

# STANDARD *M10* *C. difficile*

STANDARD™ M10 *C. difficile*

REF M10-CDF-01

## INSTRUCTIONS FOR USE

For use with STANDARD™ M10 system



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## 1. Intended Use

STANDARD M10 *C. difficile* test is a multiplex Real-Time PCR test intended for use with STANDARD M10 system for the qualitative detection of bacterial DNA from *Clostridioides difficile* (toxin B gene (*tcdB*)) in unformed (watery or soft) stool specimens collected from patients with symptoms. Positive results are indicative of the presence of toxin B (*tcdB*) DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Negative results should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. STANDARD M10 *C. difficile* test is intended to be performed by trained users in both laboratories and near-patient testing settings.

## 2. Summary and Explanation

*Clostridioides difficile* (*C. difficile*) is a spore-forming, gram-positive anaerobic bacillus that is the leading cause of approximately 20 ~ 30% of antibiotic-associated diarrhea and is the most common cause of healthcare-associated infections. In other words, it is responsible for various forms of antibiotic-associated diarrhea, which can be activated by antibiotic treatment or disruptions to the normal balance of gastrointestinal flora. While nearly all antibiotics carry a risk of contributing to this infection, it is particularly common in patients using antibiotics such as fluoroquinolone, clindamycin, carbapenems, cephalosporine, and penicillins. CDI (*Clostridioides difficile* infection) symptoms range from mild diarrhea to severe pseudomembranous colitis.

*C. difficile* produces two kinds of exotoxins, toxin A and toxin B, both of which lead to diarrhea and enteritis. These toxins, encoded by the *tcdA* and *tcdB*, are cytotoxic and proinflammatory. They can cause impairment of tight junctions and disruption of the actin cytoskeleton in human intestinal epithelial cell, resulting in fluid accumulation and damage to the intestine. These toxins have been shown to cause further fluid secretion and intestinal inflammation, releasing inflammatory cytokines not only from mast cells and macrophages, but also from epithelial cells. In cases where the toxin B(*tcdB*) gene is present, most *Clostridioides difficile* strains are identified as toxigenic. Therefore, it suggests that toxin B may have more systemic effects than previously believed. This pathogen is capable of causing disease that could be severe or fatal if not promptly diagnosed and treated.

### [Cartridge Description]

STANDARD M10 *C. difficile* is a molecular *in vitro* diagnostic assay that aids in the detection of *tcdB* based on nucleic acid amplification technology, Real-Time PCR. STANDARD M10 *C. difficile* cartridge contains bacterial DNA extraction buffers and Real-Time PCR reagents for the *in vitro* qualitative detection of *tcdB* in unformed stool specimens.

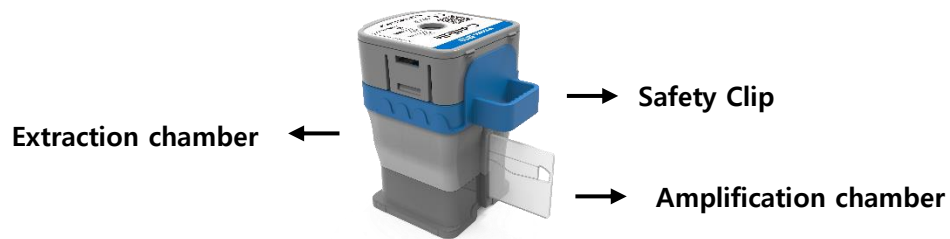


Figure 1. Layout of STANDARD M10 *C. difficile* cartridge

## 3. Principle of the Procedure

STANDARD M10 *C. difficile* test is an automated *in vitro* diagnostic test for qualitative detection of nucleic acid from *Clostridioides difficile*. STANDARD M10 *C. difficile* test is performed on STANDARD M10 system.

