Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces)

CE

INTENDED USE

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) a rapid visual immunoassay for the simultaneous detection and differentiation of Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (C. difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide.

Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. C. difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of C. difficile from feces, followed by toxin testing of the isolate, a labour-intensive assay to obtain a result.

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Glutamate Dehydrogenase (GDH), Toxin A and Toxin B in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile GDH, Toxin A&B in human feces samples.

For the Clostridium difficile GDH Rapid Test Cassette (Feces), the membrane is pre-coated with monoclonal antibodies against GDH on the test line region. During testing, the sample reacts with the particle coated with anti-GDH antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile GDH in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

For the Clostridium difficile Toxin A/B Rapid Test Cassette (Feces), the membrane is pre-coated with monoclonal antibodies against Toxin A on the A test line region and monoclonal antibodies against Toxin B on the B test line region. During testing, the sample reacts with the particle coated with anti-Toxin A and anti-Toxin B antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile Toxin or Toxin B in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) containing Clostridium difficile GDH-specific antibodies coated particles and GDH-specific antibodies coated on the membrane.

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) containing Clostridium difficile Toxin A and Toxin B antibodies coated particles and Toxin A-specific antibodies and Toxin B-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30℃). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re- use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8℃) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen at -20℃. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the

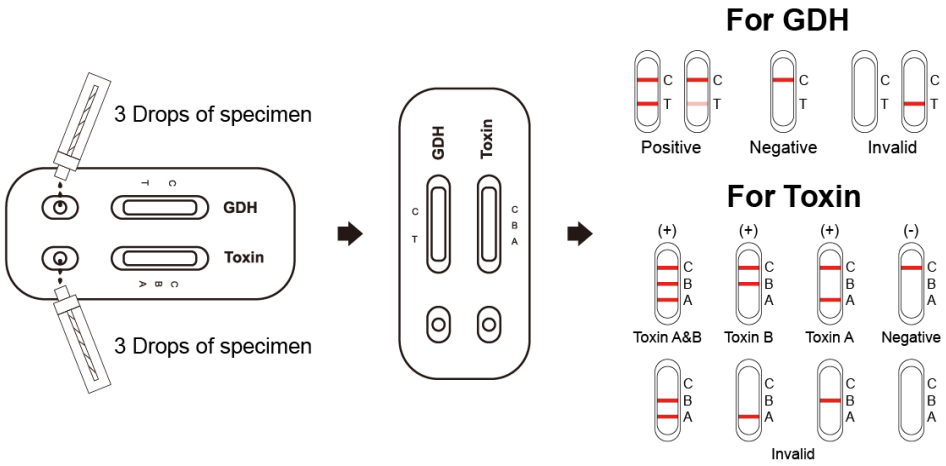
assay is performed within 6 hours after collection.

2. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
3. **For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80 μL) into the specimen collection tube containing the extraction buffer.
4. Replace the stick in the tube and tighten securely.
5. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20℃ if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30℃) prior to testing.

1. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
2. Hold the specimen collection tube upright and then unscrew and open the upper cap.
3. Squeeze 3 drops (~90 μL) of the sample solution in each sample well of the device and start the timer.
4. Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

For the GDH test:

1. **Positive:** Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).

2. **Negative:** One colored line appears in the control line region (C). No line appears in the test line region (T).

3. **Invalid:** Control line 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 your local distributor.

For the Toxin A&B test:

1. Positive:

1.1 Toxin A Positive:

The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Toxin A.

1.2 Toxin B Positive:

The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Toxin B.

1.3 Toxin A & B Positive:

The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for both Toxin A and Toxin B.

2. Negative:

One colored line appears in the control line region (C). No line appears in the test line region (T).

