Vibrio cholerae O1 Antigen Rapid Test Device

For professional in vitro diagnostic use only.

INTENDED USE

The StrongStep® Vibrio cholerae O1 Antigen Rapid Test Device (Feces) is a rapid visual immunoassay for the qualitative, presumptive detection of Vibrio cholerae O1 in human fecal specimens. This kit is intended for use as an aid in the diagnosis of Vibrio cholerae O1 infection.

INTRODUCTION

Cholera epidemics, caused by V.cholerae serotype O1, continue to be a devastating disease of immense global significance in many developing countries. Clinically, cholera may range from asymptomatic colonization to severe diarrhea with massive fluid loss, leading to dehydration, electrolyte disturbances, and death. V. cholerae O1 cause this secretary diarrhea by colonization of the small intestine and production of a potent cholera toxin, leading to massive fluid loss, with severe diarrhea and dehydration. The disease is of immense global significance in many developing countries.

The Vibrio cholerae O1 Antigen Rapid Test Device (Feces) detects Vibrio cholerae O1 through visual interpretation of color development on the internal membrane. During testing, the specimen reacts with anti-Vibrio cholerae O1 antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient Vibrio cholerae O1 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 the absence 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.

KIT COMPONENTS

| Individually packed test devices | Each device contains a strip with colored conjugates and reactive reagents precoated at the corresponding regions. |
| Specimens dilution tube with buffer | 0.1 M Phosphate buffered saline (PBS) and 0.02% sodium azide. |
| Disposable pipettes | For collecting of liquid specimens |
| Package insert | For operating instructions |

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Centrifuge
- Pipettes
- Pipette tips
- Pipette washer
- Microtiter plate
- Microtiter plate reader
- Heated water bath
- Ice
- Stool container
- Fecal collection tube containing the extraction buffer.
- Stool collection tube containing the extraction buffer.
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PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains reagents of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The specimen dilution buffer contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of specimen dilution buffer or extracted samples, always flush with copious quantities of water to prevent azide buildup.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation.
- Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

- The Vibrio cholerae O1 Antigen Rapid Test Device (Feces) is intended for use with human fecal specimens only.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimen, buffer and/or controls to room temperature (15-20°C) before use.

1. Specimen collection and pre-treatment:
   1) Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.
   2) For solid specimens: 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 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea).
   For liquid specimens: Hold the pipette vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 μL) into the specimen collection tube containing the extraction buffer.
   3) Replace the applicator back into the tube and screw the cap tightly. Be careful not to break the tip of the dilution tube.
   4) 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.

2. Testing
   1) Remove the test from its sealed pouch, and place it on a clean, level surface. Label the test with patient or control identification. For best results, the assay should be performed within one hour.
   2) Using a piece of tissue paper, break the tip of the dilution tube. Hold the tube vertically and dispense 3 drops of solution into the specimen well (S) of the test device.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result window. As the test begins to work, color will migrate across the membrane.
   3) Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

Note: If the specimen does not migrate due to the presence of particles, centrifuge the extracted specimens contained in the extraction buffer vial. Collect 100.0 μL of supernatant, dispense into the specimen well (S) of a new test device and start again, following the instructions described above.

INTERPRETATION OF RESULTS

| POSITIVE RESULT: | Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T). |
| NEGATIVE RESULT: | Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). |
| INVALID RESULT: | Control band fails to appear. Results from any test are invalid. |

FOR INFORMATION USE ONLY
Not to be used for performing the assay. Refer to the insert accompanying kit.
NOTE:
1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL
- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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 OF THE TEST
1. The Vibrio cholerae O1 Antigen Rapid Antigen Test Device (Feces) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Vibrio cholerae O1.
2. 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.
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 rule out the possibility of Vibrio cholerae O1 infection, as virus particles may be present below the minimum detection level of the test.
4. This test does not detect V.cholerae non-O1, including V.cholerae O139, a new epidemic strain causing cholera in southern Asia. The non-O1 strains may cause diarrhea and other symptoms similar to those caused by V.cholerae O1.
5. This test recognizes an antigen in V.cholerae O1. The test may detect both viable and non-viable bacteria and may be positive following successful treatment.
6. This test can differentiate V.cholerae serotype O1 from serotype non O1 but it does not support further serotyping of O1 into Inaba or Ogawa and also does not support susceptibility testing.

PERFORMANCE CHARACTERISTICS
Sensitivity:
The analytical sensitivity of StrongStep® Vibrio cholerae O1 Antigen Rapid Test Device is 1.0•10^3 CFU/ml V.cholerae O1.
Specificity:
Cross reactivity with following organisms has been studied at 1.0 x 10^5 organisms/mL. The following organisms were found negative when tested with the V.cholerae O1 Rapid Test Device (Feces).

<table>
<thead>
<tr>
<th>Organism</th>
<th>Sensitivity</th>
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</thead>
<tbody>
<tr>
<td>Aeromonas hydrophila</td>
<td>Escherichia coli</td>
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<tr>
<td>Pseudomonas aeruginosa</td>
<td>Acinetobacter spp</td>
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<tr>
<td>Enterococcus faecalis</td>
<td>Salmonella choleraeaeus</td>
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<tr>
<td>Group C Streptococcus</td>
<td>Proteus vulgaris</td>
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<tr>
<td>Klebsiella pneumoniae</td>
<td>Acinetobacter calcoaceticus</td>
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<tr>
<td>Branhamella catarrhalis</td>
<td>Vibrio cholerae non-O1</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>Chlamydia trachomatis</td>
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</tbody>
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LITERATURE REFERENCES

GLOSSARY OF SYMBOLS