Vibrio cholerae O1 (VC O1) Rapid Test Kit(Colloidal Gold)

Instruction for Use

A rapid test for the qualitative detection of Vibrio cholerae O1 in the specimens of human feces.
For professional in vitro diagnostic use only.

PRODUCT NAME

Vibrio cholerae O1 (VC O1) Rapid Test Kit(Colloidal Gold)

SPECIFICATION

25 tests/kit, 5 tests/kit, 1 test/kit

INTENDED USE

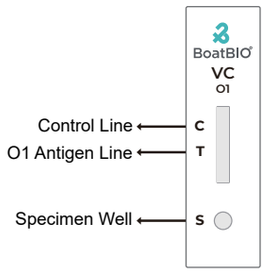
The Vibrio cholerae O1 (VC O1) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Vibrio cholerae O1 in human feces to aid in the diagnosis of Vibrio cholerae O1 infection.

SUMMARY

Cholera is an acute watery diarrheal disease caused mainly by Vibrio cholerae serogroup O1 and less commonly by V. cholerae O139. Cholera can lead to severe diarrhea and death if untreated. V. cholerae O1 and V. cholerae O139 are transmitted through fecal-oral contamination, and cholera is thus predominantly associated with lack of safe drinking water, proper sanitation and personal hygiene. Cholera is an important public health problem in many parts of Asia, Africa and Latin America [1, 2]. Globally, 3–5 million cases and over 100,000 deaths occur annually due to cholera [3]. Countries facing complex emergencies are more vulnerable to cholera outbreaks [4]. The etiological agent of cholera has been identified as Vibrio cholerae (V. cholerae), a gram negative bacterium, which is generally transmitted to humans via contaminated water and food. The species V. cholerae is divided into several serogroups on the basis of O antigens. The subgroups O1 and O139 are of special interest because both can cause epidemic and pandemic cholera. It is critical to determine as quickly as possible the presence of V. cholerae O1 and O139 in clinical specimens, water, and food so that appropriate monitoring and effective preventive measures can be undertaken by public health authorities.
The Vibrio cholerae O1 (VC O1) Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Vibrio cholerae O1 in human feces, providing results in 10 minutes. The test utilizes antibodies specific for VC O1 antigens to selectively detect VC O1 antigens in human feces or environment water specimens.

PRINCIPLE

The Vibrio cholerae O1 Rapid Test is a qualitative, lateral flow immunoassay for the detection of Vibrio cholerae O1 antigens in human feces. In this test, the membrane is pre-coated with anti-Vibrio cholerae O1 antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-Vibrio cholerae O1 antibody. The mixture migrates upward on the membrane by capillary action to react with anti- Vibrio cholerae O1 antibodies on the membrane and generate a colored line. The presence of this colored line in the test 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.



MAIN COMPONENTS

Materials Provided

Components	25 tests/kit	5 tests/kit	1 test/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Specimen Collection Tubes with extraction buffer	1 bottle (10ml)	1 bottle (3ml)	300ul/tube
Droppers	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen Collection Containers
- Pipette and Disposable tips (optional)
- Centrifuge
- Timer

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should be remained in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

- The test 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 be remained in the sealed pouch until use.
- **DO NOT FREEZE.**
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The fecal specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- Store the specimens at –20 ºC if the specimens cannot be tested in 3 days.

DIRECTIONS FOR USE

Allow the test cassette, specimen, buffer and/or controls to reach room temperature (15-30 °C) prior to testing.

<u>For Fecal Specimens</u>

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 maximum 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 in 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:

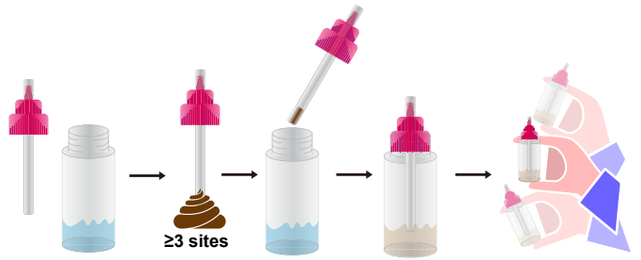
Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops of the liquid feces (approximately 80μL)** into the specimen collection tube containing the extraction buffer.

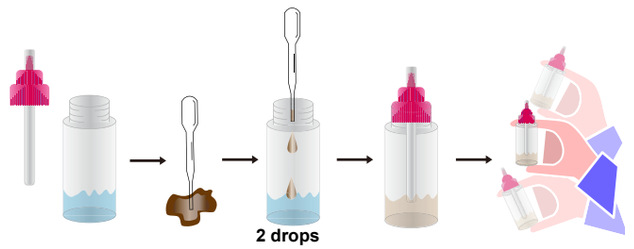
3. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.

