

**Before you begin**

- Store the STANDARD™ M10 *C. difficile* cartridges at 2 ~ 28°C (36 ~ 82°F).
- This test is only for unformed stool specimens.
- Always wear clean gloves and follow your institution's safety policy when handling patient samples.

Refer to IFU for Warnings and Precautions, Specimen Collection, Transport, storage and Quality Control.

**TEST PROCEDURE**

**I. Starting the STANDARD™ M10 system**

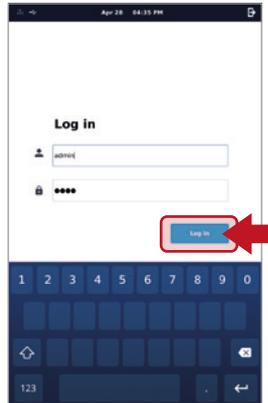
**1. Turn on M10**

Connect the M10 Console and Modules, then turn on each switch.



**2. Log in**

Enter user name and password, and touch the Log in button.



**3. Select M10 Module**

Touch the button of an available Module on the Home screen.



**4. Scan/Type Patient/Sample ID**

Scan the Patient/Sample ID using the integrated barcode reader of the M10 Console. (or type in using a virtual keyboard)



Patient ID is optional and can be turned off in the 'SETTINGS'.

**5. Scan test Cartridge**

Scan the Cartridge barcode using the integrated barcode reader of the M10 Console.



After scanning the cartridge, it automatically proceeds to the next step.

**6. Sample loading guide**

Watch the animated guide for cartridge preparation and sample loading. Touch the screen to continue.



Sample Guide screen



## TEST PROCEDURE (continued)

### II. Loading a sample into the cartridge

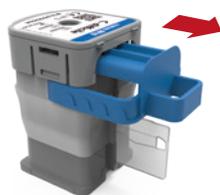


Start the test within 10 minutes of loading the sample into the STANDARD™ M10 *C. difficile* cartridge. Stool specimens must be processed by following method.

1. Open carefully the lid of the specimen collection container and avoid solid particles that may affect the test.
2. Using the disposable sampling swab, collect 0.1 g of the stool and put it in the stool pretreatment solution.
3. After closing the tube cap, vortex the tube for 10 seconds to ensure that the stool and stool pretreatment solution are thoroughly mixed.
4. Insert the barrel of the Stool pretreatment tool into the sample loading hole of the cartridge.
5. Collect 1.4ml up to the marked line on the dropper and transfer it to the barrel of the stool pretreatment tool.
6. Load the entire amount into the cartridge using the plunger of the stool pretreatment tool.

#### 1. Remove Safety Clip

Remove the Safety Clip from the Cartridge.



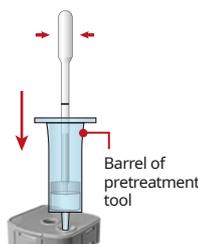
#### 2. Pierce Cartridge

Press down on the lid to pierce the sealed cartridge.



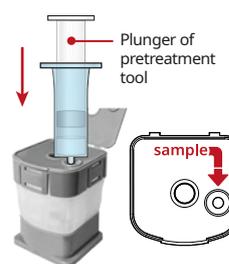
#### 3. Transfer Sample

Open the lid and transfer appropriate volume of the prepared sample using disposable dropper with volume indication.



#### 4. Inject Sample

Insert and press down the plunger.



#### 5. Close Cartridge lid

Close the cartridge lid.



### III. Running a test

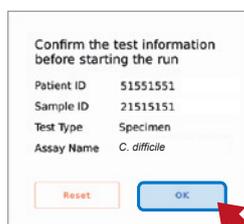
#### 1. Load Cartridge into the Module

Place the cartridge into the assigned M10 Module and close the door manually.



#### 2. Confirm the test

After confirm the sample and cartridge information, touch the 'OK' button.



Confirm the Test screen

#### 3. Start Run

The remaining time is displayed on the M10 Console monitor.



Running screen



The amplification chamber of the cartridge should face the inside of the M10 module.

## RESULT INTERPRETATION

Result	tcdB	IC
Toxigenic <i>C.difficile</i> Positive	+	+/-
Toxigenic <i>C.difficile</i> Negative	-	+
Invalid	-	-
Error	No result	

- If the IC is negative and the results for any of the targets are positive, the results for all targets are considered valid. A high copy number of target-specific gene can lead to reduced or absent IC.  
 - If an invalid result is confirmed in one or more of the pathogen results, that tests will be invalidated. Please conduct a re-test.

Outcome (Home screen)	Result (Review screen)	Description
Positive	+	At least one pathogen is positive.
Negative	-	No pathogen was detected.
Invalid	!	All pathogens are not detected and IC signal does not have a Ct value within the valid range.
Error	X	The test failed because either an error occurred or the test was canceled by the user.

Result (Summary screen)	Result (Summary screen)	Description
IC Valid	V	IC has a Ct within the valid range. : The test was completed. Report positive/negative results of target according to the interpretation shown in table 5. (If the target is positive, it is displayed as 'IC Valid' regardless of the IC Ct value.)
IC Invalid	!	All pathogens are not detected and IC signal does not have a Ct value within the valid range.
Error	X	The test failed because either an error occurred or the test was canceled by the user. Repeat test.