STANDARD M10 system automates and integrates sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in various specimens using molecular diagnostic assays. The system consists of STANDARD M10 Module and STANDARD M10 Console with preloaded software for running tests and viewing the results. The system requires the use of single-use disposable cartridges that hold the Real-Time PCR reagents and host the Real-Time PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the systems, see STANDARD M10 system User Manual.

STANDARD M10 *C. difficile* test includes reagents for the detection of DNA from *Clostridioides difficile* in unformed stool specimens. The cartridge is present to control for adequate processing of the sample and Real-Time PCR reaction.

The table below shows the target that each channel is designed to detect.

Table 1. Fluorescent channel of each target gene

Target	Channel
<i>tcdB</i>	FAM
Internal control (IC)	Cy5

## 4. Materials Provided

STANDARD M10 *C. difficile* contains sufficient reagents to process 10 specimens or quality control samples.

**Table 2. Contents of STANDARD M10 *C. difficile***

	Contents	Quantity	Usage in each reaction
1	Cartridge	10	1ea
2	Quick Reference Instructions	1	-

## 5. Storage and Handling

Store STANDARD M10 *C. difficile* kit at 2 ~ 28°C (36 ~ 82°F). If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature (20 ~ 28°C, 68 ~ 82°F). Do not remove the Safety Clip of the cartridge and do not press the cartridge until actual use. Do not use a cartridge that has leaked or is wet. Under these conditions, cartridges can be stored until the expiration date printed on the packaging.

## 6. Materials Required but Not Provided

- STANDARD M10 system with User Manual  
At least one STANDARD M10 Console (Cat. No. 11M1011) and one STANDARD M10 Module (Cat. No. 11M1012)
- Vortex mixer
- Commercially available sterilized containers for collecting unformed specimens
- STANDARD M10 Stool Pretreatment Kit (SD Biosensor, Cat. No. 11PRT20A)
- PPE (Personal Protective Equipment)
- Biohazard container

## 7. Warnings and Precautions

- 1) This kit is only for *in vitro* diagnosis.
- 2) Please read the Instructions for Use carefully before testing.
- 3) Improper specimen collection, transfer, storage, and processing may cause erroneous test results.
- 4) Do not remove the Safety Clip of the cartridge before use.
- 5) Do not press the cartridge until actual use.
- 6) Do not use a cartridge that has leaked or is wet.
- 7) Do not use the kit after its expiration date.
- 8) Do not shake, tilt, or invert the cartridge, especially after pressing the cartridge to punch the seal. It may yield invalid or false test results.
- 9) Do not use a cartridge with a damaged barcode label.
- 10) Do not reuse processed cartridges.
- 11) All patient samples should be handled as if these samples are infectious.
- 12) All materials should be considered potentially infectious and should be handled with precautions.
- 13) As this test involves extraction of bacterial DNA and PCR amplification, care should be taken to avoid contamination. Regular monitoring of laboratory contamination is recommended.
- 14) Clinical laboratories should be equipped with equipment and operators in strict accordance with the "Code of Practice for Clinical Gene Amplification Laboratories."
- 15) When using this kit, it should be operated strictly in accordance with the instructions and follow the technical requirements of the clinical gene amplification laboratory.
- 16) Follow your institution's environmental waste procedures for proper disposal of used cartridges.

## 8. Specimen Collection, Transport, and Storage

In order to obtain an adequate specimen, follow your institution's guidelines of collecting specimens for *C. difficile* testing.


1. Collect and transfer the liquid or soft stool into the commercially available sterilized container.
2. If the container with the stool is stored and transported in a refrigerator at 2 ~ 8°C / 36 ~ 46°F, the specimen can be used for testing within 5 days.
3. At room temperature (20 ~ 28°C, 68 ~ 82°F), store the specimen up to 24 hours.
4. For long-term storage, specimens should be frozen.

## 9. Procedure

### 9.1. Preparing the Specimen

1. Stabilize all reagents and specimens at room temperature for 30 minutes before testing.
2. Refer to IFU of STANDARD M10 Stool Pretreatment Kit.
  - 1) Carefully open the lid of the specimen collection container and avoid the use of 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) The prepared specimen is used in the process of 9.3.

