（**FOR RESEARCH USE ONLY. DO NOT USE IT IN CLINICAL DIAGNOSIS !**）

Human Vibrio cholerae O1/O139 Antigen Combo Lateral Flow Assay Kit

Catalog No: E-HD-C091

20T/40T

Version Number:	V1.1
Replace version:	V1.0
Revision Date:	2024.04.07

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

Toll-free: 1-888-852-8623 Tel: 1-832-243-6086 Fax: 1-832-243-6017

Email: techsupport@elabscience.com

Website: www.vetassay-elab.com

Please kindly provide us the lot number (on the outside of the box) of the kit for more efficient service.

Test principle

This kit adopts the sandwich method and utilizes the technical principle of colloidal gold immunochromatography. During the test, the sample is dropped into the sample well of the reagent, and the chromatography is performed under the capillary effect. The V. Cholera O1/O139 antigen in the sample binds to the colloidal gold-labeled O1/O139-antibody, diffuses to the test area, it is captured by the pre-coated anti-V. Cholera O1/O139 antibody, to form a complex, and gather in the test area. The quality control area was coated with goat anti-mouse IgG antibody, and the colloidal gold-labeled antibody was captured to form a complex and aggregated in the quality control area. The highly specific antigen-antibody reaction and colloidal gold immunochromatography technology are combined to qualitatively detect the content of V. Cholera O1/O139 antigen in human fecal specimen.

Kit components

Item	Specification
Detection Card	20T/40T
Stool Sampler	1 bottle
Manual	1 copy

Note: All reagent bottle caps must be tightened to prevent evaporation and microbial pollution.

Notes

1. It is a disposable reagent. Do not reuse it. Please use it within the validity date.
2. This operation manual must be read completely before performing the test. Failure to follow the manual gives inaccurate test results.
3. Please do not open the product before use. If the package is obviously damaged, please do not use it.
4. Appropriate protective measures shall be taken during the collection, disposal, storage, mixing and testing of samples.
5. There is a desiccant in the aluminum foil bag, which should not be taken orally.
6. Excessive high temperature of the experimental environment should be avoided. The cold stored test card should be opened after returning to room temperature to avoid moisture absorption.
7. Do not replace the components in this kit with components in other kits.
8. This reagent only provides qualitative results, and the test results are for reference only.
9. If the detection reagent is stored in the refrigerator, it is suggested to take it out and place at room temperature before opening for use.
10. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
11. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of oral-food borne pathogens.
12. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.

13. All specimens, waste liquid and pipes are treated as infectious pollutants. After the test, the used test card should be discarded in the corresponding biological hazard container and treated as biological hazard.
14. If you have any questions or suggestions during use, please do not hesitate to contact the manufacturer.

Storage and expiry date

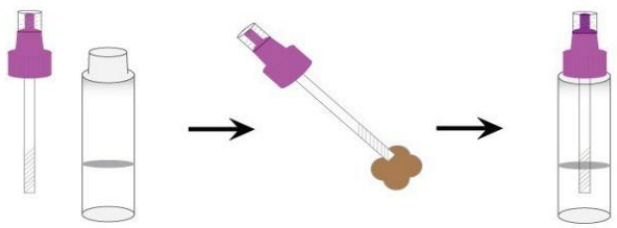
Storage: Store at 4-30℃. With cool and dry environment.

Expiry date: expiration date is on the packing box.

Requirements of sample

Before use, please read the instructions carefully and operate in strict accordance with the instructions:

1. Collect a random sample of feces into a clean container.
2. Unscrew the cap of the stool sampler sample and remove the applicator stick.
3. Insert the stick into the fecal specimen in at least five different sites. Be sure sample contacts the inside grooves.
4. Replace the stick in the tube and tighten the cap securely.
5. For a liquid stool, take 0.3 mL with a plastic pipette and then place the sample into the stool sampler.
6. It is recommended to complete the test within 4 hours. If the test cannot be completed in time, please store it at 2℃ - 8℃ (valid for up to 3 days) or -20℃ (valid for a longer period). If samples are to be shipped, they should be packed in compliance with federal regulation covering the transportation of infectious agents.
7. Bring samples to room temperature prior to testing.

