S.Typhi Antigen Rapid Test Cassette (Feces)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The S.Typhi Antigen Rapid Test Cassette is a rapid immunoassay for the qualitative detection of Salmonella Typhi (S.Typhi) antigen in human feces specimens to aid in the diagnosis of typhoid infection.

[SUMMARY]

Typhoid fever is a life threatening illness caused by the bacterium Salmonella typhus, and was observed by Eberth (1880) in the mesenteric nodes and spleen of fatal cases of typhoid fever. It is common in developing countries where it affects about 12.5 million persons annually. 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 the lamina and submucosa. They are then phagocytosed there by polymorphs and mesenteric lymph nodes, where they multiply and, via the thoracic duct, enter the blood stream. A transient bacteremia follows, during which the bacilli are seeded in the liver, gall bladder, spleen, bone marrow, lymph nodes, and kidneys, where further multiplication takes place. Towards the end of the incubation period, there occurs a massive bacteremia from these sites, heralding the onset of the clinical symptoms.

[PRINCIPLE]

The S.Typhi Antigen Rapid Test Cassette is a qualitative membrane strip based immunoassay for the detection of Salmonella Typhi (S.Typhi) antigen in human feces. The test cassette consists of: 1) a burgundy colored conjugate pad containing anti-S.Typhi antibody conjugated with colloid gold, 2) a nitrocellulose membrane strip containing one test band (T band) and a control band (C band). The T band is pre-coated with the anti-typhoid antibody, and the C band is pre-coated with goat anti mouse IgG. When an adequate volume of test specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. S.Typhi antigen, if present in the specimen, will bind to the anti-typhoid conjugates. The immunocomplex is then captured by the reagent pre-coated on the T band, forming a colored T band, indicating a typhoid antigen positive test result. A colored line will not form in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For *in vitro* diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with anti-typhoid antibody on the test line, goat anti mouse IgG on the control line, and a dye pad which contains colloidal gold coupled with anti-typhoid antibody.
The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette •Package insert
•Buffer

Materials Required But Not Provided

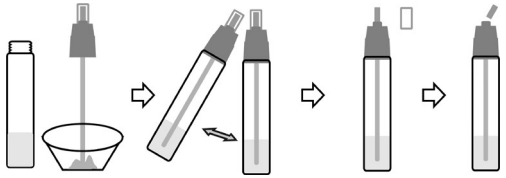
•Specimen collection container •Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The S.Typhi Antigen Rapid Test Cassette can be performed used on feces.
- 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 assays 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℃.
- Unscrew the cap of the specimen collection tube, then randomly stab the specimen collection applicator into the fecal specimen in at least 5 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
- Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

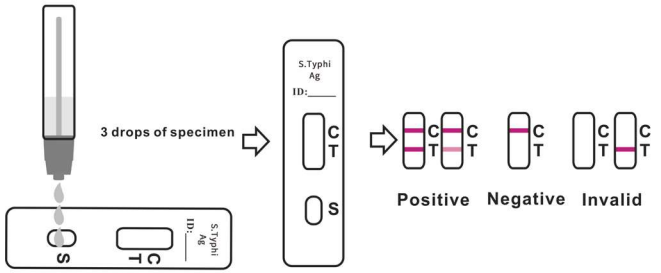


(The picture is for reference only, please refer to the material object.)

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette on a clean and level surface.
3. Holding the sample collection tube upright, carefully take off the tip of collection tube, then break off the tip of collection tube, transfer 3 drops (approximately 100 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
4. Wait for the colored line(s) to appear. Read results at 15 minutes. Do not interpret the result after 20 minutes.



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[INTERPRETATION OF RESULTS]

Positive: Two lines appear. One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This positive result indicates the S.Typhi antigen in specimen is present at the detectable level or greater than it.

Negative: One colored line appears in the control region(C). No apparent colored line appears in the test line region (T). This negative result indicates the S.Typhi antigen in specimen is present below the detectable level .