### 9.2 Starting STANDARD M10 system

 Note	For detailed instructions, refer to STANDARD M10 system User Manual. If you have scanned the cartridge barcode in STANDARD M10 and the software version is not compatible, an 'Not Supported Device' error message appears. Update the software before proceeding with the test.
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- 1) Turn on STANDARD M10 system.
- 2) Check STANDARD M10 Console and the STANDARD M10 Module is connected and working.



Figure 2. Power connection

- 3) Enter the User ID and Password on the Log In screen of STANDARD M10 Console and click the Log In button.
- 4) Touch STANDARD M10 Module to run on the Home screen.  
(The door of the selected STANDARD M10 Module will automatically open for cartridge loading.)



Figure 3. Log In screen



Figure 4. Home screen, Status of M10 module

- 5) Enter a Patient ID and Sample ID by scanning the barcode or using virtual keyboard on the M10 Console screen. (Patient ID is optional. You can turn off the Patient ID option from the 'Settings'.)
- 6) Enter a Sample ID by scanning the barcode of the specimen or using virtual keyboard on the M10 Console screen. Make sure that the specimen tube cap is firmly closed when scanning the ID barcode printed on the specimen tube. (For quality control test, tick the QC check box.)




**Figure 5. Entering Sample ID**





**Figure 6. Scanning a cartridge**

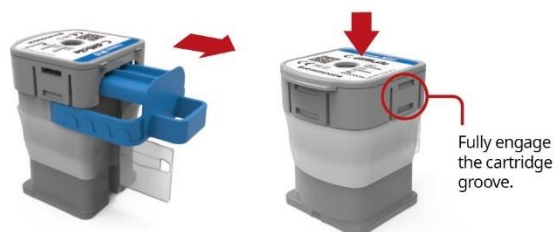
- 7) Scan STANDARD M10 *C. difficile* cartridge to be used. The STANDARD M10 Console will automatically recognize the assay to be run based on the cartridge barcode.

 Note	If you have scanned the cartridge barcode in the STANDARD M10 and the expiration date has expired, An 'Expired Device' error message appears. Check validity period and test with unexpired cartridges.
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### 9.3 Loading a sample into STANDARD M10 *C. difficile* cartridge

 Caution	If the cartridge has been refrigerated, perform the test after stabilizing it for 30 minutes at room temperature (20 ~ 28°C, 68 ~ 82°F). Once the sample has been loaded into the cartridge, start the test as soon as possible.
 Note	False negative results may occur if insufficient sample is added into the cartridge.

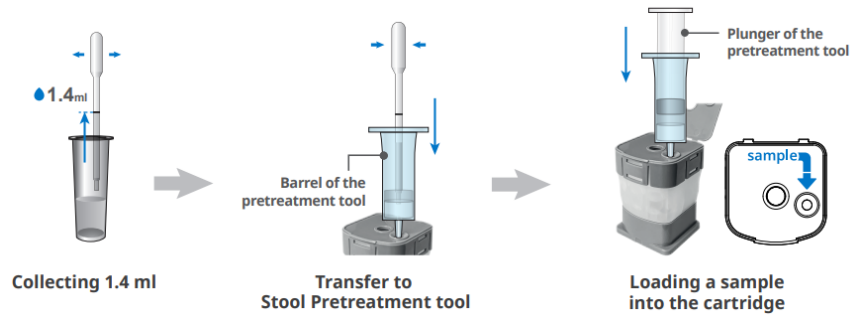
- 1) Remove the Safety Clip located underneath the lid of the cartridge.
- 2) Pierce the sealed cartridge by pressing down the lid until fully engaged into the cartridge groove.



