Atlas Medical CE

**Salmonella typhi Device**

**One Step Salmonella typhi Test Device**

A rapid and one step test for the qualitative detection of Salmonella typhi in faeces.

IVD *For In-Vitro diagnostic and professional use only*

2 30°C Store at 2-30°C

## INTENDED USE

The Salmonella typhi Device is a one step colored chromatographic immunoassay for the qualitative detection of Salmonella typhi in stool samples samples in order to detect typhoid fever in persons.

## SYNTHESIS

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 immune-suppression. In contrast, NTS have a broad vertebrate host range and epidemiology that often involves food animals, at least in industrialized countries where it usually presents as gastroenteritis. Severe, invasive disease due to NTS is usually associated with the immune-compromised 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.

Salmonella typhi Device provides a rapid detection of Salmonella typhi directly from the faecal samples.

## PRINCIPLE

The Salmonella typhi Device is a qualitative immunoassay for the detection of Salmonella typhi 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 colored conjugates (antibodies anti-S. typhi-red microspheres) which were pre-dried on the test. The mixture then 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 colored band always appears (control line). The presence of this line serves as: 1) as verification that sufficient volume was added and 2) that proper flow was obtained; 3) as an internal control for the reagents.

## PRECAUTIONS

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

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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.

## MATERIALS

### MATERIALS PROVIDED

- Devices.
- Specimen collection vial with buffer.
- Package insert.

### Materials required but no provided

- Specimen collection container.
- Timer.
- Disposable gloves.

## 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 (2-4ºC/36-40ºF) 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 –20ºC/-4ºF. Freezing and thawing cycles are not recommended.

## PROCEDURES

**To process the collected stool samples (see illustration 1):**

Uses a separate vial/testing tube for each sample. Unscrew the cap of the vial and introduce the stick in different parts of the faecal specimen to pick up the sample (approx. 125mg). Put into the vial with buffer.

Shake the vial in order to assure good sample dispersion.

For liquid stool samples, aspirate the faecal specimen with a dropper and add 125µL into the vial with buffer.

**Test Procedure (see illustration 2)**

**Allow the tests, stool samples and buffer to reach to room temperature (15-30ºC/59-86ºF) prior to testing. Do not open the pouch until ready to perform the assay.**

Remove the Salmonella typhi Device from its sealed pouch and use it as soon as possible.

Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.

Use a separate device for each sample. Dispense exactly 4 or 100µL drops into the specimen well (S). Start the timer.

Read the result at 10 minutes after dispensing the sample.

**ILLUSTRATION 1**

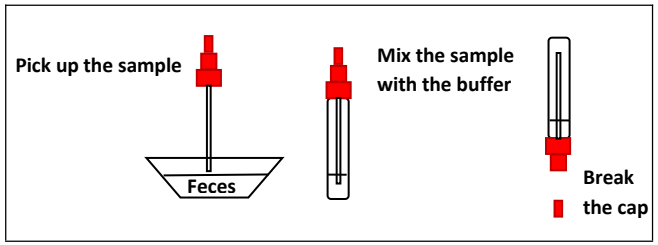
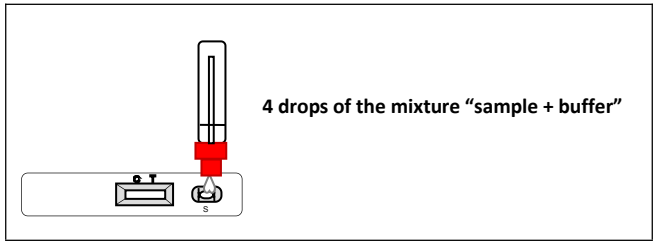
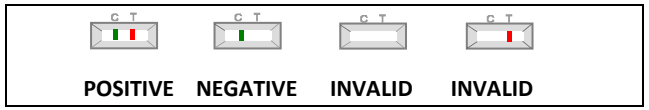



**ILLUSTRATION 2**




## INTERPRETATION OF RESULTS

**ILLUSTRATION 3**




**POSITIVE:** Two lines appears across the central window in the result line region, red test line marked with the

letter T, and in the control line region, green control line marked with the letter C.

**NEGATIVE**: Only one green band appears across the control line region marked with the letter C (control line).

**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 your local distributor.

**NOTES ON THE INTERPREATION 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.

**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.
- A clear background is an internal negative background control. If the test is working properly, the background in the result area should be clear and not interfere with the ability to read the result.

**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 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 the Salmonella typhi content in the stool sample to be 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 (typhoid fever). A confirmed infection 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.

**EXPECTED VALUES**

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**

**Sensitivity and specificity**

It was performed an evaluation using Salmonella typhi culture. It was studied 20 stool samples and the results were confirmed by Single path Salmonella (Merck). Salmonella typhi Device showed >99% of sensitivity and >97% of specificity.

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

**Cross-reactivity**

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

**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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|---|---|---|---|
| REF | **Product Reference No.** | IVD | **For in-vitro diagnostic use.** |
|  | **Caution.** |  | **Store at 2 - 30°C.** |
|  | **Read product insert before use.** |  | **Number of tests in the pack.** |
| LOT | **Lot (batch) number.** |  | **Manufacturer.** |
|  | **Expiry date.** |  | **Manufacturer telephone number.** |
|  | **Manufacturer fax number.** | | |