BactoReal® Kit *Neisseria meningitidis*

Kit version 1.1

For *in vitro* diagnostic use only

BactoReal® Kit *Neisseria meningitidis*			
Order no.	**Reactions**	**Pathogen**	**Internal positive control**
DHUB00153	50	FAM channel	Cy5 channel

Kit contents:

- Assay for detection of *Neisseria meningitidis* 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 *Neisseria meningitidis*
- Nuclease-free water

Pathogen information: *Neisseria meningitidis* is a Gram-negative bacterium causing meningitis and septicemia. There are 13 clinically significant serogroups, which are classified according to the antigenic structure of their polysaccharide capsule. Five serogroups (A, B, C, Y and W135) are responsible for virtually all cases of the disease. Serogroup B is the predominant one. The capsular transport protein (ctrA) gene is unique to *N. meningitidis* and can be found in all meningococcal serogroups.

Intended purpose: BactoReal® Kit *Neisseria meningitidis* is a non-automated CE-certified IVD real-time PCR test for the qualitative detection of DNA (two regions of the ctrA gene) of *Neisseria meningitidis*. This kit detects all up to now known serotypes of *N. meningitidis*.
Proper specimens are DNA extracts isolated from samples of EDTA blood, blood culture or cerebrospinal fluid.
This test is suitable for patients of all ages with suspected infection with *Neisseria meningitidis* 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 *N. meningitidis* 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).
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)).

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Performance data: The LoD95% (smallest number of target DNA copies which can be detected in 95% of cases) is 1.7 copies/reaction. This kit is specific for *Neisseria meningitidis*. Diagnostic evaluation was performed with bacterial isolates and with 30 clinical samples. Two different regions of the ctrA gene are amplified to minimize false-negative results due to sequence heterogeneity within the target region. It also guarantees the detection of the three *N. meningitidis* strains described as ctrA mutants by Cavrini et al. (2010) and Jaton et al. (2010).

Results of clinical validation:

	Value	95% CI
Sensitivity	93.33 %	68.05 % to 99.83 %
Specificity	100.00 %	78.20 % to 100.00 %
NPV	93.75 %	69.77 % to 99.84 %
PPV	100.00 %	76.84 % to 100.00 %
Prevalence	50.0 %	

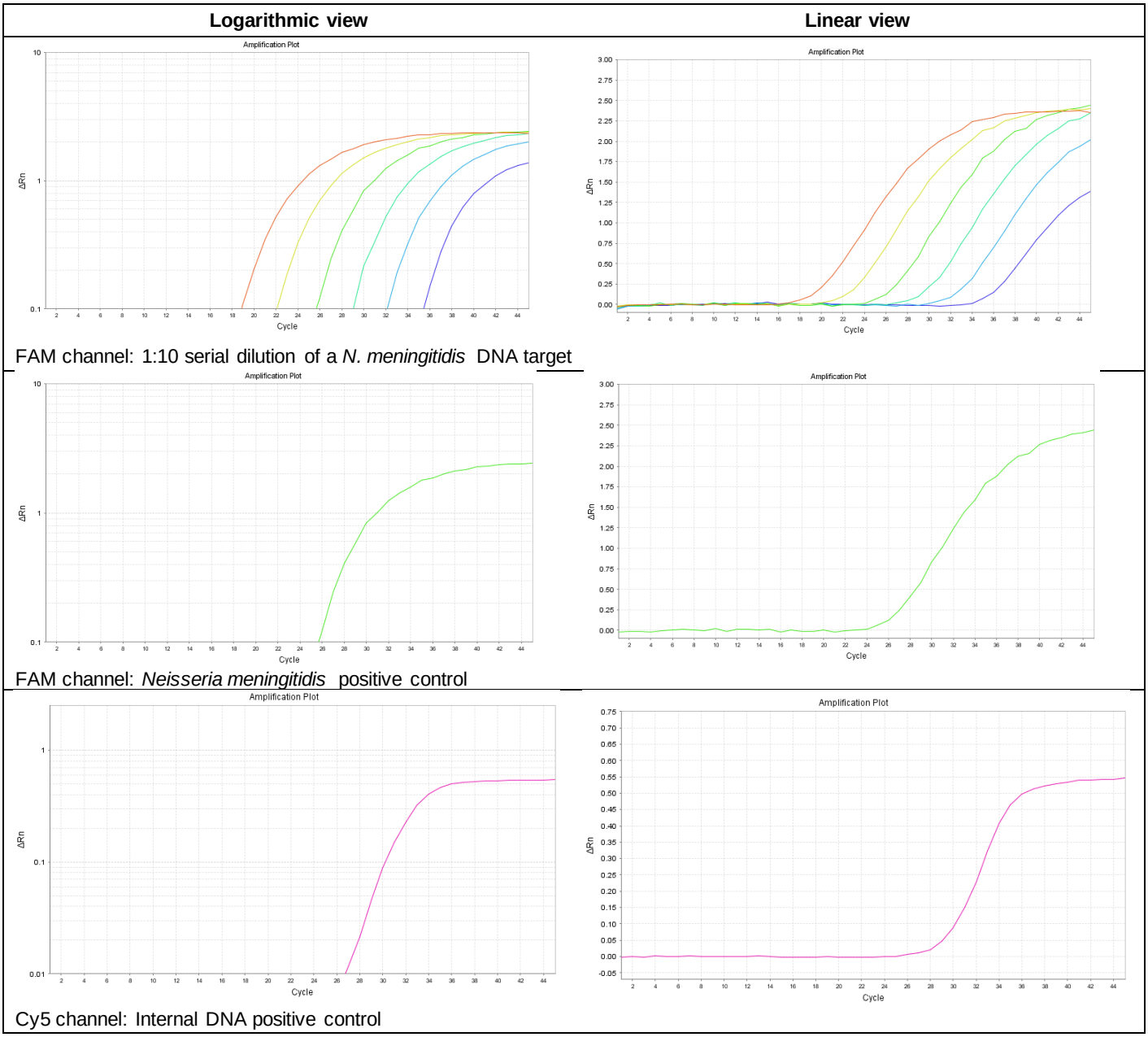

Figure 1 Performance of BactoReal® Kit *Neisseria meningitidis*