**Figure 7. Pierce the sealed cartridge**

- 3) Open the lid and check that the seal is completely punctured before loading a sample.
- 4) Carefully open the tube cap.
- 5) Insert the barrel of the Stool pretreatment tool into the sample loading hole of the cartridge.
- 6) After collecting 1.4 mL of the sample prepared by the method described in 9.1 using the STANDARD Disposable dropper;

- which belongs to the Stool Pretreatment Kit, transfer it to the barrel of the Stool Pretreatment tool.
- 7) Load the entire amount of sample into the cartridge using the plunger of the Stool Pretreatment tool.



**Figure 8. Loading a sample**

- 8) After a few seconds, Sample Guide screen will automatically change to the Insert Cartridge screen. Touch the Sample Guide screen if you want to skip the guide.
- 9) Close the lid.



**Figure 9. Sample Guide Screen**



**Figure 10. Insert Cartridge screen**

## 9.4 Running a test

- 1) Load the cartridge on the selected STANDARD M10 Module with the Amplification chamber facing the inside of the module (The status indicator of the selected module will blink green).
- 2) Close the door completely.
- 3) After confirming the sample and cartridge information, touch the OK button on the screen (Touch the Reset button to re-input the information).
- 4) Assay starts automatically, and remaining time will appear on the screen.

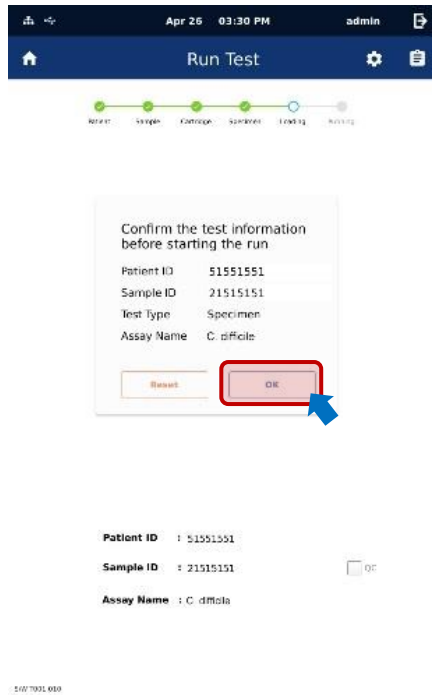


Figure 11. Confirm the test screen

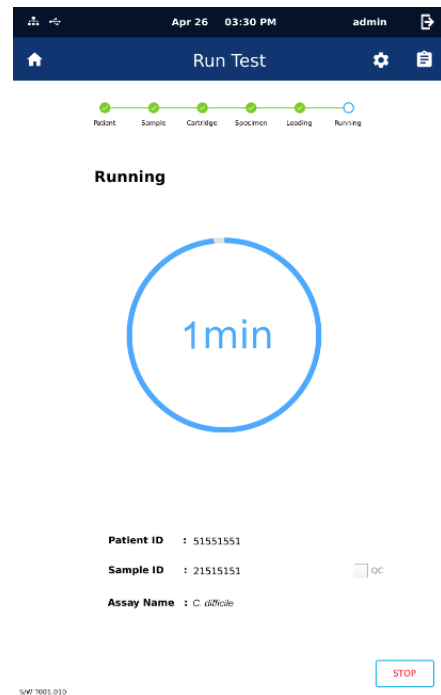







Figure 12. Running screen

- 5) When the run is finished, it switches to the Review screen and the result is displayed.
- 6) Dispose the used cartridges in the appropriate biohazard waste container according to your institution's standard practices.
- 7) To run another test, touch the Home icon  and repeat the process (If another STANDARD M10 Module connected to the STANDARD M10 Console is available, you can start a new test while another test is running).

## 10. Interpretation of Results




The results are interpreted automatically by STANDARD M10 Console and are clearly shown in the Review screen. STANDARD M10 *C. difficile* test provides test results based on the detection of *tcdB* gene targets according to the algorithms shown in Table 3.

