

BactoReal® Kit *Leptospira* spp. (16S rDNA)



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Order no.	Reactions	Pathogen	Internal positive control
DHUB00553	50	VIC/HEX channel	Cy5 channel

For Research Use Only. Not for use in diagnostic procedures.

Kit content:

- Detection assay for pathogenic and intermediately pathogenic *Leptospira* spp.
- Detection assay + target for internal DNA positive control (control of PCR amplification and DNA extraction)
- DNA reaction mix
- Nuclease-free water
- Positive control for *Leptospira* spp.



Background: The spirochaetal *Leptospira* genus consists of pathogenic species (*L. interrogans*, *L. noguchii*, *L. weilii*, *L. kirschneri*, *L. alexanderi*, *L. borgpetersenii*, *L. santarosai*, *L. kmetyi*, *Leptospira* genomospecies 1), of intermediately pathogenic species (*L. inadai*, *L. fainei*, *L. broomii*, *L. licerasiae*, *L. wolffii*) and of non- pathogenic species (*L. biflexa*, *L. meyeri*, *L. wolbachii*, *Leptospira* genomospecies 3, 4 and 5). Members of *Leptospira* can also be grouped into serovars. Currently over 200 serovars are recognized in the genus *Leptospira* and a few serovars are found in more than one species of *Leptospira*. Non-pathogenic species are saprophytes and can grow outside the host animal, while pathogenic *Leptospira* species cause leptospirosis. They affect many mammalian species, including humans. Animals may become unapparent carriers, and shedding of leptospires, primarily in the urine, serves as a source of infection for other animals and humans. The clinical signs associated with leptospirosis are variable and depend on the infecting serovar. Leptospires are present in the blood during the first 5 to 10 days after disease onset.

Description: BactoReal® Kit *Leptospira* spp. (16S rDNA) is a real-time PCR test detecting DNA of the 16S rDNA gene of pathogenic and intermediately pathogenic *Leptospira* spp. It allows the rapid and sensitive detection of the 16S rDNA gene of *Leptospira* spp. from DNA samples purified from blood, urine or kidney tissue (e.g. with the QIAamp DNA Mini Kit). *Leptospira* DNA is detected in VIC/HEX 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 *Leptospira* spp. (16S rDNA) has a sensitivity of 10 target copies/PCR reaction. The limit of detection (LoD95 = smallest number of copies of target RNA which can be detected in 95% of cases) is 20 target copies/reaction. This kit is specific for pathogenic and intermediately pathogenic *Leptospira* species. It was tested with 13 pathogenic, 1 intermediately pathogenic and 3 non-pathogenic *Leptospira* serovars as well as 2 *Leptonema* species. All species were correctly analyzed.

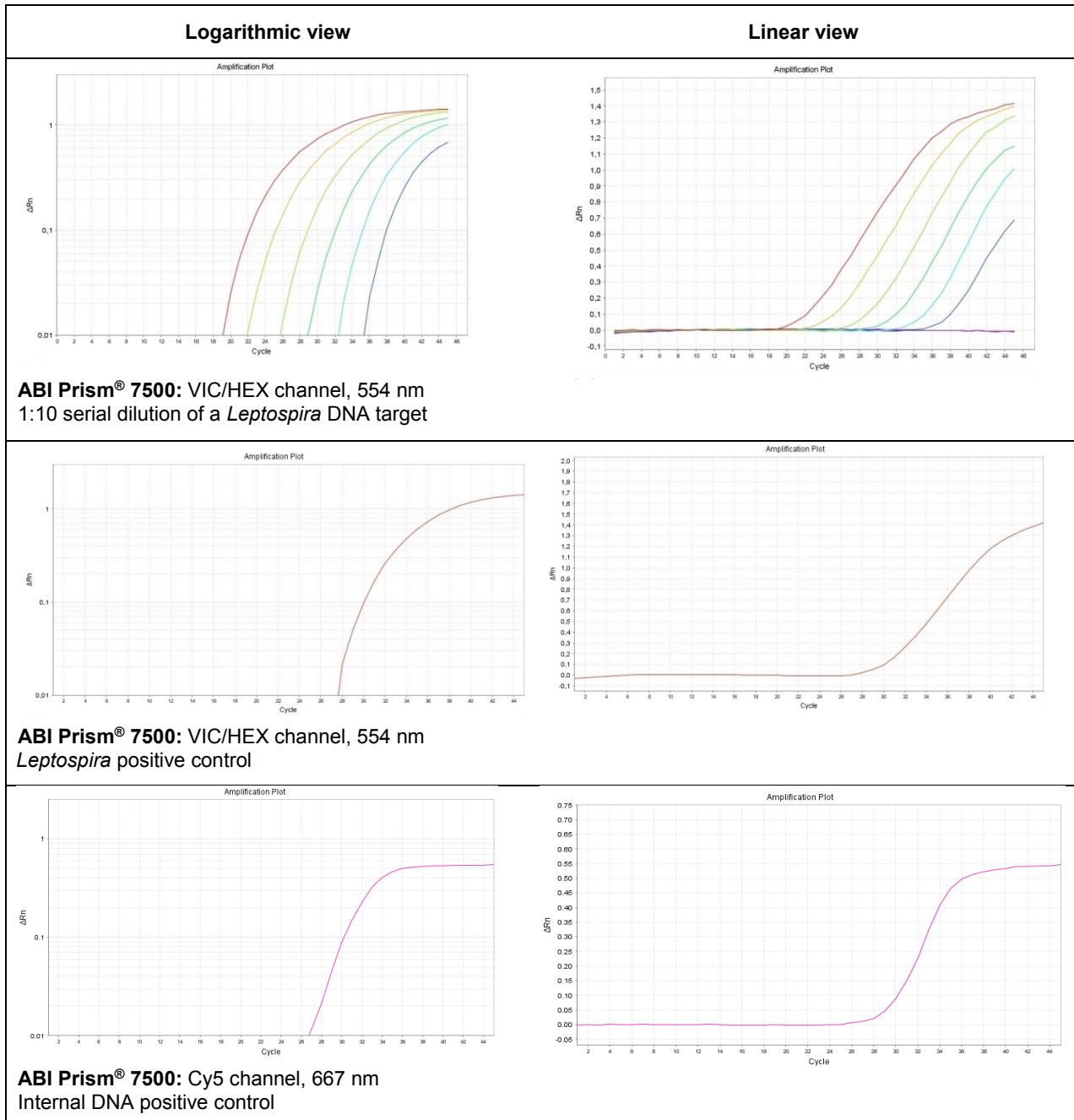


Figure 1 Performance of BactoReal® Kit *Leptospira* spp. (16S rDNA)

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