TruQuick™ C. diff Combo 10T

A rapid diagnostic test for the detection of Clostridium difficile GDH, Toxin A and Toxin B antigen in feces samples.

REF **TQ4510** IVD **Rx Only**

INTENDED USE
TruQuick C. diff Combo is a rapid chromatographic immunoassay for the qualitative detection of *Clostridium difficile* GDH, Toxin A and Toxin B in the feces specimen.

SUMMARY AND EXPLANATION OF THE TEST
Clostridium difficile is an anaerobic bacteria acting as an opportunistic pathogen: it grows in the intestine when the normal flora has been altered by treatment with antibiotics.[1-3] Toxinogenic strains of *Clostridium difficile* cause infections from mild-diarrhea to pseudomembranous colitis, potentially leading to death.[4]

Disease is caused by two toxins produced by toxinogenic strains of C. difficile: Toxin A (tissue-damaging enterotoxin) and Toxin B (cytotoxin). Some strains produce both toxins A and B, some others produce Toxin B only. The potential role of a third (binary) toxin in pathogenicity is still debated.[4]

The use of Glutamate Dehydrogenase (GDH) as an antigen marker of C. difficile proliferation has been shown to be very effective because all strains produce high amount of this enzyme.[5, 6]

TruQuick C. diff Combo allows the detection of GDH, Toxin A and Toxin B specific to C. difficile in fecal specimen.

BIOLOGICAL PRINCIPLES
TruQuick C. diff Combo detects three distinct antigens in fecal specimens for C. difficile, viz., GDH, Toxin A and Toxin B on three different test strips in a single test cassette, thus simultaneously detecting three antigens specific of Clostridium difficile.

For C. difficile-specific GDH Testing:
The membrane is precoated with anti-C. diff GDH antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-C. diff GDH antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-C. diff GDH antibody on the membrane and generate a colored line.

For C. difficile-specificToxin A Testing:
The membrane is precoated with anti-C. diff Toxin A antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-C. diff Toxin A antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-C. diff Toxin A antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

For C. difficile-specificToxin B Testing:
The membrane is precoated with anti-C. diff Toxin B antibody on the test line region. During testing, the specimen reacts with the particle coated with anti-C. diff Toxin B antibody. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-C. diff Toxin B antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result.

To serve as a procedural control, a colored line will always appear in the control line region of all the three test strips, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS/MATERIALS PROVIDED
The maximum number of tests obtained from this test kit is listed on the outer box.
- Test Cassettes: The Test Cassette contains anti-Clostridium difficile GDH, anti-Clostridium difficile Toxin A and anti-Clostridium difficile Toxin B particles gold conjugate pair with anti-Clostridium difficile GDH, anti-Clostridium difficile Toxin A and anti-Clostridium difficile Toxin B coated on the membrane.
- Specimen Collection Tube with Extraction Buffer: A buffered Extraction Buffer containing Proclin 300 as a preservative. The Extraction Buffer is supplied ready for use
- Package Insert
- Droppers

MATERIALS REQUIRED BUT NOT PROVIDED
- Stool container

PRECAUTIONS
1. For in vitro diagnostic use only. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.

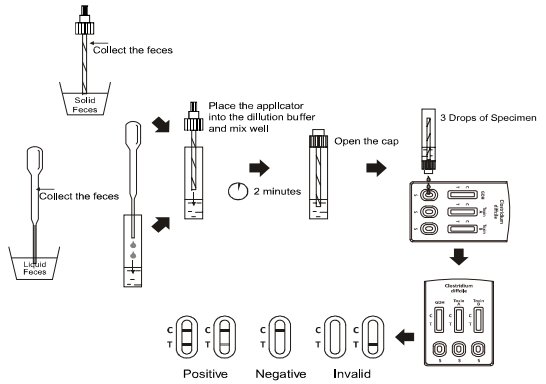
HAZARD and PRECAUTIONARY STATEMENTS
Refer to the SDS, available at www.meridianbioscience.com for Hazard and Precautionary Statements.

SHELF LIFE AND STORAGE
Store as packaged at room temperature or refrigerated (2-30 C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
1. The stool specimens must be tested as soon as possible after collection. If necessary, original feces specimen could be stored at 2-8 C for three days or -20 C for longer periods of time; extracted specimen in Buffer could be stored at 2-8 C for one week or -20 C for longer periods of time.
2. Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

TEST PROCEDURE
Allow the test, specimen, Stool Collection Buffer and/or control to reach room temperature (15-30 C) prior to testing.
1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain enough antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8 C if not tested within 6 hours. For long term storage, specimens should be kept below -20 C.
2. To process fecal specimens:
   - **For Solid Specimens**:
     Unscrew the cap of the Specimen Collection Tube, then randomly stab the specimen collection applicator into the fecal specimen at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - **For Liquid Specimens:**
     Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops of the liquid specimen (approximately 80 µL) into the Specimen Collection Tube containing the Extraction Buffer.
3. Tighten the cap onto the Specimen Collection Tube, then shake the Specimen Collection Tube vigorously to mix the specimen and the Extraction Buffer. Leave the collection tube for reaction for 2 minutes.
4. Bring the pouch to room temperature before opening it. Remove the Test Cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the Specimen Collection Tube upright and unscrew the tip of the Specimen Collection Tube. Invert the Specimen Collection Tube and transfer 3 full drops of the extracted specimen (approximately 120 µL) to each specimen well of the Test Cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read the results at 10 minutes after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the diluted sample contained in the Extraction Buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.