Table 3. Description of results

Outcome (Home screen)	Result (Review screen)	Description
Positive		Target pathogen is detected.
Negative		No target pathogen is detected.
Invalid		Target pathogen is not detected and IC signal does not have a Ct value within the valid range.
Error		The test failed because either an error occurred or the test was canceled by the user.




**Table 4. Description of IC results**

Outcome (Summary screen)	Result (Summary screen)	Description
IC Valid		IC has a Ct value 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 detected, it is displayed as 'IC Valid' regardless of the IC Ct value.)
IC Invalid		Target pathogen is not detected, and IC signal does not have a Ct value within the valid range.
IC Error		The test failed because either an error occurred or the test was canceled by the user. Repeat test.

**Table 5. Interpretation of results**

Result	Interpretation
Toxigenic <i>C. difficile</i> Positive	Toxigenic <i>C. difficile</i> target DNA is detected. <ul style="list-style-type: none"> <li>Toxigenic <i>C. difficile</i> signal has a Ct value within the valid range.</li> <li>IC: N/A (not applicable); IC is ignored because <i>C. difficile</i> target <i>tcdB</i> amplification occurred.</li> </ul>
Toxigenic <i>C. difficile</i> Negative	Toxigenic <i>C. difficile</i> target DNA is not detected. <ul style="list-style-type: none"> <li>IC: Valid; IC has a Ct within the valid range and endpoint above the minimum setting.</li> </ul>
Invalid	IC does not meet acceptance criteria. Toxigenic <i>C. difficile</i> target is not detected. Repeat test. <ul style="list-style-type: none"> <li>IC: Invalid; IC and DNA signals do not have a Ct within valid range.</li> </ul>
Error	The test failed because either an error occurred or the test was canceled by the user. Presence or absence of target nucleic acids cannot be determined. Repeat the test.

 Note	<ul style="list-style-type: none"> <li>If the IC is negative and the results for the target pathogen is positive, the result is considered valid. A high copy number of target-specific gene can lead to reduced or absent IC.</li> <li>If at least one of the IC is negative and the result for the target is negative, the sample was not properly processed. Please conduct a re-test.</li> </ul>
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## 11. Quality Control

Quality Control procedures are intended to monitor cartridge and assay performance. If the controls are not valid, the patient results cannot be interpreted.

Internal control(IC): Ensures that a proper sample has been applied, the reagents in the cartridge are well functioning, there are no other interfering factors in the sample, and the procedure has been performed correctly. In clinical samples showing positive signal for toxigenic *C. difficile*, the IC is reluctant and is ignored. If the IC fails and no toxigenic *C. difficile* is detected, the result is considered invalid.

External controls should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory's standard quality control procedures.

For external controls, it is recommended to use the list below. Please comply with the information stated on the User Manual.  
 NATrol™ Clostridium difficile Positive Control from Zeptomatrix catalog #NATCDI-6MC-IVD  
 NATrol™ Clostridium difficile Negative Control from Zeptomatrix catalog #NATCSO-6MC-IVD

Products other than the mentioned substance can be used after being evaluated and validated for efficacy by each country or hospital independently.

## 12. Performance

### 12.1. Limit of Detection Test

The LoD test was performed using two lots of test samples and a single type of standard material (*Clostridioides difficile* (Prevot) Lawson et al). The tentative Limit of Detection (LoD) was determined by serially diluting the standard material by a factor of 1/10 to prepare 5 concentrations. After 4 repeated tests for each concentration, the concentration at which 100% detection was confirmed as the initial LoD. For the LoD test, each positive standard was diluted serially by 1/3 in 5 concentrations and repeated 24 times for each concentration. Based on the test results, LoD was set through Probit analysis.

**Table 6. Limit of detection for a target of STANDARD M10 *C. difficile***

Pathogen	Target	LoD (95% CI)
<i>Clostridioides difficile</i>	<i>tcdB</i>	0.55 (95% CI 0.46~0.77) CFU/mL

## 12.2. Interference Test

The Interference test was assessed with 15 types of endogenous and exogenous interfering substances. The test was repeated 3 times with 1 lot for each case. As a result, there is no interference with the following 15 interfering substances.