3. Invalid:

If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile GDH, Toxin A&B in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) should be used only with samples from human feces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper fecal specimens must be obtained
4. 4.. A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile GDH Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Antigen GDH Rapid Test Cassette	Results	Positive	Negative	
	Positive	62	1	63
	Negative	0	50	50
Total Results		62	51	113

Relative Sensitivity: 100%
Relative Specificity: 98.0%
Accuracy: 99.1%

Table 2: The Clostridium difficile Toxin A Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	1	44
	Negative	0	69	69
Total Results		43	70	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

Table 3: The Clostridium difficile Toxin B Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	36	1	37
	Negative	0	76	76
Total Results		36	77	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile GDH & Toxin A/B Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. Detection limit values of Clostridium difficile GDH & Toxin A/B are 1 ng/mL for GDH, 2 ng/mL for Toxin A and 1 ng/mL for Toxin B.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative:

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

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin. Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
3. Sullivan, N.M. et al.: Purification and characterization of toxins A and B of Clostridium difficile. Infect. Immun. (1982); 35: 1032-1040.
4. McDonald, L.C. et al.: An epidemic, toxin gene-variant strain of Clostridium difficile. N. Engl. J. Med. (2005); 353: 23.
5. Loo, V.G. et al.: A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N. Engl. J. Med. (2005); 353. 23.
6. Bartlett, J.G., Gerding, D.N.: Clinical recognition and diagnosis of Clostridium difficile infection. CID (2008); 46 (Suppl. 1): 12-18.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054 Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GCCD-602a

Revision Date: 2022-12-06
B22719-02

Clostridium difficile Toxin A&B Rapid Test Cassette (Feces)

CE

INTENDED USE

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) a rapid visual immunoassay for the qualitative, presumptive detection of Clostridium difficile Toxin A&B in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (C. difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide.

Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. C. difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains, making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of C. difficile from feces, followed by toxin testing of the isolate, a labor-intensive assay to obtain a result.

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Toxin A&B in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile Toxin A&B in human feces samples. The membrane is pre-coated with monoclonal antibodies against Toxin A on the A test line region and monoclonal antibodies against Toxin B on the B test line region. During testing, the sample reacts with the particle coated with anti-Toxin A and anti-Toxin B antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile Toxin or Toxin B in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) containing Clostridium difficile Toxin A and Toxin B antibodies coated particles and Toxin A-specific antibodies and Toxin B-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30℃). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re-use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8℃) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen a-20℃. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

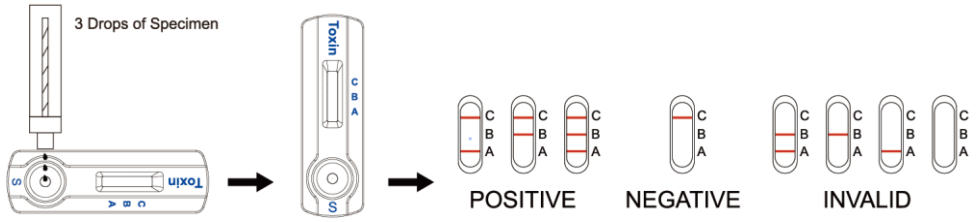
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the assay is performed within 6 hours after collection.
2. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
3. **For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80 µL) into the specimen collection tube containing the extraction buffer.
4. Replace the stick in the tube and tighten securely.
5. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20℃ if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30℃) prior to testing.

1. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
2. Holding the sample collection device upright, carefully break off the tip of collection device.
3. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the device and start the timer.
4. Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

1. Positive:

1.1 Toxin A Positive:

The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Toxin A.

1.2 Toxin B Positive:
The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Toxin B.
1.3 Toxin A& B Positive:
The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for both Toxin A and Toxin B.
2. Negative:
One colored line appears in the control line region (C). No line appears in the test line region (T).
3. Invalid:
If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile Toxin A&B in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) should be used only with samples from human feces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper fecal specimens must be obtained.
4. A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile Toxin A Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	43	1	44
	Negative	0	69	69
Total Results		43	70	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

Table 2: The Clostridium difficile Toxin B Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Toxin A&B Rapid Test Cassette	Results	Positive	Negative	
	Positive	36	1	37
	Negative	0	76	76
Total Results		36	77	113

Relative Sensitivity: 100%
Relative Specificity: 98.6%
Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile Toxin A&B Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. Detection limit values of Clostridium difficile Toxin A&B are 2 ng/mL for Toxin A and 1 ng/mL for Toxin B.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative:

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

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin. Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
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IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054 Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GCCD(Toxin A&B)-602a

Revision Date: 2022-02-21
B22718-01

Clostridium difficile Antigen GDH Rapid Test Cassette (Feces)

CE

INTENDED USE

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) a rapid visual immunoassay for the qualitative, presumptive detection of Clostridium difficile Glutamate Dehydrogenase (GDH) in human fecal specimens, as a screening test and as an aid in the diagnosis of Clostridium difficile infection.