INTERPRETATION OF RESULTS
(Please refer to the illustration above.)
The test results appear in three different test windows respectively for GDH, Toxin A or Toxin B. The interpretation criteria remain the same for positivity or negativity for specific antigens under tests as per indication of the respective Test window. The results are to be interpreted as follows:
POSITIVE:*Two distinct colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *Clostridium difficile* antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new Test Cassette. If the problem persists, discontinue using the test kit immediately and contact Meridian's Technical Services Department at 800-343-3858 or your local distributor.

QUALITY CONTROL
This test should be performed per applicable local, state, or federal regulations or accrediting agencies.
An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Controls are not supplied with this kit; however, it is recommended that positive and negative external controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXPECTED VALUES
In a healthy individual's fecal specimens, *Clostridium difficile* test should give negative test result for any of the antigens tested. TruQuick C. diff Combo has been compared with another leading commercial rapid test. The correlation between the two systems is 98.5% for C.diff GDH and 98.5% for C.diff Toxin A+Toxin B.

LIMITATIONS OF THE PROCEDURE
1. TruQuick C. diff Combo is for in vitro diagnostic use only.
2. The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.
3. A positive test does not rule out the possibility that other pathogens may be present.

SPECIFIC PERFORMANCE CHARACTERISTICS
Sensitivity and Specificity
TruQuick C. diff Combo was evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity and specificity of TruQuick C. diff Combo is 98.0% relative to other Rapid Test Cassettes.

Clostridium difficile GDH Results

Method		Other Test Cassette		Total Result
	Results	Positive	Negative	
TruQuick C. diff Combo	Positive	38	1	39
	Negative	2	109	111
Total Result		40	110	150

Sensitivity: 95% (95% CI:*83.1%-99.4%)
Specificity: 99.1% (95% CI:*95.0%-99.9%)
Correlation: 98.0% (95% CI:*94.3%-99.6%) *Confidence Intervals

Clostridium difficile Toxin A+Toxin B Results

Method		Other Test Cassette		Total Result
	Results	Positive	Negative	
TruQuick C. diff Combo	Positive	10	1	11
	Negative	1	88	89
Total Result		11	89	100

Sensitivity: 90.9% (95% CI:*58.7%-99.8%)
Specificity: 98.9% (95% CI:*93.9%-99.9%)
Correlation: 98.0% (95% CI:*93.0%-99.8%) *Confidence Intervals

REPRODUCIBILITY
Intra-Assay Precision
To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected to check inter-batch accuracy (reproducibility), some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.
Inter-Assay Precision
Between-run precision was determined by 10 independent assays on the same nine specimens: negative 1 ng/mL, 2 ng/mL 5 ng/mL GDH, specimens, negative 2 ng/mL, 5 ng/mL and 10 ng/mL Toxin A specimens and 1 ng/mL, 2 ng/mL, 5 ng/mL Toxin B specimens.

CROSSREACTIVITY
An evaluation was performed to determine the crossreactivity of TruQuick C. diff Combo. No crossreactivity against gastrointestinal pathogens occasionally present as following:

Campylobacter coli	Salmonella enteritidis	Shigella dysenteriae
Campylobacter jejuni	Salmonella paratyphi	Shigella flexneri
E. coli O157:H7	Salmonella typhi	Shigella sonnei
H. pylori	Salmonella typhimurium	Staphylococcus aureus
Listeria monocytogenes	Shigella boydii	Yersinia enterocolitica

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SYMBOL USAGE
You may see one or more of these symbols on the labeling/packaging of this product:
Key guide to symbols

	Use By	CONTROL +	Positive control
LOT	Batch Code	CONTROL −	Negative control
IVD	In vitro diagnostic medical device	EC REP	Authorized Representative in the European Community
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent
REF	Catalogue number		Do not freeze
	Consult Instructions for Use	BUF RXN	Reaction Buffer
	Manufacturer		For IVD Performance Evaluation Only
Σ	Contains sufficient for <n> tests	SOLN STOP	Stopping Solution
	Temperature limitation	CONJ ENZ	Enzyme Conjugate
SN	Serial number	CONTROL	Assay Control
TEST	Test Device	REAG	Reagent
	Date of manufacture	BUF WASH	Wash Buffer
BUF	Buffer		Warning
CONJ	Conjugate	DIL SPE	Specimen Diluent (or Sample Diluent)
SUBS	Substrate	BUF WASH 20X	Wash Buffer Concentration: 20X
RUO	Research Use Only	DET REAG	Detection Reagent
IUO	Investigational Use Only	Rx Only	Prescription Use Only
	Do not use if package is damaged		

For technical assistance, call Technical Support Services at 800-343-3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800-543-1980.