**Table 7. Substances tested in interference test**

No.	Interfering Substances	Test Concentration
1	Moist Towelettes	10% (v/v)
2	Peptobismol	10% (v/v)
3	ky jelly	1% (w/v)
4	cortizone10	1% (w/v)
5	fleet glycerin suppositories	10% (w/v)
6	yeastgard suppositories	10% (w/v)
7	PREPARATION H	10% (w/v)
8	canesten vaginal cream	10% (w/v)
9	monistat 3	1% (w/v)
10	movicol	10% (w/v)
11	imodium	10% (w/v)
12	Palmitic acid	10% (w/v)
13	Stearic acid	10% (w/v)
14	Mineral Oil	10% (w/v)
15	Metronidazole	10% (w/v)

## 12.3. Cross-reactivity

The cross-reactivity was assessed by 20 other pathogens (viral or bacterial) that may cause symptoms similar to the target pathogen. The following 20 cross-reacting substances were tested 3 times per sample with 1 lot. As a result, it was confirmed that among the 20 cross-reactants, there is no cross-reactivity with *tcdB* gene targeted by this test cartridge.

**Table 8. Substances tested in cross-reactivity test**

No.	Category	Organism	Concentration
1	Clostridium genus organisms, including non-toxigenic <i>C. difficile</i>	<i>Clostridium scindens</i>	1x10 <sup>6</sup> CFU/mL
2		<i>Clostridium sordellii</i>	1x10 <sup>6</sup> CFU/mL
3		<i>Clostridioides difficile</i> (Non-toxigenic)	1x10 <sup>6</sup> CFU/mL
4		<i>Clostridium perfringens</i>	1x10 <sup>6</sup> CFU/mL
5		<i>Clostridium sporogenes</i>	1x10 <sup>6</sup> CFU/mL
6	Other high priority organisms	<i>Acinetobacter baumannii</i>	1x10 <sup>6</sup> CFU/mL
7		<i>Candida albicans</i>	1x10 <sup>6</sup> CFU/mL
8		<i>Citrobacter freundii</i>	1x10 <sup>6</sup> CFU/mL
9		<i>Enterococcus faecalis</i>	1x10 <sup>6</sup> CFU/mL

No.	Category	Organism	Concentration	
10		<i>Lactobacillus acidophilus</i>	1x10 <sup>6</sup> CFU/mL	
11		<i>Burkholderia multivorans</i>	1x10 <sup>6</sup> CFU/mL	
12		<i>Proteus mirabilis</i>	1x10 <sup>6</sup> CFU/mL	
13		<i>Salmonella enterica subsp. arizonae</i>	1x10 <sup>6</sup> CFU/mL	
14		<i>Serratia marcescens subsp. marcescens</i>	1x10 <sup>6</sup> CFU/mL	
15		<i>Staphylococcus aureus subsp. aureus</i>	1x10 <sup>6</sup> CFU/mL	
16		<i>Vibrio parahaemolyticus</i>	1x10 <sup>6</sup> CFU/mL	
17		<i>Peptostreptococcus anaerobius</i>	1x10 <sup>6</sup> CFU/mL	
18		<i>Plesiomonas shigelloides</i>	1x10 <sup>6</sup> CFU/mL	
19		Rotavirus A	1x10 <sup>5</sup> TCID <sub>50</sub> /mL	
20		Human enterovirus 71	1x10 <sup>5</sup> TCID <sub>50</sub> /mL	
21		Positive Control	<i>Clostridioides difficile</i> (Toxigenic)	1x10 <sup>6</sup> CFU/mL
22		Negative Control	Negative Specimen Only	-

#### 12.4. Precision Test

##### 1) Repeatability

To confirm the precision of the test cartridge, STANDARD M10 *C. difficile*, positive standard material (*Clostridioides difficile* ATCC-9689) with 3X LoD at intermediate concentration, and 1X LoD at low concentration were tested twice a day for 5 days in a single lot. Each concentration was repeated twice during the test. As a result, the SD value was derived from within-run, between-run, between-day, and within-laboratory to check the repeatability, and the SD < 2.0 Ct met the acceptance criteria, confirming the repeatability.