INTRODUCTION

Clostridium difficile (C.difficile), a Gram-positive spore bearing anaerobic bacterium is the major aetiological agent of diarrhoea and colitis associated with antibiotics. C. difficile is the most common cause of health care-associated diarrhoea in developed countries and is a major source of nosocomial morbidity and mortality worldwide

Disease due to C. difficile develops when the organism is allowed to proliferate in the colon, most commonly after antibiotic use has eliminated competing flora. C.difficile can release two high-molecular-weight toxins, toxin A and toxin B, which are responsible for the clinical manifestations, which range from mild, self-limited watery diarrhoea to fulminant pseudomembranous colitis, toxic megacolon and death.

Clostridium difficile Glutamate Dehydrogenase (GDH) is an enzyme produced in large quantities by all toxigenic and non-toxigenic strains,making it an excellent marker for the organism.

The toxigenic culture (TC) is used as the gold standard technique to determine Clostridium difficile infection. This method consists in culture and isolation of C. difficile from faeces, followed by toxin testing of the isolate, a labour-intensive assay to obtain a result.

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is a rapid test to qualitatively detect Clostridium difficile Glutamate Dehydrogenase (GDH) in human feces in 10 minutes. The test can be performed by untrained or minimally skilled personnel, without cumbersome laboratory equipment.

PRINCIPLE

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is a qualitative lateral flow immunoassay for the detection of Clostridium difficile GDH in human feces samples. The membrane is pre-coated with monoclonal antibodies against GDH on the test line region. During testing, the sample reacts with the particle coated with anti-GDH antibodies, which were pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. If there is sufficient Clostridium difficile GDH in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) containing Clostridium difficile GDH-specific antibodies coated particles and GDH-specific antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Test cassettes
20 Extraction tubes with buffer
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test Cassette is stable through the expiration date printed on the sealed pouch. The test Cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged.
3. Test is for single use only. Do not re- use under any circumstances.
4. Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink or smoke in any area where specimens and kits are handled.
7. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
8. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

SPECIMEN COLLECTION AND PREPARATION

- The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) is intended for use with human fecal specimens only.
- Stool samples should be collected in clean containers. The samples can be stored in the refrigerator (2-8℃) for 7 days prior to testing. For longer storage, maximum 1 year, the specimen must be kept frozen a-20℃. In this case, the sample will be totally thawed and brought to room temperature before testing. Ensure only the amount needed is thawed because of freezing and defrosting cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

SPECIMEN PREPARATION

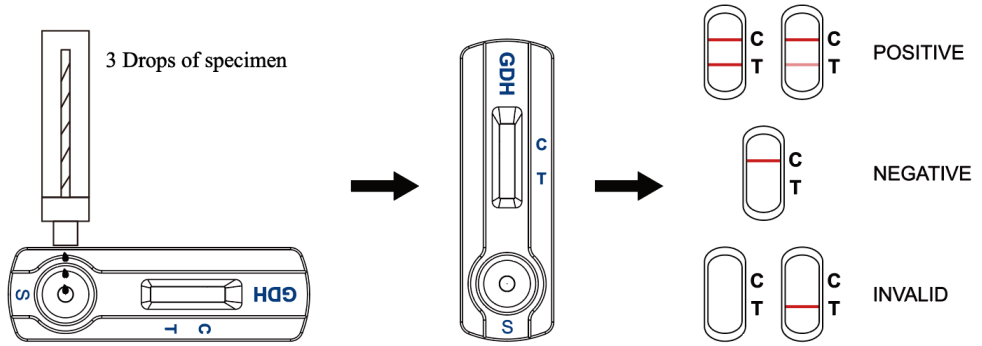
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Collect a random sample of feces in a clean, dry receptacle. Best results will be obtained if the assay is performed within 6 hours after collection.
2. Unscrew and remove the dilution tube applicator. Be careful not to spill or spatter solution from the tube. Collect specimens by inserting the applicator stick into at least 5 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
3. **For liquid specimens:** Hold the pipette vertically, aspirate fecal specimens, and then transfer 3 drops (approximately 80μL) into the specimen collection tube containing the extraction buffer.
4. Replace the stick in the tube and tighten securely.
5. Shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Specimens prepared in the specimen collection tube may be stored for 6 months at -20° C if not tested within 1 hour after preparation.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

