

BactoReal[®] Kit *Clostridium difficile*



For veterinary use only

BactoReal[®] Kit *Clostridium difficile*

| Order no. | Reactions | Pathogen | Internal positive control |
|-----------|-----------|-----------------------|---------------------------|
| DVEB04213 | 100 | FAM + VIC/HEX channel | Cy5 channel |
| DVEB04253 | 50 | FAM + VIC/HEX channel | Cy5 channel |

Kit contents:

- Detection assay for *Clostridium difficile* toxin A and B
- Detection assay for internal positive control (control of amplification)
- DNA reaction mix (contains uracil-N glycosylase, UNG)
- Positive control for *C. difficile*
- Water



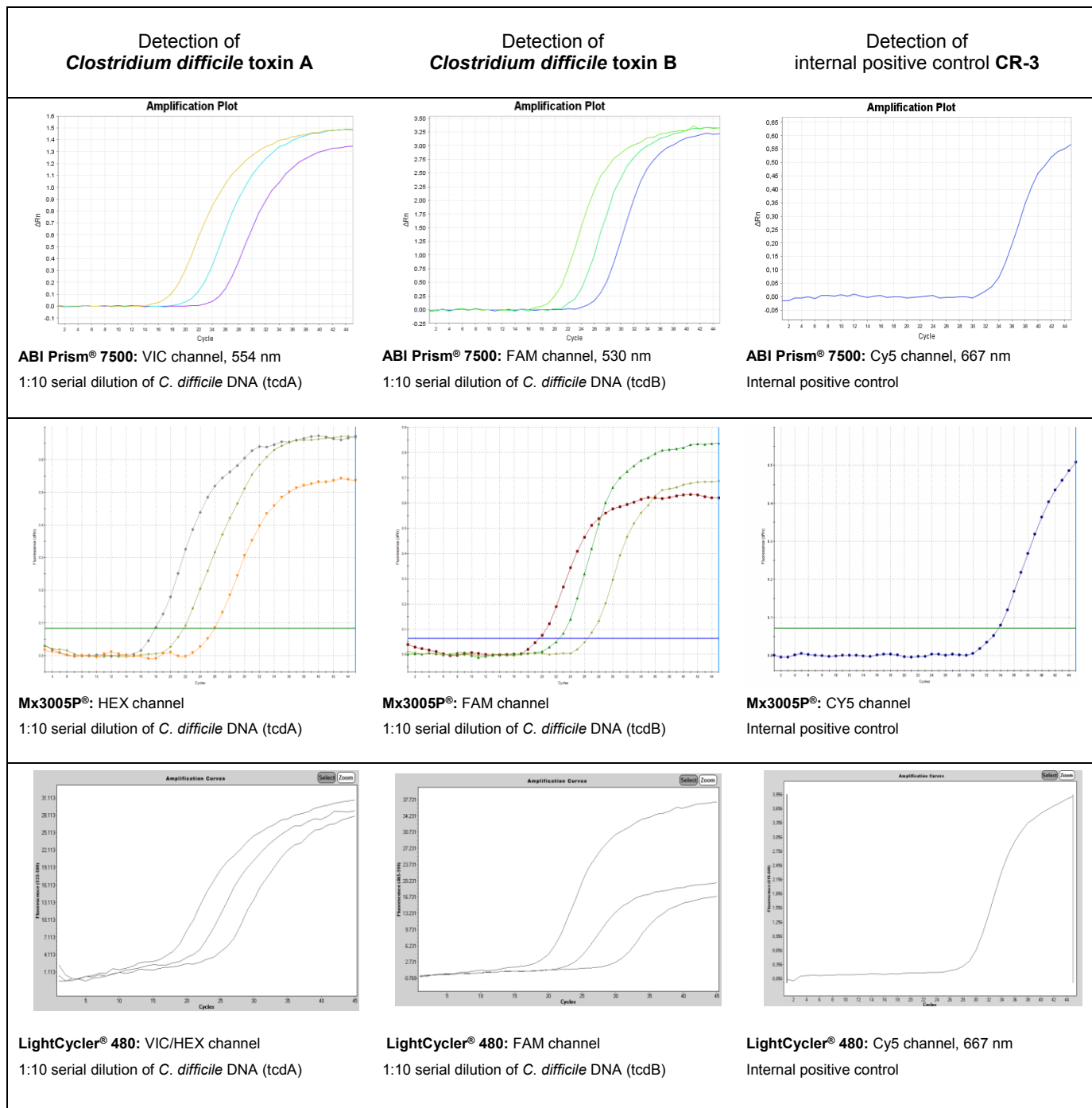
Background: *Clostridium difficile* is a gram-positive spore-forming anaerobic bacterium which is commonly found in low concentrations in the intestine of clinically normal animals and humans. In higher concentration *Clostridium difficile* is an important cause of diarrhea in neonatal swine. Affected piglets may have dyspnea, abdominal distention, and scrotal edema. Diarrhea may not be present in all pigs affected. Pathogenic *C. difficile* strains produce multiple toxins. The best characterized are enterotoxin (*Clostridium difficile* toxin A causing fluid secretion into the gut lumen) and cytotoxin (*Clostridium difficile* toxin B), both of which may produce diarrhea and inflammation. *Clostridium difficile* infection (CDI) is also a major cause of nosocomial antibiotic-associated infectious diarrhea and pseudomembranous colitis in humans.

Description: BactoReal[®] Kit *Clostridium difficile* is based on the amplification and detection of the *Clostridium difficile* toxin A (tcdA) gene and *Clostridium difficile* toxin B (tcdB) gene of *C. difficile* using multiplex real-time PCR. The tcdA gene is detected in VIC/HEX channel. The tcdB gene is detected in FAM channel. This kit allows the rapid and sensitive detection of the tcdA and tcdB gene of *C. difficile* from DNA samples purified from stool or other sample material (e.g. with the QIAamp DNA Stool Mini Kit).

PCR-platforms: BactoReal[®] Kit *Clostridium difficile* is developed and validated for the ABI PRISM[®] 7500 instrument (Life Technologies), LightCycler[®] 480 (Roche) and Mx3005P[®] QPCR System (Agilent), but is also suitable for other real-time PCR instruments.

Sensitivity and specificity: BactoReal[®] Kit *Clostridium difficile* has an analytical sensitivity of 20 target copies/reaction for toxA and of 10 target copies/reaction for toxB. The limit of detection (LoD95 = smallest number of copies of target DNA which can be detected in 95% of cases) of 52 target copies/reaction for toxA and of 33 target copies/reaction for toxB was determined by several replicates around the detection limit. It is specific for *C. difficile*.

References: Voht DE, Ballard JD. 2005. *Clostridium difficile* toxins: mechanism of action and role in disease. Clin. Microbiol. Rev. 18:247-63.



BactoReal®, MycoReal, ParoReal and ViroReal® Kits run with the same thermal cycling conditions. RNA and DNA material can be analysed in one PCR run.

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