Salmonella paratyphi Antigen Rapid Test (Feces)
For professional use

ELISURE

IVD REF SIC-RDT-ST-202076

A rapid test for the qualitative detection of salmonella paratyphi antigen in human feces.
For professional in vitro diagnostic use only.

INTENDED USE

The *Salmonella paratyphi* Antigen Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella paratyphi* antigen in human fecal specimens to aid in the diagnosis of *Salmonella paratyphi* infection.

SUMMARY

Typhoid fever and paratyphoid fever are bacterial infections caused by *Salmonella typhi (S. typhi)* and *Salmonella paratyphi (S. paratyphi)* A, B and C, which is transmitted through the ingestion of tainted food and water.[1] Worldwide an estimated 21 million cases and 222,000 associated deaths occur annually.[2] The majority of infections are cause by *S. typhi* with infections by *S. paratyphi*, B and C being more rare.[2]

S. paratyphi, B (tartrate negative), and C are bacteria that often cause a potentially severe and occasionally life-threatening bacteremic illness. While fever and gastrointestinal symptoms are common, the clinical presentation varies, including mild and atypical infections. In the United States, approximately 80 cases of paratyphoid fever caused by *S. paratyphi* are reported each year, 90% of which are acquired during international travel. Cases of paratyphoid fever caused by serotypes *S. paratyphi* B (tartrate negative) and C are reported much less frequently. Ongoing surveillance of *S. paratyphi* infections is essential to detect and control outbreaks, determine public health priorities, monitor trends in illness, and assess effectiveness of public health interventions.

The *Salmonella paratyphi* Antigen Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella paratyphi* antigen in human fecal specimens, providing results in 5 minutes.

PRINCIPLES

The *Salmonella paratyphi* Antigen Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of *S. paratyphi* antigen in human feces. In this test, the membrane is pre-coated with anti-*S. paratyphi* antibodies on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-*S. paratyphi* antibodies. The mixture migrates upward on the membrane by capillary action to react with anti-*S. paratyphi* antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials provided

- Test cassettes
- Package insert
- Specimen collection tubes with extraction buffer

Materials Required but Not Provided

- Droppers
- Centrifuge
- Timer
- Specimen collection containers
- Pipette and disposable tips (optional)

WARNINGS AND 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 eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test cassette is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

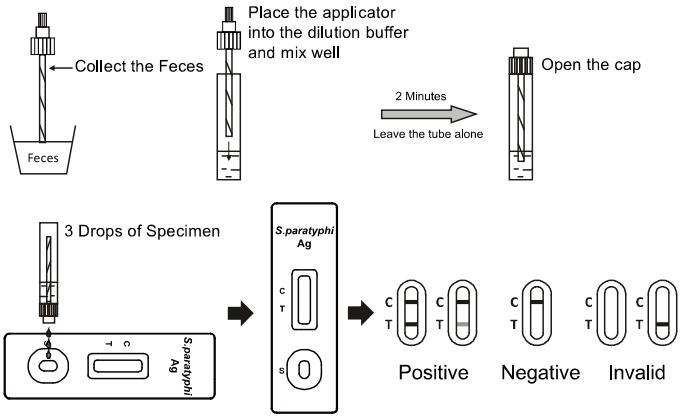
- The feces specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long term storage, specimens should be kept below -20°C.
2. To process fecal specimens:
   • For Solid Specimens:
   Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   • For Liquid Specimens:
   Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 100 µL) into the specimen collection tube containing the extraction buffer.
3. Tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer. Leave the tube alone for **2 minutes**.
4. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
5. Hold the specimen collection tube upright and open the cap onto the specimen collection tube. Invert the specimen collection tube and transfer **3 full drops of the extracted specimen** (approximately 120 µL) to specimen well (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
6. Read results at **5 minutes** after dispensing the specimen. Do not read results after 15 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimens contained in the extraction buffer vial. Collect 120 µL of supernatant, dispense into the specimen well (S) of a new test cassette and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE**: The intensity of the color in the test line region (T) will vary depending on the concentration of *S. paratyphi* antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques 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 immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal valid procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The *Salmonella paratyphi* Antigen Rapid Test (Feces) is for *in vitro* diagnostic use only. The test should be used for the detection of *S. paratyphi* antigens in fecal specimens only. Neither the quantitative value nor the rate of increase in *S. paratyphi* antigen concentration can be determined by this qualitative test.
2. The *Salmonella paratyphi* Antigen Rapid Test (Feces) will only indicate the presence of *S. paratyphi* in the specimen.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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 *salmonella paratyphi* infection.
5. Following certain antibiotic treatments, the concentration of *S. paratyphi* antigen may decrease to the concentration below the minimum detection level of the test. Therefore, diagnosis should be made with caution during antibiotic treatment.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The *Salmonella paratyphi* Antigen Rapid Test (Feces) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. The result shows that the sensitivity of the *Salmonella paratyphi* Antigen Rapid Test (Feces) is over 92.9% and the specificity is 97.3% relative to other Rapid Test.

