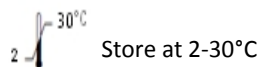## Salmonella paratyphi Device
One Step Salmonella paratyphi Test Device

A rapid and one step test for the qualitative detection of Salmonella paratyphi antigens in human feces.

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

Store at 2-30°C

INTENDED USE

The *Salmonella paratyphi* Device is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella paratyphi* antigens in human feces specimens in order to detect typhoid fever.

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 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.

Salmonella paratyphi Device provides a rapid detection of *Salmonella paratyphi* directly from the fecal samples.

PRINCIPLE

The *Salmonella paratyphi* Device is a qualitative lateral flow immunoassay for the detection of *Salmonella paratyphi* antigens in human feces samples. The membrane is pre-coated with monoclonal antibodies against *Salmonella paratyphi* antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*S. paratyphi* 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*

paratyphi 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: as verification that sufficient volume was added, that proper flow was obtained; and 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
- Instructions for use
- Specimen collection vial with buffer

MATERIALS REQUIRED BUT NO PROVIDED

- Specimen collection container
- Disposable gloves
- Timer

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/36-46.4ºF) 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):

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. 125mg). 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 125µL into the specimen collection vial with buffer.

Test Procedure (see illustration 2)

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

1. Remove the Salmonella paratyphi Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device 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.
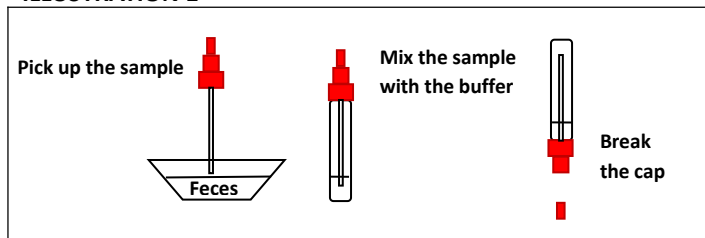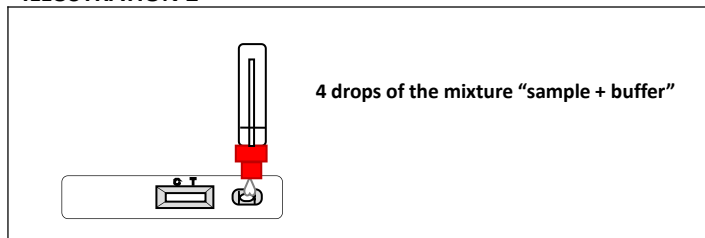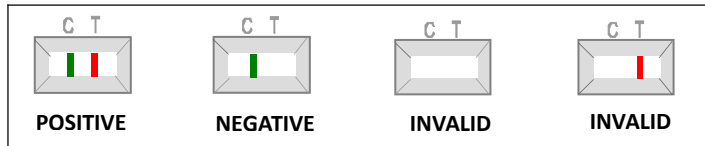
ILLUSTRATION 1

Pick up the sample — Feces — Mix the sample with the buffer — Break the cap

ILLUSTRATION 2

4 drops of the mixture "sample + buffer"

INTERPRETATION OF RESULTS
ILLUSTRATION 3

POSITIVE	NEGATIVE	INVALID	INVALID

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. See illustration 3.

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.

LIMITATIONS
1. Salmonella paratyphi Device will only indicate the presence of Salmonella paratyphi in the specimen (qualitative detection) and should be used for the detection of Salmonella paratyphi antigens in feces specimens only. Neither the quantitative value nor the rate of increase in Salmonella paratyphi antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines 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 paratyphi content in the stool sample to be too small. A Salmonella paratyphi determination should be carried out on a sample from an enrichment culture.
6. This test provides a presumptive diagnosis of Salmonella paratyphi (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
Detection limit
The detection limit test is 3.125×10^7 CFU/mL.

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

Cross-reactivity
It was performed an evaluation to determine the cross reactivity of *Salmonella paratyphi* Device. There is not cross reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces:

- *Campylobacter*	- *Helicobacter pylori*	- *Staphylococcus aureus*
- *Clostridium difficile*	- *Listeria monocytogenes*	- *Yersinia enterolitica*
- *Escherichia coli O157:H7*	- *Shigella*	

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.

ATLAS Medical
Unit 4, William James House
Cowley Rd, Cambridge, CB4 0WX
Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

PPI934A01
Rev A (03.11.2015)

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.		