

STANDARD M10**Versatile Point-of-Care
Molecular Diagnostic
Platform**

This product is used
with SD BIOSENSOR's
M10 Console & Module.

**IVDR**

STANDARD **M10**

C. difficile

Detection of Clostridioides difficile that diarrhea disease caused by treatment with antibiotics.

Molecular C. difficile Point-of-Care Test

- Detection of **toxin B gene (tcd B)**
- Unformed stool sample

All-in-one Cartridge Sample-in Result-out

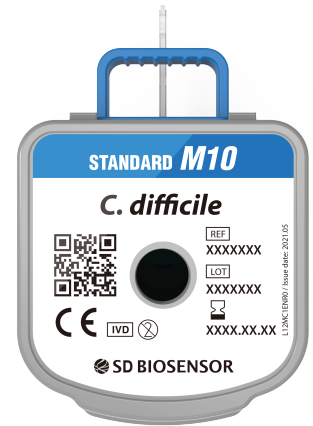
- Real-Time PCR
- **NA extraction + amplification**
- Multiplex assay up to **12-plex**
- Including internal control
- Lyophilized reagents for stability
- Room temperature storage

Versatile Point-of-Care Molecular diagnostic Platform

- Small footprint
- Random access
- Scalable configuration
- Simple sputum pretreatment process
- **47 minutes** of testing time

SPECIFICATIONS

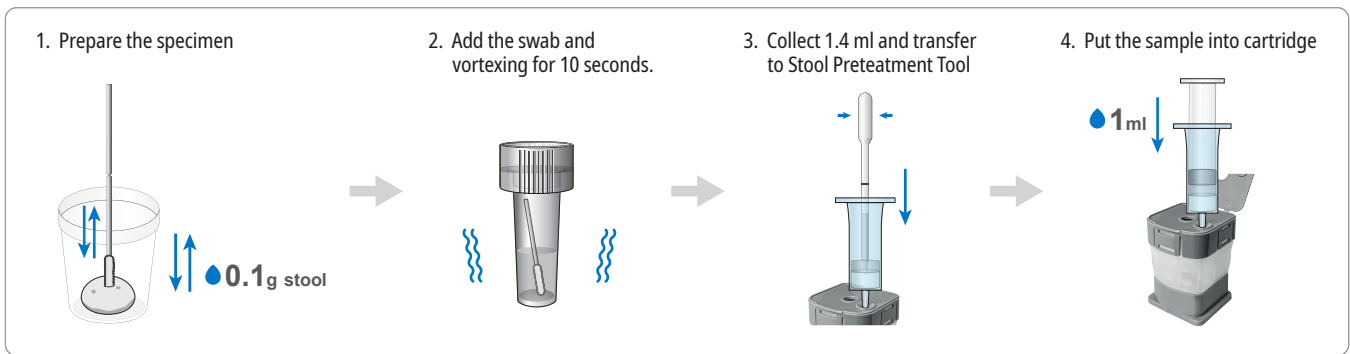
Cat no.	11CDC10A
Method	All-in-one Cartridge Bacterial DNA Extraction Nucleic Acid Amplification: Real-Time PCR
Target gene	Toxin B (<i>tcdB</i>) Internal Control (IC) – Exogenous gene
Sample type	Unformed stool, 1 ml
Testing time	47 minutes
Storage temp.	2 ~ 28°C
Test / Kit	10 Tests



STANDARD™ M10 *C. difficile*

TEST PROCEDURE

0 Specimen preparation



1 Sample ID Scan



2 Cartridge Scan



3 Sample Transfer



4 Cartridge Loading



ORDERING INFORMATION

Instrument

Cat. No.	Product	Contents
11M1011	STANDARD M10 Console	1 M10 Console (Operational module)
11M1012	STANDARD M10 Module	1 M10 Module (Analytical module)

Cartridge

Cat. No.	Product	Pathogens
11CDC10A	STANDARD M10 <i>C. difficile</i>	Toxin B (<i>tcd B</i>)