

## *Chlamydia pneumoniae* *Mycoplasma pneumoniae*

### Panel composition

This EQA panel for the detection of *Chlamydia pneumoniae* and *Mycoplasma pneumoniae* consisted of 5 samples containing various concentrations of *Chlamydia pneumoniae*, 5 samples containing various concentrations of *Mycoplasma pneumoniae* and 2 samples negative for both.

### 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 **Chla/Myco pneumo r-gene®** (bioMérieux - ref.: 71-044) on LightCycler® 480 (Roche).

### Results and discussion

Panel Code	QCMD Results			Chla/Myco pneumo r-gene® Results	
	Sample Content	Sample Type*	Dilution factor	CT (530 nm) <i>C. pneumoniae</i>	CT (560 nm) <i>M. pneumoniae</i>
CP.MP13-01	<i>M. pneumoniae</i> (BAL)	Educational	5 x 10 <sup>-7</sup>	Negative	38.35
CP.MP13-02	<i>C. pneumoniae</i> (STM)	Educational	1 x 10 <sup>-7</sup>	38.80	Negative
CP.MP13-03	<i>C. pneumoniae</i> (STM)	Core	1 x 10 <sup>-5</sup>	32.23	Negative
CP.MP13-04	<i>C. pneumoniae</i> (BAL)	Core	1 x 10 <sup>-4</sup>	28.71	Negative
CP.MP13-05	<i>C. pneumoniae</i> (STM)	Educational	1 x 10 <sup>-6</sup>	35.40	Negative
CP.MP13-06	<i>M. pneumoniae</i> (BAL)	Educational	1 x 10 <sup>-7</sup>	Negative	38.58
CP.MP13-07	<i>M. pneumoniae</i> (STM)	Educational	1 x 10 <sup>-7</sup>	Negative	37.54
CP.MP13-08	CP/MP Negative (BAL)	Core	-	Negative	Negative
CP.MP13-09	<i>M. pneumoniae</i> (STM)	Core	5 x 10 <sup>-7</sup>	Negative	34.99
CP.MP13-10	CP/MP Negative (STM)	Core	-	Negative	Negative
CP.MP13-11	<i>M. pneumoniae</i> (STM)	Educational	1 x 10 <sup>-8</sup>	Negative	38.84
CP.MP13-12	<i>C. pneumoniae</i> (BAL)	Core	1 x 10 <sup>-5</sup>	32.22	Negative

\* «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.  
STM : Sample Transport Medium ; BAL : Bronchoalveolar Lavage

- The 5 *Chlamydia pneumoniae*-positive samples of the CP/MP 2013 QCMD panel are detected with Chla/Myco pneumo r-gene®.
- The 5 *Mycoplasma pneumoniae*-positive samples of the CP/MP 2013 QCMD panel are detected with Chla/Myco pneumo r-gene®.
- No cross-reaction is observed between *Chlamydia pneumoniae* and *Mycoplasma pneumoniae*.
- The 2 "Core" negative samples are undetected as expected with Chla/Myco pneumo r-gene®.
- The results show the good sensitivity and specificity of the Chla/Myco pneumo r-gene® (ref.: 71-044).

### Sensitivity of Chla/Myco pneumo r-gene®

Analytical sensitivity has been performed on a serial dilutions of a *Chlamydia pneumoniae*-positive sample and of a *Mycoplasma pneumoniae*-positive sample in a nasopharyngeal sample, tested negative for both pathogens prior to the experiment.

The results have shown :

- a 95% probability to detect *Chlamydia pneumoniae* in a sample containing 0.16 IFU/mL
- a 95% probability to detect *Mycoplasma pneumoniae* in a sample containing 180 CCU/mL

"The data presented in this document illustrates the performance of the Chla/Myco pneumo r-gene® assay when testing the Chlamydia pneumoniae and Mycoplasma pneumoniae 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)".