##### 2) Reproducibility

To confirm the precision of this test cartridge, STANDARD M10 *C. difficile*, positive standard material with 3X LoD at intermediate concentration, and 1X LoD at low concentration were tested twice a day for 5 days in 2 lots, 2 sets of equipment at 2 sites, 2 inspectors for each concentration per test. Each concentration was repeated twice during the test. As a result, the SD < 2.0Ct and CV < 5% for each lot, equipment, location, tester met the acceptance criteria, confirming reproducibility.

#### 12.5 Clinical Trial

The test results of the STANDARD M10 *C. difficile* were compared with the confirmed results from both positive samples and negative samples. The study was conducted using a total of 334 samples, consisting of 135 positive samples and 199 negative samples.

Based on this data, the clinical sensitivity and specificity of the medical device were calculated for the clinical performance test. The results are as shown in the table below.

**Table 9. Summary of the clinical sensitivity and specificity test results**

Result		Confirmed		Total
		Positive	Negative	
STANDARD M10 <i>C. difficile</i>	Positive	133	3	136
	Negative	2	196	198
Total		135	199	334

- Clinical sensitivity: 98.52% (133/135, 95% CI: 94.75% - 99.82%)

- Clinical specificity: 98.49% (196/199, 95% CI: 95.66% - 99.69%)


















## 13. Limitations

- 1) STANDARD M10 *C. difficile* detects the *tcdB* gene. Toxigenic *C. difficile* strains without the *tcdB* gene are very rare. Incorrect test results may occur from specimens that do not contain *tcdB* gene but are toxigenic.
- 2) Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been evaluated.
- 3) A false negative result may occur if :
  - Sample concentrations are near or below the limit of detection of the test.
  - A specimen is improperly collected, transported or handled.
  - Inadequate number of organisms are present in the specimen.
  - Cartridges are exposed to improper environmental factors (temperature / humidity).
- 4) False positive results may happen from cross-contamination between patient samples, specimen mix-up and/or DNA contamination during product handling.
- 5) Qualitative detection of positive results in this kit does not indicate the presence of live bacteria. It is recommended to use other methods for confirmation at the same time.
- 6) This kit only classifies and identifies the *Clostridioides difficile*. The test results are for clinical reference only. The clinical diagnosis and treatment of patients should be combined with their symptoms / signs, medical history, other laboratory tests and treatment responses considering.
- 7) Detection of *C. difficile* nucleic acid in stools confirms the presence of these organisms in diarrheal patients but may not indicate that *C. difficile* is the etiologic agents of the diarrhea.

## 14. References

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## 15. Symbols

	Reference number		Batch code
	<i>In vitro</i> diagnostics medical device		CE marking - European Conformity
	Consult Instructions for Use		Manufacturer
	Contains Sufficient for <n> Tests		Date of manufacture
	Caution		Authorized representative in the European Community
	Note		Keep dry
	Do not re-use.		Keep away from sunlight
	Temperature limit		Do not use if packaging is damaged
	Use-by date		

For further information on

**STANDARD M10**  
***C. difficile***

Please contact your  
SD BIOSENSOR representative

 **Manufacturer**  
**SD Biosensor, Inc.**

**Head office** : C-4th&5th, 16, Deogyong-daero 1556beon-gil, Yeongtong-gu,  
Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA

**Manufacturing site** : 14, Jeungpyeongsandan-ro, Jeungpyeong-eup,  
Jeungpyeong-gun, Chungcheongbuk-do, 27915, REPUBLIC OF KOREA



Authorized Representative

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**For In Vitro Diagnostic Use Only**

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