Vibrio Cholerae Rapid Test Kit

Cat No. S015-01

In vitro diagnostics

INTENDED USE

Rapid V.Cholerae O1 Test is a rapid immunochromatographic assay for the qualitative detection of Vibrio Cholerae serogroups O1 in human fecal specimens, environment water, or solid food specimens. The test can be used as a rapid screening test for V. Cholerae in specimens. The test is intended for healthcare professionals use.

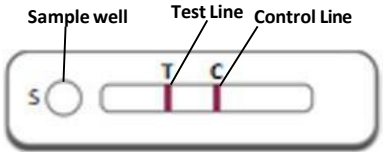
SUMMARY & TEST DESCRIPTION

Vibrio Cholerae is a Gram-negative, non-spore-forming, arc-shaped or comma-shaped bacterium with a polar flagellum that causes cholera in humans. Currently the V. Cholerae is classified into 206 "O" serogroups, based on the differences in the sugar composition of the heat-stable surface somatic "O" antigen. The O1 serogroup exists as two biotypes: classical biotype and EL-Tor biotype. From 19th century on, there recorded seven pandemics of cholera throughout the humankind history. Between 1817 and 1961, O1 serogroup causes the majority of outbreaks, while O139 – first identified in Bangladesh and India in 1992 – is confined to South-East Asia. Non-O1 non-O139 V.Cholerae can cause mild diarrhoea but do not generate epidemics.

Cholera, caused by V. Cholerae, is a severe intestinal infectious disease that usually transmitted by the fecal-oral route though contaminative water and/or undercooked foods such as seafood, vegetables etc. Clinically, cholera may range from asymptomatic colonization to severe diarrhea with massive fluid loss, leading to dehydration, electrolyte disturbances, and even death within hours. Therefore, a simple, fast and reliable method for detection V. Cholerae is a great value for clinicians in managing the disease and for public health officials in instituting control measures. Rapid V.Cholerae O1 Test is an rapid immune-chromatographic assay. The test is simple and easy to perform and an accurate result can be visually interpreted within 10 minutes.

TEST PRINCIPLE

Rapid V. Cholerae O1 Test is a double antibody sandwich immunoassay. Colloidal gold conjugated anti-V. cholerae antigen specific monoclonal antibody complexes are dry-immobilized in the test device. When the sample is added, it migrates by capillary diffusion through the strip rehydrating the gold conjugate complexes. If present, V. Cholerae O1 antigen will react with the gold conjugate complexes forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by anti- V. Cholerae O1 antibodies immobilized there and a visible red line appears. If there is no V. Cholerae O1 antigen in sample, no red line will appear in the Test Zone (T). The gold conjugate complexes will continue to migrate alone until they are captured in the Control Zone (C) by immobilized goat anti-mouse IgG antibody aggregating a red line, which indicates the validity of the test.



One red colored line appears at the C region indicating a negative for V. Cholerae O1 in the sample. Two colored lines appear at both C and T region indicating a positive for V. Cholerae O1 in the sample. To serve as a procedural control, a colored line will always appear in the control line region (C) indicating that proper volume of specimen has been added and the device is working properly.

REAGENTS & MATERIALS PROVIDED

1. Each pouch contains
   a. one test card and dropper
   b. Dessicant
2. Alcohol swab
3. Lancet
4. Assay Diluent
5. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch / carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNINGS

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Use only the buffer supplied along with the kit.
4) Do not mix components from different kits.
5) Do not use with specimen containing precipitates

SAMPLE PREPARATION

1.Direct test: The watery stool specimens can be used directly for the test.

2.Test after enrichment of bacteria:

a. Watery stool: 1～2 mL sample is added into 8～9 mL alkaline peptone water, cultured for 6～8 hours or overnight at 37 ℃.

b. Water: Adjust PH value of 450 mL water sample to 8.4～9.2 with 1M NaOH, then add 50 mL 10X alkaline peptone water. 0.25～
0.5 mL of 1% potassium tellurite and 1 mL of 1000 U/mL Penicillin can be added to inhibit the growth of other bacteria, then cultured overnight at 37 ℃.

d. Solid food specimen: Grinding 50 ～ 100 g food samples, inoculate into alkaline peptone water (5～10 times amounts of the food sample), then culture for 6～8 hours or overnight at 37 ℃.

e. Feces: 1～2 g fecal specimens inoculated into 8～9 mL alkaline peptone water, mixing and culture for 6～8 hours or overnight at 37 ℃.

quickVET RAPID

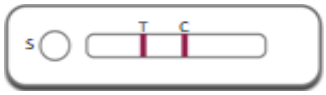
TEST PROCEDURE

1. Remove the test card from the sealed foil pouch, label the test card with specimen identity on the "ID " area of the cassette and place the test card on a flat horizontal surface.
2. Using the transfer pipet to draw up the specimen, holding it vertically, dispense 2 - 3 drops (approximately 80 - 120 µL) of specimen into the sample well.
3. Read the result at 10 minutes after adding the specimen.
   Note: Results after 10 minutes may not be accurate.

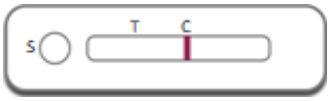
INTERPRETATION OF TEST RESULT

(IMPORTANT NOTE: INTERPRET THE RESULTS WITH RESPECT TO THE WRITINGS 'C' & 'T' ON THE DEVICE AS SHOWN BELOW)

Positive: A clear pink control band ("C") and a detectable test band ("T") appear, indicating the presence of V.Cholerae O1 in the sample.



Negative: A pink colored band appears only at control region ("C") indicating the absence of V.Cholerae O1 in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Canine V. Cholerae Rapid Test single- step detection of V. Cholerae are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

ubio Biotechnology Systems Pvt Ltd No 15A Biotechnology Zone
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