

## Application Brief

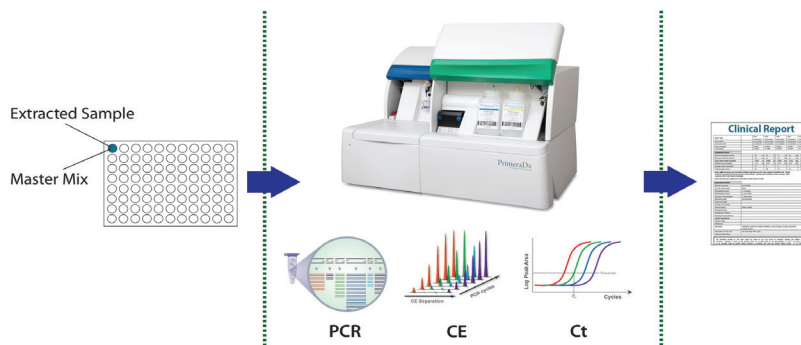
# ICEPlex *Clostridium difficile* Panel

## INTRODUCTION

*Clostridium difficile* (*C. difficile*) infection is one of the most prevalent causes of healthcare associated infection and it is rapidly spreading in the healthcare communities. *C. difficile* infection most commonly develops after treatment with certain antibiotics and it is a toxin-mediated intestinal disease. Toxin B is generally recognized as a major virulent factor associated with *C. difficile* infection. PrimerADx has developed ICEPlex® *Clostridium difficile* Panel for qualitative detection of the *Clostridium difficile* toxin B gene (*tcdB* gene) in human stool samples from patients suspected of having *C. difficile* Associated Diseases (CDAD).

## SUMMARY

- Detects *tcdB* gene of *C. difficile* in stool samples.
- Can test up to 42 samples in a single run.
- Includes an Internal Control for monitoring the nucleic acid extraction efficiency and to ensure quality reporting.



## CRITICAL RESULTS IN LESS THAN 4 HOURS

## METHOD HIGHLIGHTS

- Primers were designed using PrimerADx's unique strategy that can selectively amplify unique genomic region of *C. difficile*. One of the primers in each primer set was labeled with FAM dye.
- Nucleic acids were extracted using commercially available extraction system from stool samples.
- The Internal Control served as extraction efficiency control.
- Multiplex PCR reactions were subjected to thermocycling in a standard 96-well PCR plate on the ICEPlex system.
- Fluorescently labeled amplicons were then automatically injected, separated and detected in the capillary electrophoresis module of the ICEPlex system.
- Amplification curves for all targets and controls were generated automatically by the ICEPlex software and cycle thresholds (Cts) were calculated.
- The built-in ICEPlex software generated result reports where the results from the testing were displayed as "Positive" or "Negative" for *tcdB* gene of *C. difficile*.

## TYPICAL DATA

The ICEPlex *C. difficile* Panel detected *tcdB* gene of *C. difficile*. The results from the test on ICEPlex were automatically generated and reported after the end of the run, which took about 3 1/2 hours.

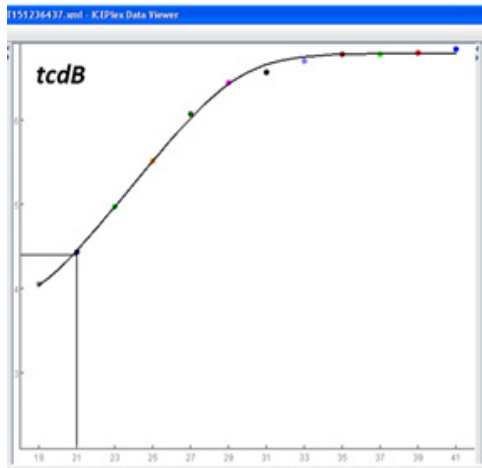


Figure 1. Representative amplification curve for the *tcdB* target in *C. difficile* Panel on the ICEPlex system.

		<i>tcdB</i>	Internal Control
Sample 1	Result	Negative	Pass
Sample 1	Result	Positive	Pass
Sample 1	Result	Negative	Pass

Table 1. Representative results of the tested samples for *C. difficile* on the ICEPlex system.

## FOR MORE INFORMATION

For a list of publications and to find out more about how PrimeraDx can help your lab, please contact us at 508.618.2300 or visit [www.primeradx.com](http://www.primeradx.com).

The ICEPlex system and ICEPlex Clostridium difficile Panel are for Research Use Only and have not been approved for in vitro diagnostic use by the FDA. The presented information is for demonstration purposes only.