Accu-Screen Salmonella AntigenTest Device(feces)
Package Insert

A rapid test for the qualitative detection of Salmonella typhi (S.typhi) antigen in human feces.

For professional in vitro diagnostic use only.

INTENDED USE

The *S.typhi* Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella typhi* antigens in human feces specimens to aid in the diagnosis of *Salmonella typhi* infection.

SUMMARY

Typhoid fever is a life threatening illness caused by the bacterium *Salmonella typhi*,and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever[1]. The infection is acquired typically by ingestion.On reaching the gut,the bacilli attach themselves to the epithelial cells of the intestinal villi and penetrate to the lamina and submucosa. They are then phagocytosed there by polymorphs and macrophages.The ability to resist intracellular killing and to multiply within these cells is a measure of their virulence. They enter the mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream[2]. The *S.typhi* Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of *Salmonella typhi* antigens in human feces specimens,providing results in 5 minutes.The test utilizes antibodies specific for *Salmonella typhi* antigens to selectively detect *S.typhi* antigens in human feces.

PRINCIPLE

The *S.typhi* Antigen Rapid Test Device is a qualitative, lateral flow immunoassay for the detection of *S. typhi* antigens in human feces. In this test, the membrane is pre-coated with anti-S.typhi antibodies on the test line region of the test.During testing,the specimen reacts with the particle coated with anti-S.typhi antibodies.The mixture migrates upward on the membrane by capillary action to react with anti-S.typhi 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.

REAGENTS

The test Device contains monoclonal anti-S.typhi antibodies coated particles and monoclonal anti-S.*typhi* antibodies coated on the membrane.

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 Device is stable through the expiration date printed on the sealed pouch. The test Device 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 federal regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

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

Materials required but not provided

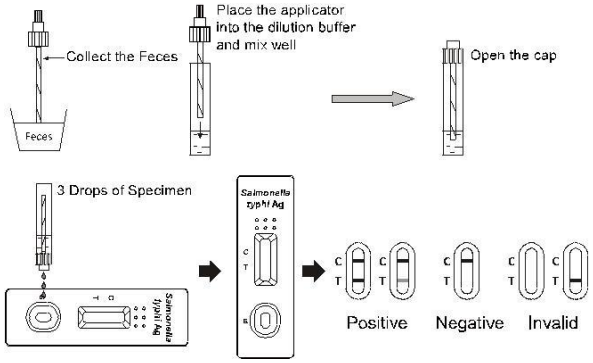
- Specimen collection containers
- Pipette and disposable tips (optional)
- Timer
- Centrifuge

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 (1-2mL 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℃ if not tested within 6 hours. For long term storage, specimens should be kept below -20℃.
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 50mg 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 100μL) into the specimen collection tube containing the extraction buffer.
   Tighten the cap onto the specimen collection tube,then shake the specimen collection tube vigorously to mix the specimen and the extraction buffer.
3. Bring the pouch to room temperature before opening it.Remove the test Device 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.
4. 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 120μL) to the specimen well (S) of the test Device,then start the timer. Avoid trapping air bubbles in the specimen well (S).See illustration below.
5. 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 120μL of supernatant,dispense into the specimen well(S) of a new test Device and start afresh following the instructions mentioned above.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:*Two lines appear.One colored line should be in the control line region (C) and another apparent 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.*Typhi* 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 S.t*yphi* Antigen Rapid Test Device is for in vitro diagnostic use only.The test should be used for the detection of *S.typhi* antigens in feces specimens only. Neither the quantitative value nor the rate of increase in *S.typhi* antigen concentration can be determined by this qualitative test.
2. The *S.typhi* Antigen Rapid Test Device will only indicate the presence of *S.typhi* 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 typhi infection.
5. Following certain antibiotic treatments, the concentration of *S.typhi* antigens may decrease to the concentration below the minimum detection level of the test.Therefore,diagnosis should be made with caution during antibiotic treatment.

EXPECTED VALUES

The *S.typhi* Antigen Rapid Test Device has been compared with other Rapid Test Device, demonstrating an overall accuracy of 98.3%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The *S.typhi* Antigen Rapid Test Device has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals.The result shows that the sensitivity of the *S.typhi* Antigen Rapid Test Device is 96.2% and the specificity is 99.2% relative to other Rapid Test Device.

Method		Other Test Device		Total Result
S.*typhi* Antigen Rapid Test Device	**Results**	**Positive**	**Negative**	
	Positive	51	1	52
	Negative	2	125	127
Total Result		53	126	179

Relative Sensitivity: 96.2% (95%CI*: 87.0%-99.5%) *Confidence Interval
Relative Specificity: 99.2% (95%CI*: 95.7%-100%) Accuracy: 98.3% (95%CI*: 95.2%-99.7%)

Precision

Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: negative, low titer positive,middle titer positive and high titer 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 titer positive,middle titer positive and high titer positive specimens. Three different lots of the S.*typhi* Antigen Rapid Test Device 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 S.*typhi* Antigen Rapid Test Device:

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	

BIBLIOGRAPHY

1. Ivanoff B. Typhoid fever, global situation and WHO recommendations.Southeast Asia J. Trop. Med. Public Health, 1995, 26:supp2 1-6
2. Parry CM, Hien TT Dougan G et al., Typhoid fever, N. Eng. J. Med. 2002, 347:1770-82.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

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