

BactoReal® Kit Bordetella Multiplex



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Order no.	Reactions	Pathogen	Internal positive control
DHUB00453	50	FAM + VIC channel	Cy5 channel

Kit contents:

- Detection assay for *Bordetella* and for internal DNA positive control (control of PCR amplification and DNA extraction)
- Target for internal DNA positive control
- DNA reaction mix
- Nuclease-free water
- Positive control for *B. pertussis* + *B. parapertussis*



Background: *Bordetella pertussis* is a gram-negative bacterium of the genus *Bordetella* and the causative agent of pertussis, an acute respiratory disease. Transmission occurs by droplet infection. *Bordetella parapertussis*, *Bordetella holmesii* and *Bordetella bronchiseptica* can cause a whooping cough-like illness with a milder clinical course. While *Bordetella pertussis* and *Bordetella parapertussis* only infect humans, *Bordetella bronchiseptica* occurs mainly in animals and is occasionally isolated from humans. The IS481 is a multicopy gene found up to 249 times in the genome of *B. pertussis*. The IS1001 is also multicopy gene, found up to 22 times in the genome of *B. parapertussis*.

Intended purpose: BactoReal® Kit Bordetella Multiplex is a non-automated IVD test, based on real-time PCR, for the qualitative detection of DNA of *Bordetella pertussis*, *Bordetella parapertussis*, *Bordetella holmesii* and some strains of *Bordetella bronchiseptica*. This test detects the insertion sequence IS481 of *B. pertussis*, *B. holmesii* and *B. bronchiseptica* as well as the insertion sequence IS1001 of *B. parapertussis*, *B. bronchiseptica* and *B. holmesii*. IS481 or IS1001 may be present in *B. bronchiseptica* in rare cases.

Proper specimens are DNA extracts of samples from the human respiratory tract (sputum, BAL, nasal swabs, throat swabs, bronchial secretion, tracheal secretion).

This test is suitable for patients of all ages with suspected respiratory infection with *Bordetella* (causative agent of whooping cough and whooping cough-like infections) 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 for professional use only and the use is limited to qualified personnel instructed in real-time PCR and *in vitro* diagnostic procedures.

Bordetella DNA is detected in FAM and VIC 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 (artificial DNA) is extracted with the sample.

PCR-platforms: BactoReal® Kit Bordetella Multiplex is compatible with real-time PCR instruments which detect and differentiate fluorescence in FAM, VIC and Cy5 channel. Recommended are ABI® 7500 instrument (Thermo Fisher Scientific), QuantStudio™ 7 real-time PCR system (Thermo Fisher Scientific), LightCycler® 480 II (Roche Diagnostics) and Mic instrument (bio molecular systems).

Performance data: The LoD95 is 0.06 genome copies/reaction for *B. pertussis* and 0.18 genome copies/reaction for *B. parapertussis*. This kit is specific for *B. pertussis*, *B. parapertussis*, *B. holmesii* and *B. bronchiseptica*, but cross reacts with *Achromobacter denitrificans*. Clinical validation was performed with 181 clinical samples (Table 1).

Table 1 Results of clinical validation

	Value	95% CI
Sensitivity	100.00%	95.55% to 100.00%
Specificity	100.00%	96.38% to 100.00%
NPV	100.00%	
PPV	100.00%	
Prevalence	44.75%	37.37% to 52.31%

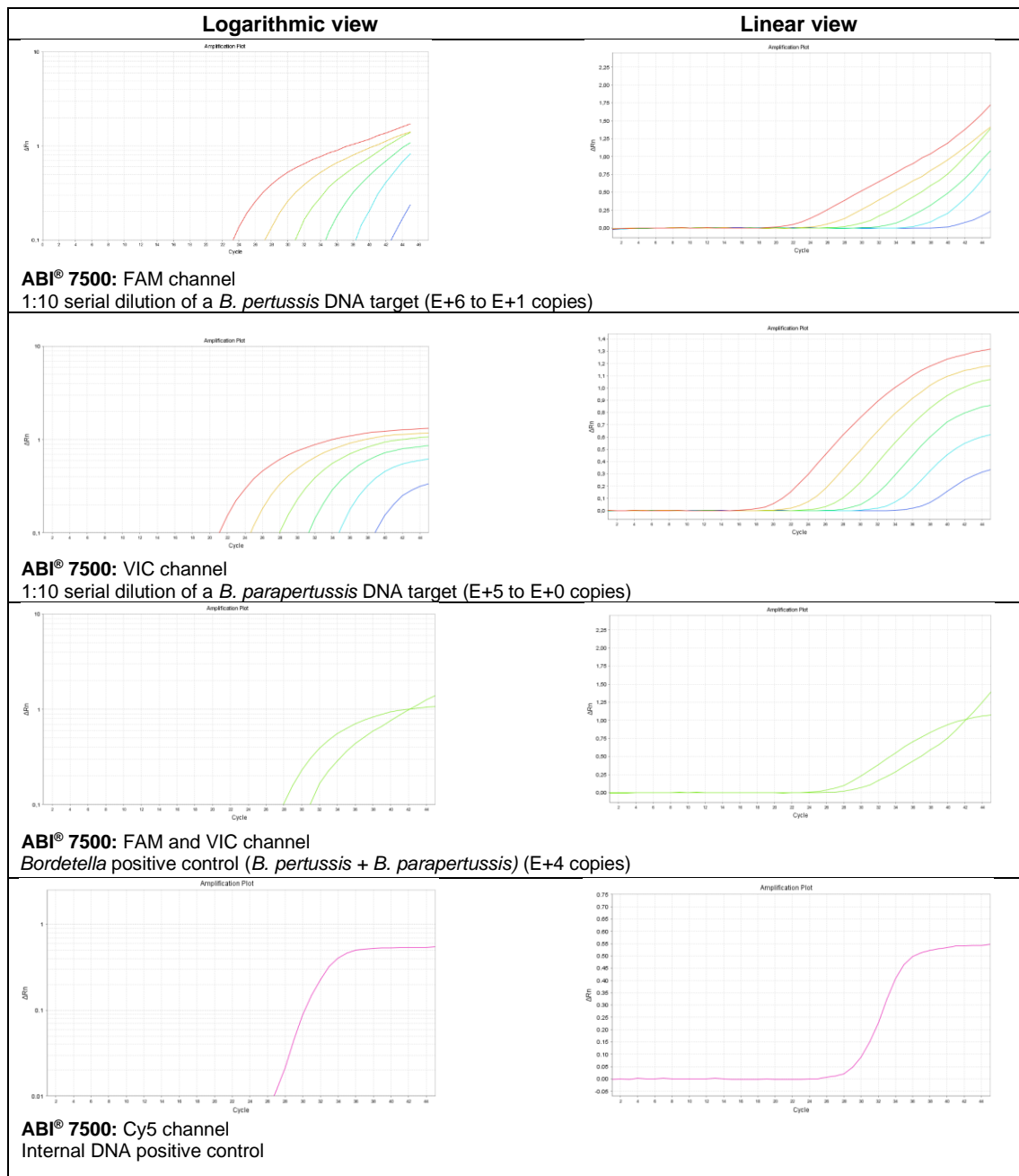


Figure 1 Performance of BactoReal® Kit *Bordetella* Multiplex

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