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]

- The S.Typhi Antigen Rapid Test Cassette is for *in vitro* diagnostic use only. The test should be used for the detection of S.Typhi antigen in human feces only. Neither the quantitative value nor the rate of increase in S.Typhi antigen can be determined by this qualitative test.
- The test is limited to the qualitative detection of S.Typhi antigen level in specimen. The exact concentration of the S.Typhi antigen cannot be determined by this assay.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the S.Typhi Antigen Rapid Test and commercially available S.Typhi rapid tests. 489 clinical specimens from three Professional Point of care sites were evaluated with the S.Typhi Antigen Rapid Test and the commercial kit. The discrepant specimens were checked with a commercially available ELISA to confirm the presence of S.Typhi antigen in the specimens. The following results are tabulated from these clinical studies:

Agreement with Commercial S.Typhi Rapid Test

S.Typhi antigen		Commercial S.Typhi Rapid Test		Total
		Positive	Negative	
	Positive	108	3	111
	Negative	3	375	378
Total		111	378	489

The agreement between these two devices is 97.30% for positive specimens, and 99.21% for negative specimens. This study demonstrated that the S.Typhi Antigen Rapid Test is substantially equivalent to the commercial device.

Agreement with ELISA

S.Typhi antigen		ELISA		Total
		Positive	Negative	
	Positive	106	5	111
	Negative	5	373	378
Total		111	378	489

A statistical comparison was made between the results yielding a clinical sensitivity of 95.50%, a clinical specificity of 98.68% and an accuracy of 97.96%.

Cross-Reactivity and Interference

1. Other common causative agents of infectious diseases were evaluated for cross-reactivity with the test. Some positive specimens of other common infectious diseases were spiked into the S.Typhi positive and negative specimens and tested separately. No cross-reactivity was observed with specimens from patients infected with HIV, HAV, HBsAg, HCV, HTLV, CMV and TP.
2. Potentially cross-reactive endogenous substances including common components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the S.Typhi positive and negative specimens and tested, separately. No cross-reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20 mg/mL	+	-
Bilirubin	10 µg/mL	+	-
Hemoglobin	15 mg/mL	+	-
Glucose	20 mg/mL	+	-
Uric Acid	200 µg/mL	+	-
Lipids	20 mg/mL	+	-

3. Some other common biological analytes were spiked into the S.Typhi positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

Analytes	Conc.	Specimens	
		Positive	Negative
Acetaminophen	200 µg/mL	+	-
Acetoacetic Acid	200 µg/mL	+	-
Acetylsalicylic Acid	200 µg/mL	+	-
Benzoylecgonine	100 µg/mL	+	-
Caffeine	200 µg/mL	+	-
EDTA	800 µg/mL	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200 µg/mL	+	-
β - Hydroxybutyrate	20,000 µg/mL	+	-
Methanol	10.0%	+	-
Phenothiazine	200 µg/mL	+	-
Phenylpropanolamine	200 µg/mL	+	-
Salicylic Acid	200 µg/mL	+	-

Reproducibility

Reproducibility studies were performed for S.Typhi Antigen Rapid Test at three physician office laboratories (POL). Sixty (60) clinical specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study.Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100%. The inter-site agreement was 100%.

[BIBLIOGRAPHY]

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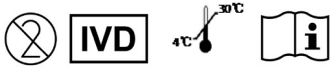

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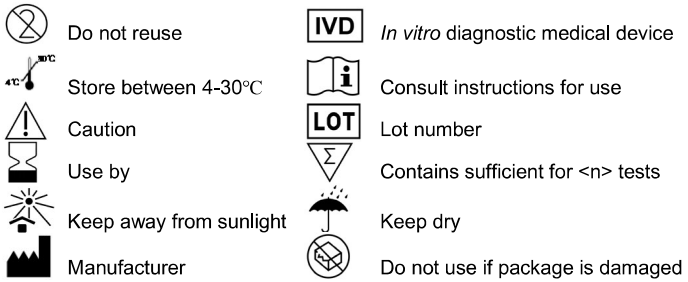

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