Method		Other Rapid Test		Total Results
***Salmonella paratyphi* Antigen Rapid Test**	**Results**	Positive	Negative	
	Positive	39	3	42
	Negative	3	109	112
Total Results		42	112	154

Relative Sensitivity: 92.9% (95%CI*: 80.5%-98.5%) *Confidence Interval
Relative Specificity: 97.3% (95%CI*: 92.4%-99.4%)
Accuracy: 96.1% (95%CI*: 91.7%-98.6%)

Limitation of Detection

The minimum detection level is 1E+06org/ml for Salmonella paratyphi Antigen positive specimen.

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low positive, middle positive and high positive specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, low positive, middle positive and high positive specimens. Three different lots of the *Salmonella paratyphi* Antigen Rapid Test (Feces) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

Cross reactivity with following organisms has been studied at 1.0E+09organisms/mL. The following organisms were found negative when tested with the *Salmonella paratyphi* Antigen Rapid Test (Feces):

Acinetobacter calcoaceticus	*Acinetobacter spp*	*Branhamella catarrhalis*
Candida albicans	*Chlamydia trachomatis*	*Enterococcus faecium*

E.coli	*Enterococcus faecalis*	*Gardnerella vaginalis*
Group A Streptococcus	*Group B Streptococcus*	*Group C Streptococcus*
Hemophilus influenza	*Klebsiella pneumonia*	*Neisseria gonorrhea*
Neisseria meningitides	*Proteus mirabilis*	*Proteus vulgaris*
Pseudomonas aeruginosa	*Rotavirus*	*Helicobacter Pylori*
Staphylococcus aureus	*Adenovirus*	

Interfering Substances

The following potentially Interfering Substances were added to salmonella paratyphi negative and positive specimens, no interference was observed:

Ascoribic acid: 20 mg/dL	*Oxalic acid: 60 mg/dL*
Uric acid: 60 mg/dL	*Aspirin: 20 mg/dL*
Ttriglycerides: 40 mg/dL	*Albumin: 2,000 mg/dL*
Creatine: 40 mg/dL	*Metacortandracine: 20 mg/dL*
Salicylic acid: 4.34 mmol/L	*Hemoglobin: 2,000 mg/dL*
Bilirubin: 100 mg/dL	*Norfloxacin: 20 mg/dL*
Urea: 2,000 mg/dL	

BIBLIOGRAPHY

1. Ivanoff BN, Levine MM, Lambert PH. Vaccination against typhoid fever: present status. Bulletin of the World Health Organization 1994; 72: 957-71.
2. Immunization, Vaccines and Biologicals. Whild Health Organization (WHO). http://www.who.int/immunization/diseases/typhoid/en/

INDEX OF SYMBOLS

	Consult instructions for use		Contains sufficient for <n> tests
IVD	*In vitro* diagnostic medical device		Use-by date
	Temperature limit	LOT	Batch code
	Do not use if package is damaged		Manufacturer
REF	Catalogue number		Do not re-use

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