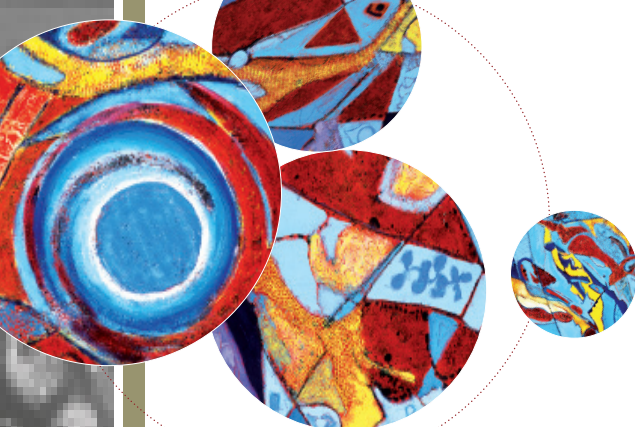


HCoV / HPIV



Panel composition

The EQA panel for the detection of Coronavirus consisted of 9 samples containing various concentrations of Coronavirus OC43, NL63 & 229E and 1 negative sample. The EQA panel for the detection of Parainfluenzavirus consisted of 9 samples containing various concentrations of Parainfluenzavirus 1, 2, 3 & 4 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 HCoV/HPIV r-gene® (bioMérieux - ref.: 71-045) on Dx Real-Time System (Bio-Rad).

Results and discussion

	QCMD Results				HCoV/HPIV r-gene® Results	
	Panel code	Sample Content	Sample Type*	Dilution factor	HCoV Ct (530 nm)	HPIV Ct (560 nm)
Panel HCoV 2013	CV 13-01	Coronavirus - OC43	Educational	1.0 x10 ⁻⁶	37.12	Negative
	CV 13-02	Coronavirus - NL63	Core	1.0 x10 ⁻³	25.19	Negative
	CV 13-03	Coronavirus - OC43	Core	1.0 x10 ⁻⁵	33.81	Negative
	CV 13-04	Negative	Core	-	Negative	Negative
	CV 13-05	Coronavirus - NL63	Educational	1.0 x10 ⁻⁵	31.88	Negative
	CV 13-06	Coronavirus - 229E	Educational	1.0 x10 ⁻⁶	36.00	Negative
	CV 13-07	Coronavirus - NL63	Core	1.0 x10 ⁻⁴	28.39	Negative
	CV 13-08	Coronavirus - 229E	Core	1.0 x10 ⁻⁵	32.30	Negative
	CV 13-09	Coronavirus - OC43	Core	1.0 x10 ⁻⁴	30.67	Negative
	CV 13-10	Coronavirus - 229E	Core	1.0 x10 ⁻⁴	28.47	Negative

	QCMD Results				HCoV/HPIV r-gene® Results	
	Panel code	Sample Content	Sample Type*	Expected results	HCoV Ct (530 nm)	HPIV Ct (560 nm)
Panel HPIV 2013	PINF 13-01	Parainfluenza virus Type 2	Core	Positive	Negative	31.13
	PINF 13-02	Parainfluenza virus Type 1	Educational	Positive	Negative	37.75
	PINF 13-03	Parainfluenza virus Type 3	Core	Positive	Negative	27.52
	PINF 13-04	Parainfluenza virus Type 1	Educational	Positive	Negative	42.11
	PINF 13-05	Parainfluenza virus Type 2	Educational	Positive	Negative	40.54
	PINF 13-06	Parainfluenza virus Type 1	Core	Positive	Negative	34.89
	PINF 13-07	Negative	Core	Negative	Negative	Negative
	PINF 13-08	Parainfluenza virus Type 4	Educational	Positive	Negative	35.98
	PINF 13-09	Parainfluenza virus Type 2	Core	Positive	Negative	28.46
	PINF 13-10	Parainfluenza virus Type 1	Educational	Positive	Negative	Negative

* «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-2012-general-announcement. Consequently the educational samples are considered as challenging due to very low concentrations, they are clearly detection limits.

- The 6 "Core" positive Coronavirus samples of Panel CV RNA 2012 and the 4 "Core" positive Parainfluenza virus samples of the Panel PINF RNA 2013 are detected with hCoV/hPIV r-gene®.
- The "Core" negative samples of both panels are undetected as expected with HCoV/HPIV r-gene®.
- 4/5 "Educational" HPIV samples (i.e. challenging samples) and all 3 "Educational" HCoV samples (i.e. challenging samples) are detected with hCoV/hPIV r-gene®.
- The results show the good sensitivity and specificity of the HCoV/HPIV r-gene®- ref 71-045.

Sensitivity of HCoV/HPIV r-gene®

Analytical sensitivity of the HCoV/HPIV r-gene® (bioMérieux) has been evaluated through a limit dilution method. The results indicate :

- a LoD₉₅ of 0.20 TCID₅₀/mL for Coronavirus 229E
- a LoD₉₅ of 86.85 TCID₅₀/mL for Coronavirus OC43
- a LoD₉₅ of 0.002 TCID₅₀/mL for Coronavirus NL63
- a LoD₉₅ of 18.07 cp/mL for Coronavirus HKU1
- a LoD₉₅ of 379.79 TCID₅₀/mL for Parainfluenzavirus 1
- a LoD₉₅ of 529.93 TCID₅₀/mL for Parainfluenzavirus 2
- a LoD₉₅ of 245.28 TCID₅₀/mL for Parainfluenzavirus 3
- a LoD₉₅ of 0.21 TCID₅₀/mL for Parainfluenzavirus 4

"The data presented in this document illustrates the performance of the HCoV/HPIV r-gene® assay when testing the Coronavirus and the Parainfluenzavirus RNA EQA 2013 QCMD panels. 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)." 