2 (09-015681)	Educational	91	1.96	0.95	1.01
HSVDNA 13-10	VZV	Core	Negative	Negative	Negative	NA

«The QCMD EQA panels contain a range of samples, designed to look at different aspects of assay performance. Panel members are designated 'core proficiency samples' on the basis of scientific information, clinical relevance and clinical experience (...). Laboratories are expected to correctly analyse and report the core proficiency samples in order to show acceptable proficiency.» QCMD 2013 general announcement
Consequently, the educational samples are considered as challenging due to very low concentrations. They are clearly detection limits.

- **The 3 "Core" positive HSV-1 samples of HSV 2013 Panel are detected with HSV1 HSV2 VZV R-gene®.**
- **The 2 "Core" positive HSV-2 samples of HSV 2013 Panel are detected with HSV1 HSV2 VZV R-gene®.**
- **The 2 "Core" negative samples, including a VZV-positive sample, are undetected as expected with the premixes specific for HSV-1 and HSV-2 in HSV1 HSV2 VZV R-gene®.**
- **2/3 "Educational" sample (i.e. challenging sample), corresponding to a low HSV-1 positive sample (189 copies/mL) and a very low HSV-2 positive sample (91 copies/mL), are detected on parameter. The undetected "Educational" sample (i.e. challenging sample) corresponds to a low HSV-2 positive sample (249 copies/mL).**
- **In the absence of an International Standard for HSV-1 and HSV-2, quantifications obtained in copies/mL with different methods are difficult to compare due to a lack of standardization of quantification.**
- **The results show the good sensitivity and specificity of the HSV1 HSV2 VZV R-gene® (ref.: 69-004B).**

Sensitivity of HSV1 HSV2 VZV R-gene®

Analytical sensitivity has been performed on a cell culture infected with HSV-2 (ATCC strain VR-734).
The results have shown :

- a 95% probability to detect HSV-2 in a sample containing 70 copies/mL
- a 5% probability to detect HSV-2 in a sample containing 50 copies/mL.

"The data presented in this document illustrates the performance of the HSV1 HSV2 VZV R-gene® assay when testing the HSV DNA EQA 2013 QCMD panel. The results are not representative of the QCMD EQA program report and full details on the QCMD EQA program can be obtained from the QCMD website (www.qcmd.org)".

BIOMÉRIEUX

HSV1 HSV2 VZV R-gene®