Vibrio Cholerae O1 Antigen Rapid Test Cassette (Feces)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Vibrio Cholerae O1 Antigen Rapid Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of Vibrio Cholerae O1 antigens in human faces to aid in the diagnosis of O1 group Cholera infection.

[SUMMARY]

Cholera is an infection in the small intestine caused by the bacterium Vibrio cholerae. The main symptoms are watery diarrhea and vomiting. Transmission occurs primarily by drinking water or eating food that has been contaminated by the feces (waste product) of an infected person, including one with no apparent symptoms. The severity of the diarrhea and vomiting can lead to rapid dehydration and electrolyte imbalance, and death in some cases. The primary treatment is oral rehydration therapy, typically with oral rehydration solution, to replace water and electrolytes. If this is not tolerated or does not provide improvement fast enough, intravenous fluids can also be used. Antibacterial drugs are beneficial in those with severe disease to shorten.

The Vibrio Cholerae O1 Antigen Rapid Test Cassette is a rapid test to qualitatively detect the presence of Vibrio cholerae O1 antigen in, providing results within 15 minutes.

[PRINCIPLE]

The Vibrio Cholerae O1 Antigen Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of Vibrio cholerae O1 antigen in human faces sample. In this test, antibody specific to Vibrio cholerae O1 carbohydrate antigen is coated on the test line region of the test. During testing, the extracted fecal sample reacts with an antibody to Vibrio cholerae O1 that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Vibrio cholerae O1 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.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test panel contains a membrane strip coated with Vibrio cholerae O1 antibody on the test line, goat anti-mouse antibody on the control line, and a dye pad which contains colloidal gold coupled with Vibrio cholerae O1 antibody.

The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

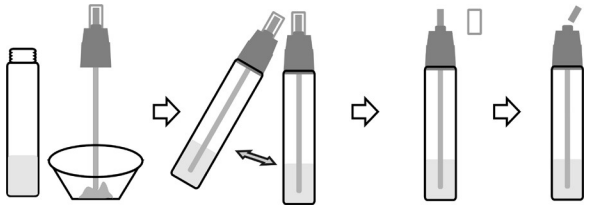
[SPECIMEN]

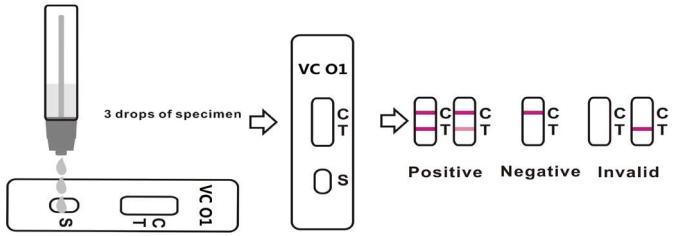
- The Vibrio Cholerae O1 Antigen Rapid Test Cassette can be performed used on human feces.
- Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assays performed within 6 hours after collection.
- Specimen collected may be stored for 3 days at 2-8℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
- Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

[TEST PROCEDURE]

Allow the test device and specimens to reach temperature 15-30℃ (59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface.
3. Holding the specimen collection tube upright, carefully take off the tip of collection tube, then break off the tip of collection tube, transfer 3 drops (approximately 100 µL) to the specimen well (S) of the test device, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.





(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

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

Negative: One colored line appears in the control region (C). No line appears in the test 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 using a new test cassette. If the problem persists, discontinue using the lot immediately and contact your local distributor.

[QUALITY CONTROL]

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

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The Vibrio Cholerae O1 Antigen Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of Vibrio cholerae O1 antigen in human faces only. Neither the quantitative value nor the rate of increase In Vibrio cholerae O1 antigen concentration can be determined by this qualitative test
- This test will only indicate the presence of Vibrio cholerae O1 antigen in the specimen.
- A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Vibrio cholerae O1 antigen present in the fecal sample is not adequate or is below the detectable level of the test.
- Excess blood on the specimen may interfere with test performance and may yield a false positive result.

