Human Salmonella Typhi Rapid test

Cat.No: DTSXY-Z3
Lot. No. (See product label)

Size

20T

Intended use

The Salmonella Typhi Rapid test is a rapid chromatographic immunoassay for the qualitative detection of Salmonella typhi antigens in human feces specimens in order to detect typhoid fever. Only for laboratory use.

General Description

Clinical syndromes in humans caused by infection with Salmonella enterica are divided into typhoid fever, caused by S. enterica serovars typhi and paratyphi, and a range of clinical syndromes, including diarrhoeal disease, caused by the non-typhoid Salmonellae (NTS) of which there are around 2,500 serovars. Typhoid fever is a human-restricted and highly adapted invasive systemic disease of adults and children that shows little association with immunosuppression. In contrast, NTS have a broad vertebrate host range and epidemiology that often involves food animals, at least in industrialised countries where it usually presents as gastroenteritis. Severe, invasive disease due to NTS is usually associated with the immunocompromised state common in HIV-infected adults. Invasive NTS disease is also common in young African children with co-morbidities such as severe anaemia, malnutrition and HIV infection. The Salmonella Typhi Rapid test kit provides a rapid detection of Salmonella typhi directly from the fecal samples.

Principle Of The Test

The Salmonella Typhi Rapid test is a qualitative lateral flow immunoassay for the detection of Salmonella typhi antigens in human feces samples. The membrane is precoated with monoclonal antibodies against Salmonella typhi antigens on the test line region. During testing, the sample reacts with the particle coated with anti-S. typhi antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result, a RED color line will be visible in the result line region. Whether there is presence of Salmonella typhi or not, the mixture continues to move across the membrane to the immobilized antibody placed in the control band region and a GREEN coloured band always appears (control line). The presence of this line 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. Rapid
2. Salmonella typhi Card tests
3. Instructions for use
4. Specimen collection vial with buffer

Materials Required But Not Supplied

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1. Specimen collection container
2. Disposable gloves
3. Timer

Specimen Collection And Preparation

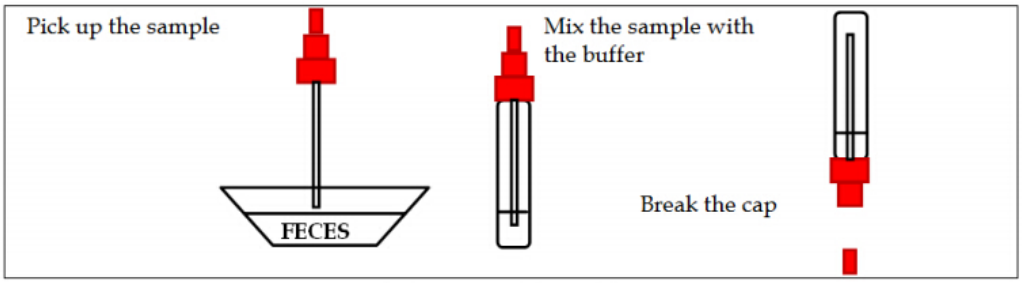
Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C /36-46.4°F) for 1-2 days prior to testing. The sample will be totally thawed,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

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 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 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 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 Card 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.

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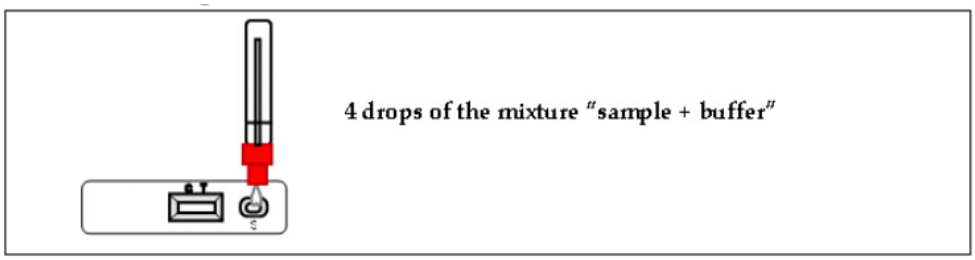

Quality Control

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 appear across the central window, a **red** test line marked with the letter T and a **green** control line marked with the letter C.
NEGATIVE: Only one **green** line appears across the control line region marked with the letter C (control line).
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 test 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

Detection limit
The detection limit of the test is 1.25x107 CFU/mL.

Sensitivity and specificity
It was performed an evaluation using Salmonella typhi culture. The results were confirmed by Singlepath®Salmonella (Merck).
Sensitivity >99% and specificity >99%.

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Cross-reactivity

It was performed an evaluation to determine the cross reactivity of this test. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces: Campylobacter, Clostridium difficile, Escherichia coli O157:H7, H. pylori, Listeria monocytogenes, Shigella, Staphylococcus aureus, Yersinia enterocolitica.

Detection Limit

The detection limit of the test is 1.25x107 CFU/mL

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. Human Salmonella Typhi Rapid Card will only indicate the presence of Salmonella typhi in the specimen (qualitative detection) and should be used for the detection of Salmonella typhi antigens in feces specimens only. Neither the quantitative value nor the rate of increase in Salmonella typhi 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 green line.
4. Freezing and thawing cycles for the sample are not recommended, it could cause wrong results. 5. A negative result is not meaningful because it is possible that Salmonella typhi content in the stool sample is too small. A Salmonella typhi determination should be carried out on a sample from an enrichment culture.
6. This test provides a presumptive diagnosis of Salmonella typhi infections (typhoid fever). A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated must be based in the correlation of the results with further clinical observations.

References

1. GORDON, M, et al, "Invasive salmonellosis in Malawi". J Infect Developing Countries 2008; 2(6):438-442.
2. SANCHEZ-JIMENEZ, M. et al. "Validation of a PCR for diagnosis of typhoid fever and salmonellosis by amplification of the hilA gene in clinical simples from Colombian patients", Journal of Medical Microbiology (2004), 53, 875–878.

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