Human Shigella Rapid test

*Cat.No: DTSXY-Z4
Lot. No. (See product label)*

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**Intended use**

The Shigella Rapid test is a rapid chromatographic immunoassay for the qualitative detection of Shigella in stool samples in order to detect shigellosis in infected human. Only for laboratory use.

**General Description**

Clinical syndromes in humans caused by infection with Shigella are divided into S. dysenteriae, S. flexneri, S. boydii and S. sonnei, and a range of clinical syndromes, including diarrhoeal disease, fever and stomach cramps. Shigellosis are associated with poor sanitation, contaminated food and water, and crowded living conditions and usually resolves in 5 to 7 days. The predominant serogroups of Shigella are particularly common and it causes recurrent problems in settings where hygiene is poor and can sometimes sweep through entire communities. The Shigella Rapid test kit provides a rapid detection of Shigella directly from the fecal samples.

**Principle Of The Test**

The Shigella Rapid test is a qualitative lateral flow immunoassay for the detection of Shigella antigens in fecal samples. The membrane is pre-coated with monoclonal antibodies against Shigella antigens on the test line region. During testing, the sample reacts with the particle coated with anti-Shigella antibodies which was pre-dried on the strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

**Reagents And Materials Provided**

1. Cards
2. Specimen collection vials with buffer
3. Instructions for use

**Materials Required But Not Supplied**

1. Specimen collection container
2. Disposable gloves
3. Timer
Specimen Collection And Preparation

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C/36-46.4°F) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at -20°C/4°F. Freezing and thawing cycles are not recommended. In this case, the sample will be totally thawed, and brought to room temperature before testing.

Reconstitution And Storage

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Assay Procedure

To process the collected stool samples:
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (approx. 125 mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125 µL into the specimen collection vial with buffer.

Test Procedure: Allow the tests, stool samples and buffer to reach the room temperature (15-30°C/59-86°F) prior to testing. Do not open the pouch until ready to perform the assay.

1. Remove The Rapid test from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the cap of the vial.
3. Use a separate card for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.
Quality Control

Internal procedural controls are included in the test:
A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

Interpretation Of Results

POSITIVE: Two lines appears across the central window in the result line region, a red test line marked with the letter T and in the control line region, a green control line marked with the letter C.
NEGATIVE: Only one green band appears across the control line region marked with the letter C.
INVALID: Total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the testing with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

NOTES ON THE INTERPRETATION OF RESULTS:
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

Performance Characteristics

Sensitivity and specificity
It was performed an evaluation using this test. It was studied some stool samples and the results were confirmed by culture. The test showed >99% of sensitivity and >99% of specificity.

Cross-reactivity
It was performed an evaluation to determine the cross reactivity of the test. There is not cross reactivity with common intestinal pathogens: Escherichia coli O157:H7, H. pylori, Listeria monocytogenes, Salmonella, Staphylococcus aureus, Yersinia enterocolitica.
Precautions

1. Do not use after expiration date.
2. The test should remain in the sealed pouch until use.
3. Do not use the test if pouch is damaged.
4. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
5. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
6. The test should be discarded in a proper biohazard container after testing.
7. The test must be carried out within 2 hours of opening the sealed bag.

Limitations

1. The test will only indicate the presence of Shigella antigens in the specimen (qualitative detection) and should be used for the detection of Shigella antigens in feces specimens only. Neither the quantitative value nor the rate of increase in Shigella antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. Freeze and thaw several times the fecal samples could cause wrong results.
5. 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 Shigella infection.
6. This test provides a presumptive diagnosis of Shigellosis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

References