[PERFORMANCE CHARACTERISTICS]

Accuracy

Agreement with Commercial Vibrio Cholerae O1 Antigen Rapid Test

A side-by-side comparison was conducted using the Vibrio cholerae O1 Antigen Rapid Test and commercially available Vibrio cholerae O1 Antigen rapid tests. 242 clinical specimens from three hospitals were evaluated with the Vibrio cholerae O1 Antigen Rapid Test and the commercial kit. The following results are tabulated from these clinical studies:

		Commercial Vibrio cholerae O1 Antigen Rapid Test		Total
		Positive	Negative	
	Positive	84	3	87
	Negative	1	154	155
Total		85	157	242

The agreement between these two devices is 98.82% for positive specimens, and 98.09% for negative specimens. This study demonstrated that the Vibrio Cholerae O1 Antigen Rapid Test is substantially equivalent to the commercial device.

Cross-Reactivity and Interference

1. Cross-reactivity with following organisms has been studied at $1.0x10^9$ organisms/mL. The following organisms were found negative when tested with the Vibrio Cholerae O1 Antigen Test.

Candida albicans	*Campylobacter jejuni*
Clostridium difficile	*Escherichia coli*
Enterobacter aerogenes	*Enterococcus faecalis*
Proteus vulgaris	*Klebsiella pnenmoniae*
Pseudomonas aeruginosa	*Proteus mirabilis*
Salmonella choleraesuis	*Shigella dysenteriae*
Salmonella typhimurium	*Salmonella typhi*

2. Potentially cross-reactive endogenous substances including common components, such as lipids, hemoglobin and bilirubin, were spiked at high concentrations into the Vibrio cholerae O1 antigen positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	20 µg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
Lipids	20 mg/mL	+	-

3. Some other common biological analytes were spiked into the Vibrio cholerae O1 antigen positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc.	Specimens	
		Positive	Negative
Acetaminophen	200 µg/mL	+	-
Acetoacetic Acid	200 µg/mL	+	-
Acetylsalicylic Acid	200 µg/mL	+	-
Ampicillin	200 µg/mL	+	-
Ascorbic Acid	200 µg/mL	+	-
Atropine	200 µg/mL	+	-
Benzoylecgonine	100 µg/mL	+	-
Caffeine	200 µg/mL	+	-
EDTA	800 µg/mL	+	-
Ethanol	1.0 %	+	-
Gentisic Acid	200 µg/mL	+	-
β - Hydroxybutyrate	20,000 µg/mL	+	-
Methanol	10.0 %	+	-
Phenothiazine	200 µg/mL	+	-
Phenylpropanolamine	200 µg/mL	+	-
Salicylic Acid	200 µg/mL	+	-
Tetracycline	200 µg/mL	+	-

Reproducibility

Reproducibility studies were performed for Vibrio Cholerae O1 Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical serum specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 99.4% at two sites, and 100% at one site. The inter-site agreement was 99.6%.

[BIBLIOGRAPHY]

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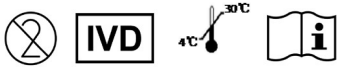

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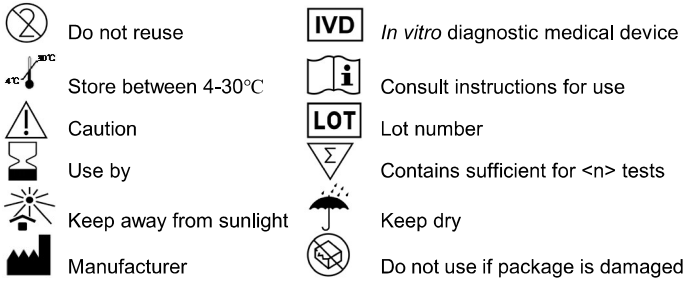

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