

BactoReal[®] Kit Borrelia burgdorferi sensu lato



| BactoReal [®] Kit <i>Borrelia burgdorferi</i> sensu lato | | | |
|---|-----------|-------------|---------------------------|
| Order no. | Reactions | Pathogen | Internal positive control |
| DHUB05053 | 50 | FAM channel | Cy5 channel |

Kit contents:

- Detection assay for Borrelia species belonging to the B. burgdorferi sensu lato complex
- Detection assay + target for internal DNA positive control (control of PCR amplification and DNA extraction)
- DNA reaction mix
- Nuclease-free water
- Positive control for Borrelia burgdorferi s.l.



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IVD

Background: Borrelia are Gram-negative bacteria belonging to the Spirochaetaceae. The genus Borrelia consists of numerous species. Besides the species belonging to the *B. burgdorferi* sensu lato-complex there are also human pathogenic Borrelia species causing relapsing fever (*B. recurrentis, B. duttonii* and *B. hermsii*). Species belonging to the *B. burgdorferi* sensu lato-complex and causing Lyme disease (Lyme borreliosis) are Borrelia burgdorferi sensu stricto, *B. garinii, B. afzelii, B. valaisiana, B. lusitaniae, B. bavariensis, B. bissettii* and *B. spielmanii*. These are associated with different genospecies-specific symptoms. They are transmissed by ticks, mainly by *Ixodes ricinus*. Lyme disease is a multisystemic illness, which can affect various organs, especially the nervous system, skin, heart and joints.

Description: BactoReal[®] Kit *Borrelia burgdorferi* sensu lato is an *in vitro* diagnostic real-time PCR test detecting DNA of the ospA gene of *Borrelia* species belonging to the *Borrelia burgdorferi* sensu lato (s.l.) complex. This test allows the rapid and sensitive detection of DNA of *B. burgdorferi* s.l. from samples purified from tissue, blood, synovial or cerebrospinal fluid (e.g. with the QIAamp DNA Mini Kit, Qiagen).

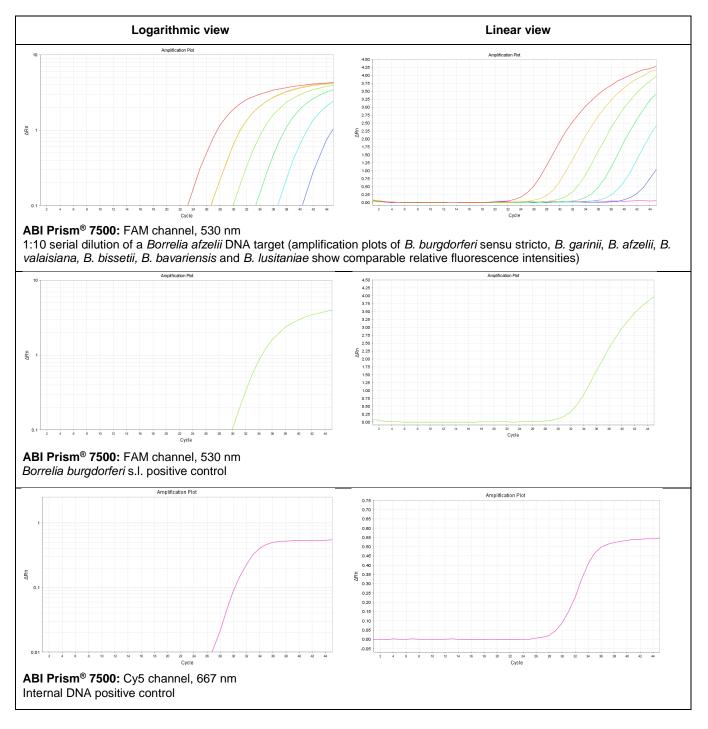
B. burgdorferi s.l. DNA is detected in FAM channel. The internal DNA positive control (DNA IPC) is detected in Cy5 channel and is used as DNA extraction as well as PCR inhibition control. The DNA IPC target is extracted with the sample.

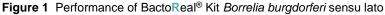
PCR-platforms: This kit has been validated with Applied Biosystems[®] 7500 Fast Real-time PCR System (Thermo Fisher Scientific) and tested with LightCycler[®] 480 Instrument II (Roche) and Mx3005P[®] QPCR System (Agilent). It is compatible with real-time PCR instruments detecting and differentiating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

Specificity and sensitivity: BactoReal[®] Kit *Borrelia burgdorferi* sensu lato is specific for *Borrelia* species belonging to the *Borrelia burgdorferi* sensu lato (s.l.) complex (*Borrelia burgdorferi* sensu stricto, *B. garinii*, *B. afzelii*, *B. valaisiana*, *B. lusitaniae*, *B. bavariensis*, *B. bissettii* and *B. spielmanii*). This kit 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 42 copies/reaction. *Borrelia spielmanii* is detected with lower sensitivity. Diagnostic evaluation was performed with bacterial isolates and with clinical samples.

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