

BactoReal® Kit *Haemophilus influenzae*



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Order no.	Reactions	Pathogen	Internal positive control
DHUB01053	50	FAM channel	Cy5 channel

Kit contents:

- Detection assay for *Haemophilus influenzae*
- Detection assay + target for internal DNA positive control (control of PCR amplification and DNA extraction)
- DNA reaction mix
- Nuclease-free water
- Positive control for *Haemophilus influenzae*



Background: The 16 species of *Haemophilus* are Gram-negative bacteria occasionally colonizing the mucosa of humans and animals. Some *Haemophilus* species are the causative agents of various infections. For example, *H. aegyptius* causes purulent conjunctivitis, *H. parainfluenzae* is a rare cause of a form of endocarditis. *Haemophilus influenzae* can be found exclusively in the mucosa of humans, mainly in the upper respiratory tract. Transmission occurs through close contact with contaminated respiratory droplets. In sum, six capsular serotypes (a-f) can be distinguished, out of which type b (Hib) is the most prevalent and virulent one causing bloodstream infections and meningitis mainly in children less than 5 years. In contrast, unencapsulated strains (also called nontypeable *H. influenzae*, NTHi) of *H. influenzae* are part of the normal bacterial flora of humans and are occasionally pathogen. These strains can cause otitis, sinusitis, epiglottitis, bronchitis, pneumonia and less frequently meningitis and bacteraemia. The Omp P6 gene of *H. influenzae* is present in both the encapsulated and unencapsulated strains of *H. influenzae*.

Description: BactoReal® Kit *Haemophilus influenzae* is an *in vitro* diagnostic test detecting DNA of the Omp P6 gene of encapsulated and unencapsulated (also called nontypeable *H. influenzae*, NTHi) *H. influenzae* strains using real-time PCR. This test allows the rapid and sensitive detection of DNA of *Haemophilus influenzae* from samples purified from the respiratory tract and cerebrospinal fluid (e.g. with the QIAamp DNA Mini Kit, Qiagen).

Haemophilus influenzae DNA is detected in FAM channel. The internal DNA positive control (DNA IPC) is detected in Cy5 channel and is used as DNA extraction as well as PCR inhibition control. The DNA IPC target is extracted with the sample.

PCR-platforms: This kit has been validated with Applied Biosystems® 7500 Fast Real-time PCR System (Thermo Fisher Scientific) and tested with LightCycler® 480 Instrument II (Roche) and Mx3005P® QPCR System (Agilent). It is compatible with real-time PCR instruments detecting and differentiating fluorescence in FAM and Cy5 channel.

Specificity and sensitivity: BactoReal® Kit *Haemophilus influenzae* detects at least 10 target copies/reaction. The limit of detection (LoD95 = smallest number of target DNA copies which can be detected in 95% of cases) is 36 copies/reaction. This kit can also detect some strains of *H. haemolyticus* and *H. parainfluenzae*, albeit with lower sensitivity. Diagnostic evaluation was performed with bacterial isolates and with clinical samples.

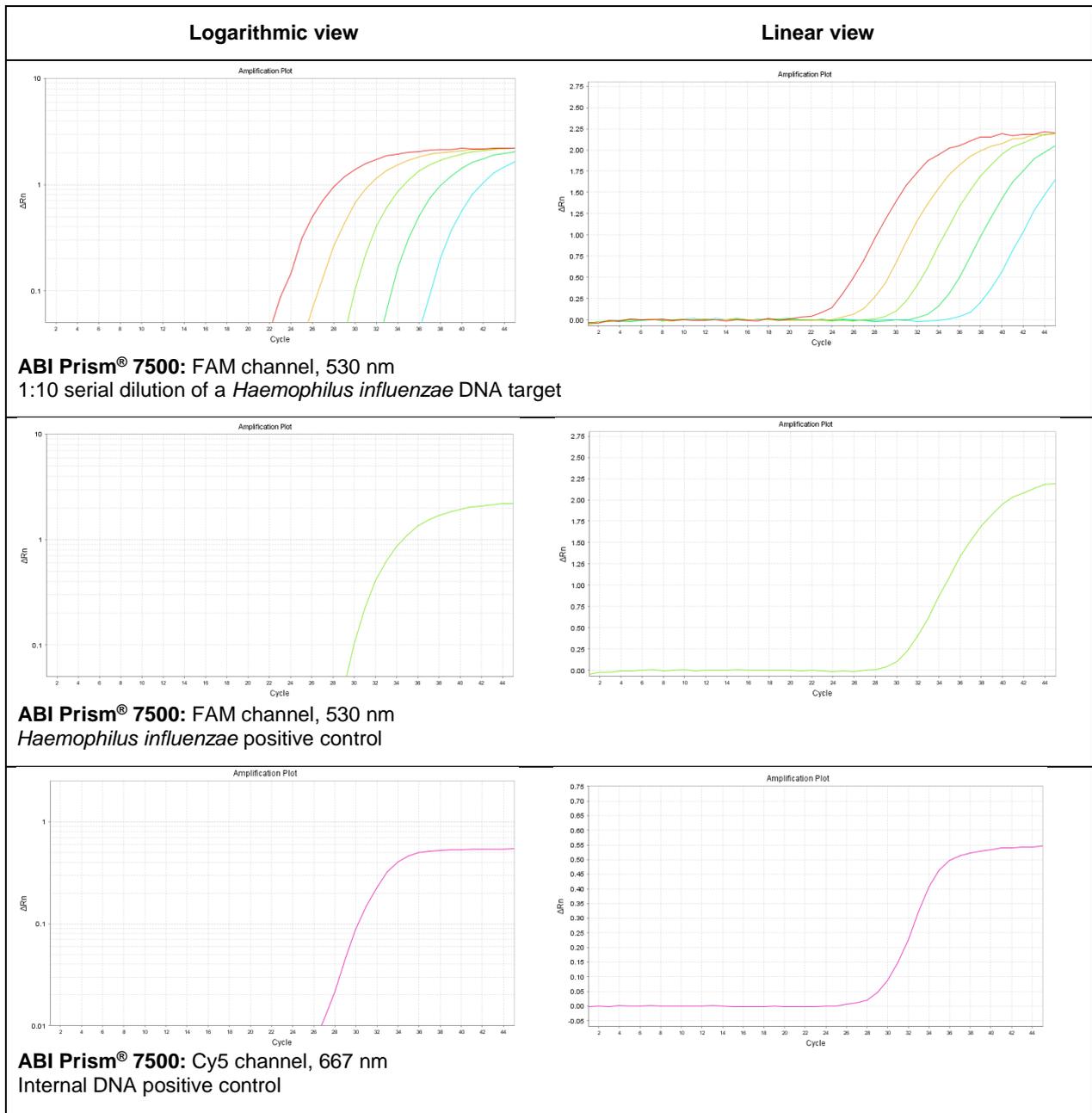


Figure 1 Performance of BactoReal® Kit *Haemophilus influenzae*

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