1. Remove the test from the sealed pouch and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed immediately after opening the foil pouch.
2. Holding the sample collection device upright, carefully break off the tip of collection device.
3. Squeeze 3 drops (~90μL) of the sample solution in the sample well of the device and start the timer.
4. Wait for the colored line(s) to appear. Read results in 10 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line 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 your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) will only indicate the presence of parasites in the specimen (qualitative detection) and should be used for the detection of Clostridium difficile GDH in faeces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) should be used only with samples from human faeces. The use of other samples has not been established. The quality of the test depends on the quality of the sample; proper faecal specimens must be obtained
4. Positive results determine the presence of Clostridium difficile in faecal samples; never the less it can be due to toxigenic or non-toxigenic strains of Clostridium difficile. A positive result should be flowed up with additional laboratory techniques (toxigenic culture) to determine the strain.
5. A negative result is not meaningful because of it is possible the antigen concentration in the stool samples is lower than the detection limit value. If the symptoms or situation still persist, a Clostridium difficile determination should be carried out, on a sample from an enrichment culture.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

1. Clinical Sensitivity, Specificity and Accuracy

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) has been evaluated with specimens obtained from patients. ELISA method was used as the reference method. The results show that the Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) has a high overall relative accuracy.

Table 1: The Clostridium difficile Antigen GDH Rapid Test vs ELISA

Method		ELISA		Total Results
Clostridium difficile Antigen GDH Rapid Test Cassette	Results	Positive	Negative	
	Positive	62	1	63
	Negative	0	50	50
Total Results		62	51	113

Relative Sensitivity: 100%
Relative Specificity: 98.0%
Accuracy: 99.1%

2. Analytical Sensitivity

The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) was determined by testing serial dilutions of recombinant antigen. The Clostridium difficile Antigen GDH Rapid Test Cassette (Feces) can detect the levels of Clostridium difficile GDH recombinant antigen as low as 1ng/mL.

3. Cross-Reactivity

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: *Campylobacter*

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

REFERENCE

1. Knoop, F.C. et al.: Clostridium difficile: Clinical disease and diagnosis. Clin.Microbiol. Rev. (1993); 6: 251-265.
2. Kelly, C.P. et al.: Clostridium difficile Colitis. New Engl. J. Med. (1994); 330: 257-262.
3. Sullivan, N.M. et al.: Purification and characterization of toxins A and B of Clostridium difficile. Infect. Immun. (1982); 35: 1032-1040.
4. McDonald, L.C. et al.: An epidemic, toxin gene-variant strain of Clostridium difficile.N. Engl. J. Med. (2005); 353: 23.
5. Loo, V.G. et al.: A predominantly clonal multi-institutional outbreak of Clostridium difficile-associated diarrhea with high morbidity and mortality. N. Engl. J. Med. (2005); 353.23.
6. Bartlett, J.G., Gerding, D.N.: Clinical recognition and diagnosis of Clostridium difficile infection. CID (2008); 46(Suppl. 1): 12-18.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054 Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GCCD(GDH)-602a

Revision Date: 2022-02-21
B22717-01

Strep A Rapid Test Cassette (Throat Swab)

INTENDED USE

The Strep A Rapid Test Cassette (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3,4] The Strep A Rapid Test Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The Strep A Rapid Test Cassette (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color 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, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. 20 Test cassettes 2. 20 Sterile swabs 3. 20 Extraction tubes and tips 4. 1 Workstation and 1 package insert 5. 1 Reagent B (0.2M acetic acid): 10.0 mL		
6. 1 Reagent A (2M sodium nitrite): 10.0 mL	⚠ Warning	Harmful if swallowed. Wash thoroughly after handling.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.
6. Do not use test if pouch is damaged.
7. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