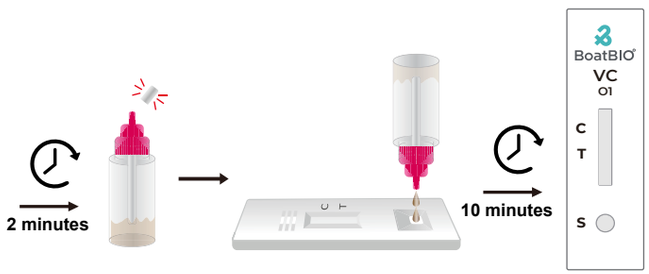
4.For Fecal specimen: Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen (approximately 80μL)** to the specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.

5. Read 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 extracted specimens contained in the extraction buffer vial. Collect 80 μL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.

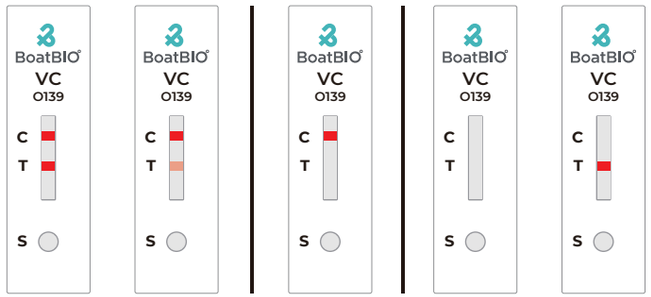






RESULT INTERPRETATION

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).
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Vibrio cholerae O1 antigen 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 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1.The Vibrio cholerae O1 Test is for in vitro diagnostic use only. The test should be used for the detection of Vibrio cholerae O1 antigens in feces or environment water specimens. Neither the quantitative value nor the rate of increase in Vibrio cholerae O1 antigens concentration can be determined by this qualitative test.
2.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
3.If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Vibrio cholerae O1 infection.
4.Following certain antibiotic treatments, the concentration of Vibrio cholerae O1 antigens may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

EXPECT VALUE

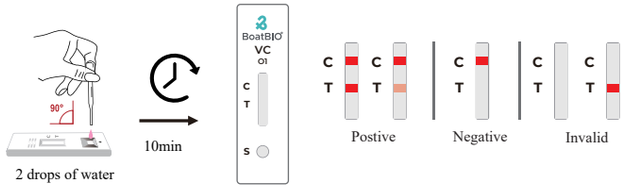
The Vibrio cholerae O1 (VC O1) Rapid Test has been compared with PCR methods, demonstrating an overall accuracy of 97.3%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
The Vibrio cholerae O1 (VC O1) Rapid Test has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the Vibrio cholerae O1 Rapid Test is 96.2% and the specificity is 97.8% relative to PCR methods.

Vibrio cholerae O139 Test (Feces)	RT-PCR		
BESTest	Positive	Negative	Total
Positive	75	4	79
Negative	3	178	181
Total	78	182	260
Relative Sensitivity: 96.2% (95%CI*:89.2%-99.2%) Specificity: 97.8% (95%CI*: 94.5%-99.4%) Overall Accuracy: 97.3% (95%CI*: 94.5%-98.9%) *Confidence Interval Relative			

NOTE
The Vibrio cholerae O1 (VC O1) Rapid Test can also be used for detection of V. cholerae O1 antigens in environmental water. For this, environmental water should be collected in a clean and dry container and test should be performed by transfering **2 drops of environment water (approximately 80μL)** to the specimen area. Test time is 10 minutes same as fecal specimens. For Interpretation of results also, the interpretation is same as with fecal specimen. Testing with environmental water is based on the technical premises that V. cholerae O1 antigens are available in environmental water same as in fecal specimen.



Precision

Intra-Assay
Within-run precision has been determined by using 3 replicates of four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. The specimens were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 3 independent assays on the same four specimens: negative, low titer positive, middle titer positive and high titer positive specimens. Three different lots of the Vibrio cholerae O1 Test have been tested using these specimens. The specimens were correctly identified >99% of the time.
Cross-reactivity
Cross reactivity with following organisms has been studied at 1.0E+07 organisms/ml. The following organisms were found negative when tested with the Vibrio cholerae O1 Rapid Test:

Citrobacter freundii	*Clostridium difficile*	*Coxsackie*
Candida albicans	*Chlamydia trachomatis*	*Echovirus*
Enterococcus faecium	*E.coli*	*Enterococcus faecalis*
Gardnerella vaginalis	*Neisseria gonorrhea*	*Proteus mirabilis*
Proteus vulgaris	*Pseudomonas aeruginosa*	*Staphylococcus aureus*
Salmonella Infantis	*Shigella dysenteriae*	
Shigella dysenteriae	*Corynebacterium diphtheria*	

BIBLIOGRAPHY

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3.Cholera vaccines: WHO position paper. Wkly Epidemiol Rec. 2010; 85(13):117–28.
4.Organization WH. Prevention and control of cholera outbreaks: WHO policy and recommendations. Geneva: World Health Organization, Global Task Force on Cholera Control. 2010.

INDEX OF SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don't use the product when the package is damaged		Keep dry
	Date of manufacture	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

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