BactoReal® Kit *Mycoplasma pneumoniae*

Kit version 1.1

For *in vitro* diagnostic use only

BactoReal® Kit *Mycoplasma pneumoniae*			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUB01253	50	FAM channel	Cy5 channel

Kit contents:

- Assay for detection of *Mycoplasma pneumoniae* and of internal DNA positive control (IPC)
- IPC-Target DNA (control of DNA extraction and of PCR amplification)
- DNA reaction mix (contains a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs with dUTP and Uracil-N glycosylase (UNG) to eliminate amplicon carryover, ROX™ dye (passive reference) and buffer components – additives optimized to handle PCR inhibitors)
- DNA positive control for *Mycoplasma pneumoniae*
- Nuclease-free water

Pathogen information: *Mycoplasma pneumoniae* is a very small bacterium lacking a cell wall. This bacterium has a global distribution and is an obligate pathogen and highly infectious. Transmission occurs through close contact with contaminated respiratory droplets. *Mycoplasma pneumoniae* infects the mucosal membrane of the respiratory tract and is a common cause of both upper and lower respiratory infections, including tracheobronchitis and primary atypical pneumonia (community-acquired pneumonia, CAP), but it can also cause pharyngitis, meningitis, and otitis media.

Intended purpose: BactoReal® Kit *Mycoplasma pneumoniae* is a non-automated CE-certified IVD real-time PCR test for the qualitative detection of DNA (16S rRNA gene) of *Mycoplasma pneumoniae*.
Proper specimens are DNA extracts isolated from samples of the human respiratory tract.
This test is suitable for patients of all ages with suspected infection with *Mycoplasma pneumoniae* and is intended as an aid in the diagnosis of infection with this pathogen in combination with patient history and additional clinical information.
The test is intended for professional use and is limited to qualified personnel instructed in the procedures of real-time PCR and *in vitro* diagnostic procedures.
A probe-specific amplification-curve in the FAM channel indicates amplification of *M. pneumoniae* specific DNA. The internal DNA positive control (IPC) is detected in the fluorescence channel Cy5 and serves as a control for DNA extraction and possible real-time PCR inhibition. The target for the DNA IPC (artificial target DNA) is added during sample extraction.

PCR-platforms: This test has been validated with the ABI® 7500 Fast Real-Time PCR System (fast cycle parameters are not supported, Thermo Fisher Scientific) and tested with a LightCycler® 480 II (Roche Diagnostics) and Mx3005P® (Agilent).
The test is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM and Cy5 channel (e.g., QuantStudio™ 5, QuantStudio™ 6, QuantStudio™ 7 real-time PCR system (Thermo Fisher Scientific), qTOWER^{3}G (Analytik Jena), Mic instrument (bio molecular systems), cobas z 480 Analyzer (Roche)).

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Performance data: BactoReal® Kit *Mycoplasma pneumoniae* detects at least 10 target copies/reaction. The LoD95% (smallest number of target DNA copies which can be detected in 95% of cases) is 39 copies/reaction. This kit is specific for *Mycoplasma pneumoniae*. Diagnostic evaluation was performed with bacterial isolates and with 80 clinical samples.

Results of clinical validation:

	Value	95% CI
Sensitivity	100%	90.75% to 100%
Specificity	100%	91.59% to 100%
NPV	100%	91.59% to 100%
PPV	100%	90.75% to 100%
Prevalence	47.5 %	

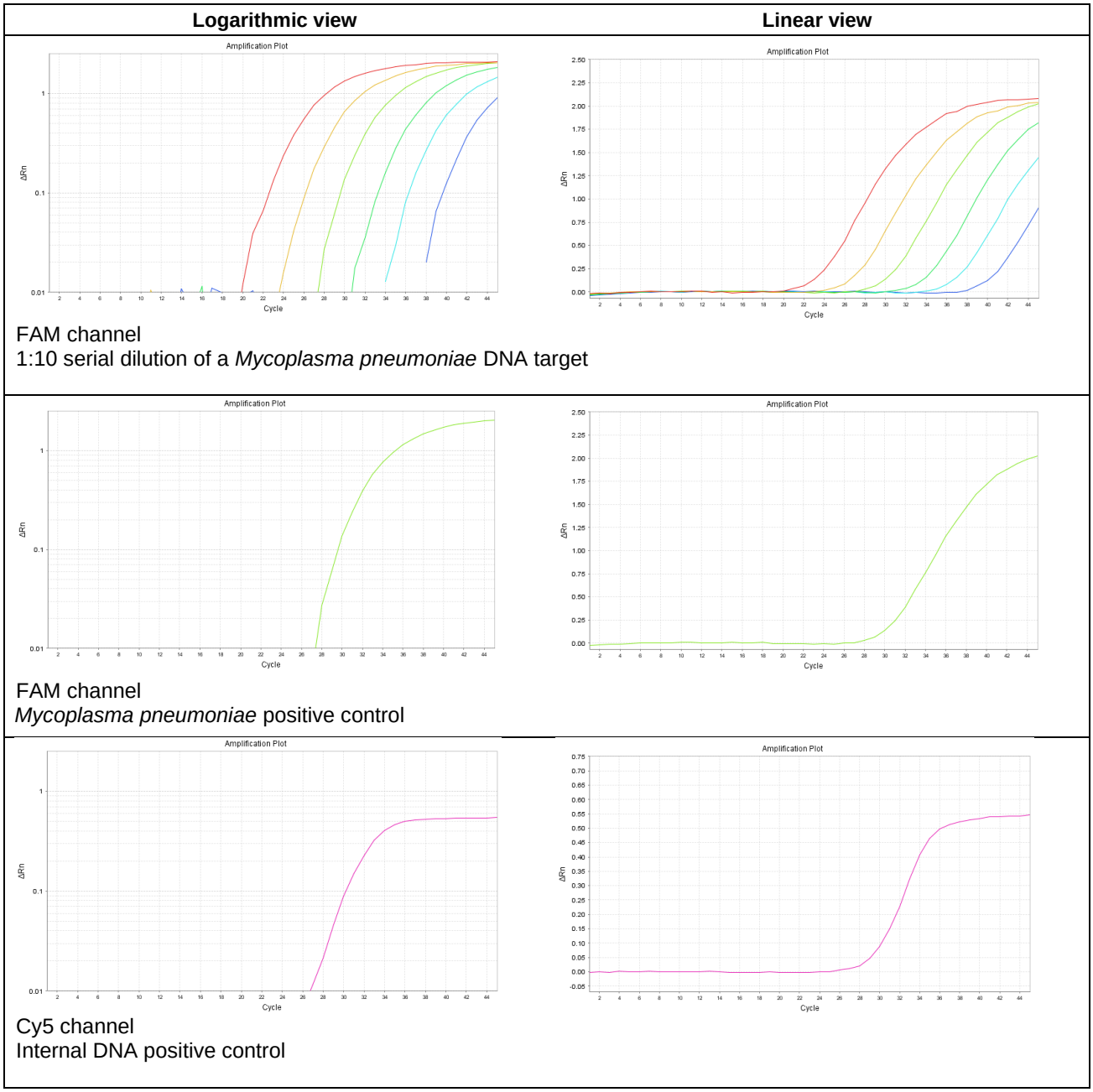

Figure 1 Performance of BactoReal® Kit *Mycoplasma pneumoniae*

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