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

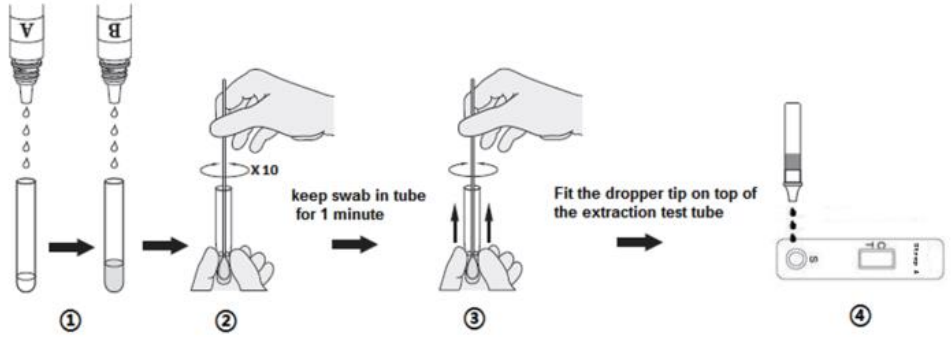
SPECIMEN COLLECTION AND STORAGE

1. Only use reagents and sterile swabs provided in the kit.
2. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
3. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Cassette (Throat Swab).

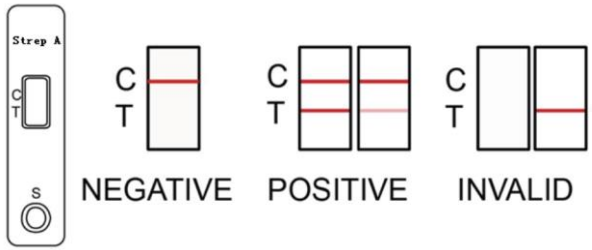
TEST PROCEDURE

Allow the test device, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed 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.
2. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab to the extraction tube of yellow solution. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. Add 3 full drops of solution to the specimen well (S) and then start the timer.
5. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



INTERPRETATION OF RESULTS



Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).
Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.
NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS

1. The Strep A Rapid Test Cassette (Throat Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A streptococcus bacteria.
3. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

The Strep A Rapid Test Cassette (Throat Swab) was used to evaluate 368 throat swab specimens collected from three physician offices patients presenting with pharyngitis. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Strep A Rapid Test vs. Culture

Strep A Rapid Test Cassette (Throat Swab) Results	Reference Culture Results		Total
	Positive	Negative	
Positive	200	1	201
Negative	6	161	167
Total	206	162	368

Sensitivity: 97.1% (200/206); 95%CI = 93.7% - 98.8%
Specificity: 99.4% (161/162); 95%CI = 96.2% - 100.0%

Clinical Performance Stratified by Age

Age	Sensitivity	Sensitivity(95%CI)	Specificity	Specificity(95%CI)
0 ~ 5	97.4% (74/76)	90.4% - 99.8%	98.1% (52/53)	89.1% - 100.0%
5+ ~ 21	96.7% (119/123)	91.7% - 99.0%	100% (88/88)	95.0% - 100.0%
21+	100% (7/7)	59.6% - 100.0%	100% (21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0%

Cross-Reactivity

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette (Throat Swab). No mucoid-producing strains were tested.

Group B Streptococcus	Neisseria meningitidis	Serratia marcescens
Group F Streptococcus	Neisseria sicca	Klebsiella pneumoniae
Streptococcus pneumoniae	Branhamella catarrhalis	Bordetella pertussis
Streptococcus mutans	Group C Streptococcus	Neisseria gonorrhea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Enterococcus faecalis	
Pseudomonas aeruginosa	Staphylococcus epidermidis	

Physician's Office Laboratory (POL) Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Cassette (Throat Swab). Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

REFERENCE

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4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
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7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP CMC Medical Devices & Drugs S.L
C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054 Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GCSTR-502a

Swab information

Jiangsu ChangFeng Medical Industry Co., LTD
Address: Touqiao Town, Guangling DISTRICT, Yangzhou, Jiangsu 225109 China

CE 0197

EC REP Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124 Heidelberg, Germany
Email-info@llins-service.com

Digitally signed by Dolgopol Iulian
Date: 2025.09.04 17:04:35 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Revision Date: 2022-04-12
B20402-04