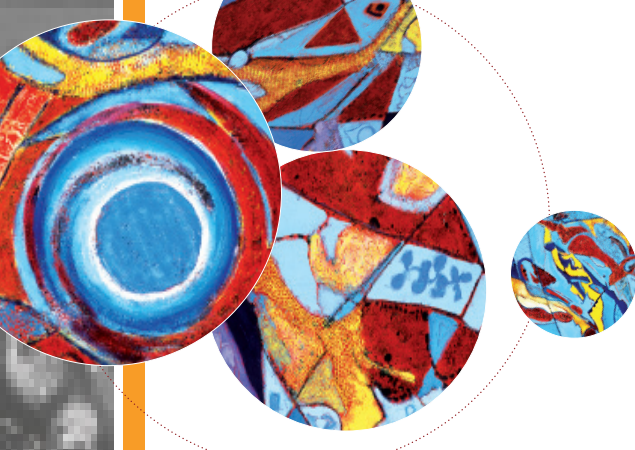


Bordetella pertussis



Panel composition

This EQA panel for the detection of *Bordetella pertussis* consisted of 5 samples containing various concentrations of *B. pertussis*, 1 sample containing *B. bronchiseptica* IS481+, 1 sample containing *B. bronchiseptica* IS481-, 1 sample containing *B. holmesii* IS481+, 1 sample containing *B. parapertussis*, 1 sample containing *B. hinzii*, 1 sample containing *H. influenzae* and 1 negative sample.

Material and methods

The QCMD panel was prepared using NucliSENS® easyMAG® (bioMérieux) for sample extraction with Specific A protocol (200/110).

Subsequently, the samples were analysed by real-time PCR using **BORDETELLA R-gene®** (bioMérieux - ref.: 69-011B) on Dx Real-Time System (Bio-Rad).

Results and discussion

Panel code	QCMD Results			BORDETELLA R-gene® Results
	Sample Content	Sample Type*	Sample concentration (CFU/mL)	Ct
BP13-01	<i>B. bronchiseptica</i> IS481+	Educational	1.0 x 10 ³	40.09
BP13-02	<i>B. pertussis</i>	Educational	1.0 x 10 ²	34.15
BP13-03	<i>B. hinzii</i>	Educational	1.0 x 10 ³	Negative
BP13-04	<i>B. pertussis</i>	Core	1.0 x 10 ^{2.5}	30.93
BP13-05	<i>H. influenzae</i>	Core	1.0 x 10 ³	Negative
BP13-06	<i>B. pertussis</i>	Core	1.0 x 10 ^{2.5}	30.28
BP13-07	<i>B. pertussis</i>	Core	1.0 x 10 ³	30.76
BP13-08	Negative	Core	Negative	Negative
BP13-09	<i>B. bronchiseptica</i> IS481-	Educational	1.0 x 10 ³	Negative
BP13-10	<i>B. pertussis</i>	Educational	1.0 x 10 ¹	38.25
BP13-11	<i>B. parapertussis</i>	Educational	1.0 x 10 ³	Negative
BP13-12	<i>B. holmesii</i> IS481+	Educational	1.0 x 10 ³	30.03

*«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" *B. pertussis*-positive samples of Panel *Bordetella pertussis* 2013 are detected with **BORDETELLA R-gene®**
- The 2 "Core" negative expected samples, BP13-05 (*H. influenzae* sample) and BP13-08 (negative sample) are undetected as expected with **BORDETELLA R-gene®**
- 2/2 "Educational" *B. pertussis*-positive samples are detected with **BORDETELLA R-gene®**
- The samples of *B. bronchiseptica* IS481+ and *B. holmesii* IS481+ are detected as claimed since the **BORDETELLA R-gene®** assay targets the IS481.
- As expected, no cross-reaction is observed with *B. bronchiseptica* containing no IS481, *B. parapertussis* and *B. hinzii*.
- The results show the sensitivity and specificity of the **BORDETELLA R-gene®** - ref.: 69-011B.

"The data presented in this document illustrates the performance of the **BORDETELLA R-gene®** assay when testing the *Bordetella pertussis* 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)."