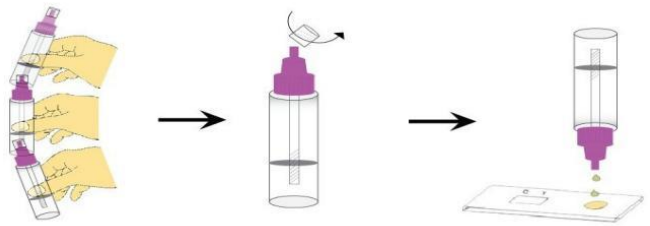


NOTE: This figure is only used as a reference.

Assay procedure

1. Before the test, please read the operation manual completely and equilibrate the test reagent to room temperature (15℃ - 30℃). The test should be conducted at room temperature.
2. Take out the test cassette from the aluminum foil packaging bag, and use it within 1 hour after unsealing to prevent moisture of test card.
3. Shake the sample collection tube vigorously to ensure an effective liquid suspension.
4. Add samples: hold the tube upright, unscrew the cap of the stool sampler. Dispense 2 drops of the solution into the sample well of the cassette, and start timing.

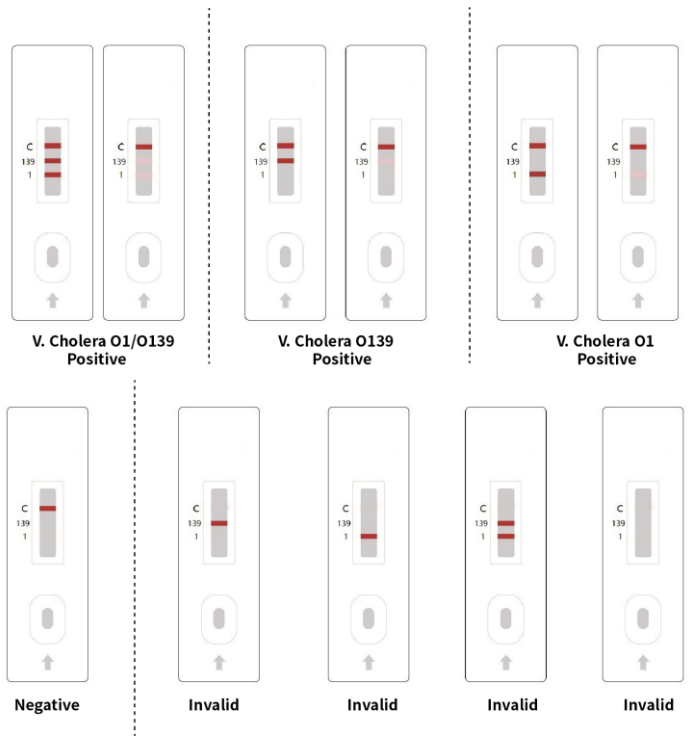
5. Interpretation: observe the result after 1 minute. The result is only valid within 10 minutes.



NOTE: This figure is only used as a reference.

Interpretation of results

1. Positive: a purplish red band appears on both the test line (T1 and T139) and quality control line (C). The purplish red band on the T1 line indicates that Vibrio Cholerae O1 antigen is detected; the purplish red band on the T139 line indicates that Vibrio Cholerae O139 antigen is detected.
2. Negative: a purplish red band only appears on the quality control line (C).
3. Invalid: no purplish red band appears on the quality control line (C), indicating incorrect operation or deterioration of the reagent. In this case, please read the instructions carefully again and retest with a new reagent.



NOTE: This figure is only used as a reference.

Limitations of this test method

1. The Vibrio cholerae O1/O139 Antigen Combo Test Kit is limited to the qualitative detection of V. Cholera O1 and O139 antigen in human fecal specimen. The intensity of the test band does not have linear correlation with the antigen concentration of the specimen.
2. The test results of this reagent are for reference only, and should not be used as the only basis for final conclusion.
3. The Test Procedure and the Interpretation of Results must be followed closely when testing the presence of V. Cholera antigen in human fecal specimen from individual subject. Failure to follow the procedure may give inaccurate results.
4. A negative result for the sample indicates absence of detectable V. Cholera antigen. However, a negative test result does not preclude the possibility of exposure to or infection with V. Cholera bacteria.
5. A negative result can occur if the quantity of the V. Cholera antigen present in the specimen is below the detection limits of the assay or the antigen that are detected are not present in the fecal specimen picked by the sample extraction tube device.
6. If the symptom persists, while the result from Vibrio cholerae O1/O139 Antigen Combo Test Kit is negative, it is recommended to re-sample the patient or test with an alternative test method.
7. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
8. The test result of this reagent can only be used as auxiliary tool. The test result should be combined with other data.