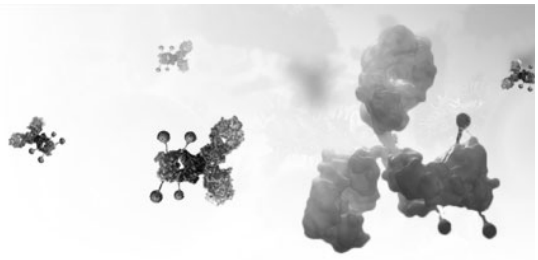

# Salmonella typhi Rapid Test (DST-CL001)

This product is for research use only and is not intended for diagnostic use.

## PRODUCT INFORMATION

**Intended Use**

The Rapid-VIDITEST Salmonella typhi Card is a one step coloured chromatographic immunoassay for the qualitative detection of Salmonella typhi in faecal samples in order to detect typhoid fever in persons.

**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.
Rapid-VIDITEST Salmonella tyhpi Card provides a rapid detection of Salmonella typhi directly from the faecal samples.

**Principles of Testing**

Rapid-VIDITEST Salmonella typhi Card is a qualitative immunoassay for the detection of Salmonella in faecal samples. The membrane is pre-coated with antibodies, on the test band region, to recognize Salmonella typhi antigen. During testing, the sample is allowed to react with the coloured latex particles coated with anti-salmonella typhi antibodies which were pre-dried on the test. The mixture then moves upward on the membrane by capillary action. As the sample flows through the test membrane, the coloured particles conjugate migrate. In the case of a positive result the specific antibodies present on the membrane will capture the coloured particles (conjugate). The mixture continues to move across the membrane to the immobilized antibody placed in the control band region, a GREEN coloured band always appears. A green coloured band 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.

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**Reagents And Materials Provided**

1. Rapid-VIDITEST Salmonella typhi Card tests.
2. Instructions for use.
3. Specimen collection vial with buffer.

**Materials Required But Not Supplied**

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

**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.

**Specimen Collection And Preparation**

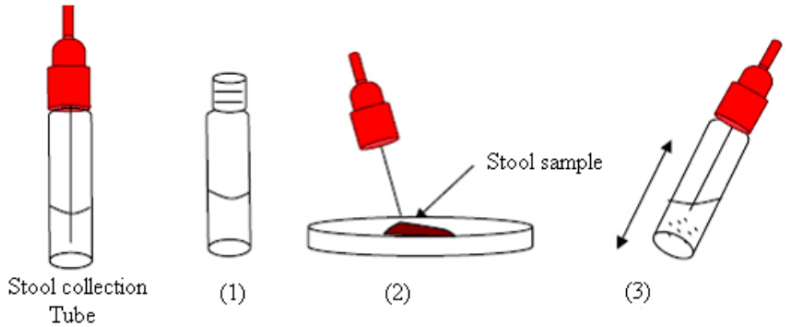
Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C/36-40°F) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20°C/4°F. More than three freezing and thawing cycles are not recommended. The sample will be totally thawed, brought to room temperature and mix as thoroughly as possible before testing.

**Assay Procedure**

**To process the collected stool samples:**

Use a separate vial for each sample.

Unscrew the cap of the vial (1) and introduce the stick in different parts of the faecal specimen to pick up the sample (approx. 150mg) (2) and put into the vial with buffer. Shake the vial in order to assure good sample dispersion (3). For liquid stool samples, aspirate the faecal specimen with a dropper and add 150µL into the vial with buffer.

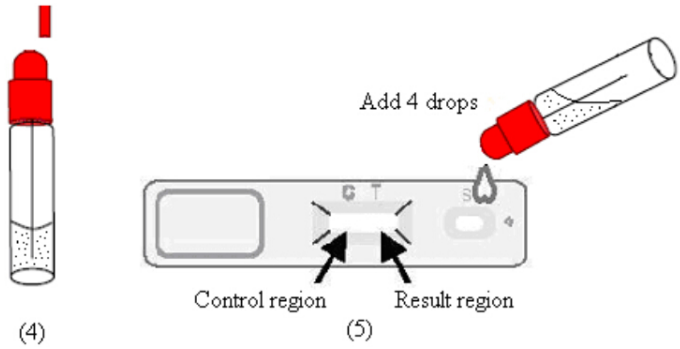



**Test Procedure:**

**Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not**

**open the pouch until ready to perform the assay.**

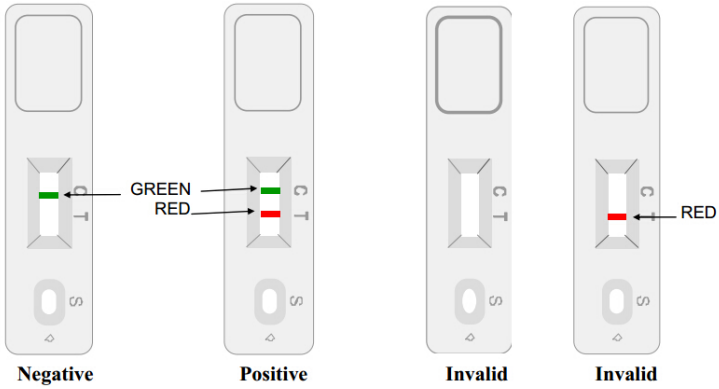
1. Remove the Rapid-VIDITEST Salmonella typhi Card from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion. Break off the cap of the vial (4).
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S) (5). 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:** A 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 you local distributor.

**NOTES:** 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.

**Evaluation**

Typhoid fever and salmonellosis are public health problems in developing countries, where the incidence of cases per year is 200-500/100 000. Transmission occurs by contamination of water or food with bacteria. Animals and humans are the principal reservoirs.

**Performance Characteristics**

**Detection limit**

The detection limit is: S. typhi: 1x104 bacteria/mL.

**Sensitivity and specificity**

It was performed an evaluation using Salmonella typhi culture. The correlation between two assays, Salmonella and Rapid-VIDITEST Salmonella typhi Card was >99%. It was also evaluated 20 stool samples using both assays. The results showed a high sensitivity and specificity using Rapid-VIDITEST Salmonella typhi Card.

The antibodies used to elaborate this test recognise S. typhi epitopes found in stool of patients, as well as in preparations from the bacteria cultures in vitro.

This preliminary values has to be taken with precaution until more evaluation data will be available.

**Cross-reactivity**

It was performed an evaluation to determine the cross reactivity of Rapid-VIDITEST Salmonella typhi Card. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in faeces: H. pylori, Escherichia coli O157:H7, Listeria monocytogenes, Campylobacter.

**Precautions**

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

**Limitations**

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. Some stood 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.

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5. A negative result is not meaningful because it is possible the Salmonella typhi content in the stool sample to be too small. A Salmonella typhi determination should be carried out on a sample from a 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.

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