

BD MAX™ Cdiff - Simplified Protocol



- For more detailed information see Instructions for Use: bd.com/e-labeling
- To access sample preparation video, please scan the QR code.

1. Reagent, Storage and Stability

Ref.	Name	Storage	Stability	Quantity
442555	BD MAX™ Cdiff	2–25°C	Unopened reagents: up to expiration date. Opened reagent pouches: up to 31 days and re-sealing of the pouch.	24 tests: Sample Buffer Tubes, Septum caps, Strips, Extraction tubes and Master Mix tubes
437519	BD MAX™ PCR Cartridges	2–25°C	Until expiration date.	24 cartridges

2. Specimen Stability

- Collected specimens should be kept between 2°C and 25°C during transport. Protect against freezing or exposure to excessive heat.
- Specimens can be stored for up to 120 hours (5 days) at 2–8 °C or for up to 48 hours at 2–25 °C before testing.

3. Specimen Collection and Transport

In order to obtain an adequate specimen, the procedure for specimen collection must be followed closely. Using a dry, clean container, liquid or soft stool specimens are collected according to the following procedure:

- Transfer liquid or soft stool (but not urine) into the container. Avoid mixing toilet paper, water, or soap with the sample.
- Label the container and ship the container to the laboratory according to the hospital standard operating procedures.

4. Sample Preparation

- Label a bar-coded BD MAX™ Sample Buffer Tube (clear cap) with the appropriate specimen identification. Do not obscure, write or label over the 2D-barcode.
- Vortex the specimens at high speed for 15 seconds and dip a 10 µL inoculating loop into the stool material for testing.
 - For soft stool specimens, remove any excess stool present on the outside of the loop in order to take approximately 10 µL.
- Remove the cap from the Sample Buffer Tube then place the loop into the liquid. Roll the loop between fingers in order to release the specimen in the tube.
- Recap the tube with a Septum Cap.
- Vortex all prepared Sample Buffer Tubes at maximum speed for one (1) minute. The BD MAX™ Cdiff assay must be performed immediately after the vortexing step.
- Proceed to the BD MAX™ Rack and BD MAX™ System Run section below.



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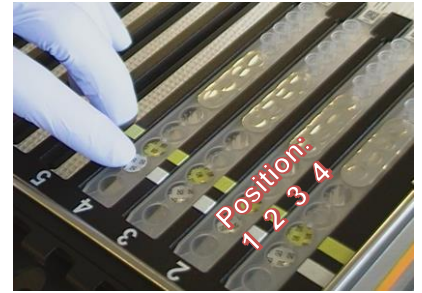


The BD MAX™ System, the BD MAX™ Cdiff Assay are in vitro diagnostic medical devices, bearing a CE mark.

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3. BD MAX™ Rack and BD MAX™ System Run

- a. For each sample to be tested, place one Unitized Reagent Strip into the BD MAX™ Rack.
- b. Snap one Extraction Tube (white foil) into each Strip in Position 1.
- c. Snap one Master Mix Tube (green foil) into each Strip in Position 2.
- d. Leave Strip Position 4 unfilled.
- e. Create the Worklist making sure to select the correct Test:
 - < **BD MAX Cdiff 56** >
- f. Place the prepared Sample Buffer Tubes in the BD MAX™ Rack corresponding to the appropriate assembled Strip.
- g. Place the assembled BD MAX™ Rack(s) and required number of BD MAX™ PCR Cartridge(s) into the instrument.
- h. Close BD MAX™ door and Start run.



4. Results and Repeats

- a. The BD MAX™ System software automatically interprets test results and reports results for each sample.
 - i. A test result may be called as NEG (negative), POS (positive) or UNR (unresolved) based on the amplification status of the target and of the Sample Processing Control.
 - ii. In the case of an IND, INC and UNR, it is recommended to repeat the test.
- b. Prepared Sample Buffer Tubes can be stored at 2–8°C for up to 120 hours (5 days) or at 25 ± 2°C for a maximum of 5 hours. Sufficient volume is available for one repeat test from the Sample Buffer Tube.

	BD MAX Cdiff 56
Channel 475/520 LIS code	<i>tcdB</i> gene Cdiff
Channel 530/565	
Channel 585/630	Sample Processing Control
Channel 630/665	
Channel 680/715	

Assay	PCR time	Time in minutes	number of samples					
			24	20	16	12	8	4
Cdiff	40	prep time	81	76	70	61	53	45
		time to results	122	116	111	101	92	84