BactoReal® Kit *Streptococcus pneumoniae*

Kit version 1.1

For *in vitro* diagnostic use only

BactoReal® Kit *Streptococcus pneumoniae*			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUB01453	50	FAM channel	Cy5 channel

Kit contents:

- Assay for detection of *Streptococcus 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 *Streptococcus pneumoniae*
- Nuclease-free water

Pathogen information: *Streptococcus pneumoniae* (pneumococci) is a gram-positive, alpha-hemolytic bacterium which can cause pneumonia (community-acquired pneumonia, CAP), bronchitis, otitis media, meningitis and sepsis. Pneumococci commonly colonize the upper human respiratory tract and can also be found in healthy persons (40% und 70%). Transmission occurs through close contact with contaminated respiratory droplets. The risk of a pneumococcal infection is much increased in persons with a weak immune system.

Intended use: BactoReal® Kit *Streptococcus pneumoniae* is a non-automated CE-certified IVD real-time PCR test for the qualitative detection of DNA of *Streptococcus pneumoniae*.
Proper specimens are DNA extracts isolated from samples of cerebrospinal fluid and of the respiratory tract.
This test is suitable for patients of all ages with suspected infection with *Streptococcus pneumoniae* and is intended as an aid in the diagnosis of infection with this pathogen. Results must be interpreted in combination with medical history with other laboratory data and clinical parameters in context, as *S. pneumoniae* can also colonize the mucosa of healthy individuals.
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 *S. pneumoniae* specific DNA. The internal DNA positive control (IPC) is detected in the fluorescence channel Cy5 channel 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 instrument (fast cycle parameters are not supported, Thermo Fisher Scientific) and tested with a LightCycler® 480 II (Roche Diagnostics) and Mx3005P® (Agilent).
It is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM and Cy5 channel (e.g., QuantStudio™ 5, QuantStudio™ 7 real-time PCR system (Thermo Fisher Scientific), qTOWER^{3}G (Analytik Jena), Mic instrument (bio molecular systems), cobas z 480 Analyzer (Roche)).

ingenetix GmbH
Haidingergasse 1, 1030 Vienna, Austria
T +43(0)1 36 198 01
office@ingenetix.com
www.ingenetix.com

Performance data: BactoReal® Kit *Streptococcus pneumoniae* detects up to 10 target copies/reaction of *S. pneumoniae.* The LoD95% (smallest number of target DNA copies which can be detected in 95% of cases) is 27 copies/reaction. This kit is specific for *S. pneumoniae*. Clinical validation was performed with bacterial isolates and with 47 clinical samples.

Results of clinical validation:

	Value	95% CI
Sensitivity	100.00%	75.29% to 100.00%
Specificity	88.24%	72.55% to 96.70%
NPV	100.00%	
PPV	76.47%	56.42% to 89.08%
Prevalence	27.66%	15.62% to 42.64%
Accuracy	91.49%	79.62% to 97.63%

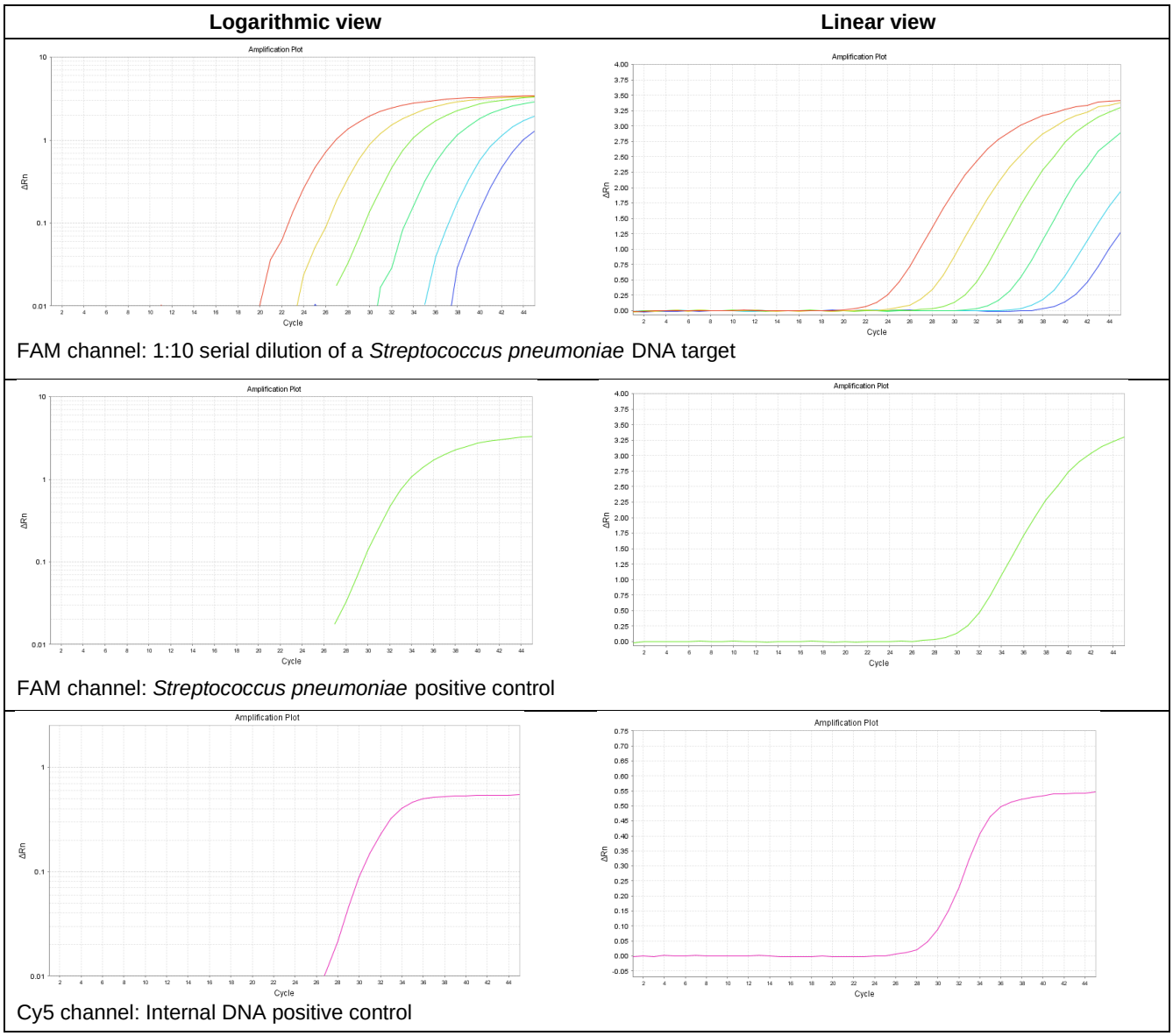

Figure 1 Performance of BactoReal® Kit *Streptococcus pneumoniae*