AG- SALMONELLA TYPHI Ag RAPID TEST KIT

INSTRUCTIONS FOR USE

AstraGene Salmonella Typhi Ag rapid test kit is a rapid and convenient immunochromatographic assay for the qualitative detection of S.typhi and Paratyphi antigens in human fecal, whole blood, serum or plasma samples. It is intended for professional use as an aid in the diagnosis of Salmonella Typhi and Paratyphi bacterial infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

PRINCIPLE

AstraGene Salmonella Typhi Ag rapid test kit is an antigen-capture immunochromatographic assay, which detects the presence of S. typhi and paratyphi bacteria in fecal, whole blood and serum/plasma samples. Monoclonal antibodies specifically against S. typhi and paratyphi Aare 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test zone (T1 and T2) of the nitrocellulose membrane, respectively. When a fecal or whole blood or serum/plasma sample is added, the gold-antibody conjugate is rehydrated and the S. Typhi and paratyphi antigens, if any in the sample, will interact with the colloidal gold conjugated antibodies. The antigen-antibody-colloidal gold complex will migrate towards the test window until the Test Zone (T1 and T2) where it will be captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive results. If S. typhi or paratyphi is absent in the sample, no pink line will appear in the Test Zone (T1 and T2), indicating a negative result. To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a pink control line in the Control Zone is an indication of an invalid result.

PACKAGE CONTENTS

Description	**10 tests**	1 test
Test Cassette and Desiccant	10 Cassette's	1 Cassette
Sample Dropper	10 No's	1 No.
Fecal Specimen Collection tube with sample buffer(1mL/tube)	10 tubes	1 tube
IFU	1 No.	1 No.

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/S.TYPH/24/01	AG/RTK/S.TYPH/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or timer.
- Pipette
- Latex gloves

STORAGE &STABILITY

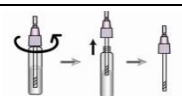
- The test device in the sealed pouch should be stored at 2-30ºC up to the expiration date. Do not freeze the test device.
- The Fecal Specimen Collection Device containing the buffer should be stored at 2-30ºC.
- The test device should be kept away from direct sunlight, moisture and heat. and heat.

SPECIMEN COLLECTION & PREPARATION

- Bacteria detection is improved by collecting the specimens at the onset of symptoms. It has beenreported that the maximum excretion of S. typhi and paratyphi in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigens may not be sufficient to obtain a positive result or the antigens detected may not be linked to the diarrheic episode.
- Perform testing as soon as possible after specimen collection. Best results will be obtained if the assay is performed right after collecting fecal samples. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 72 hours. Specimens prepared in the specimen collection tube may be stored at -20°C within 1 hour after preparation for 6 months.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

PROCEDURE

Bring tests, specimens, the buffer and/or controls at room temperature (15-30˚C) before use.

Use clean, dry containers for specimen collection.	
Unscrew the cap of the fecal specimen collectiontube and take out specimen collection stick.	
For solid specimens: Stab the specimen collection stick into the fecal specimen in at least 3 different sites of the fecesto collect approximately 50 mg of feces (equivalent to 1/4 of a pea).Do not scoop the fecal specimen.	
For liquid specimens: Hold the pipette vertically, aspirate the fecal specimens, and then transfer 6 drops (approximately 300µl) into the specimen collectiontube containing the extraction buffer.	

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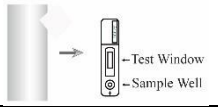
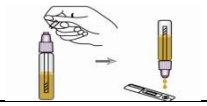
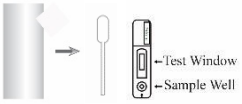
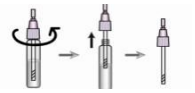
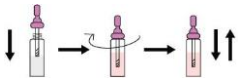
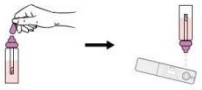
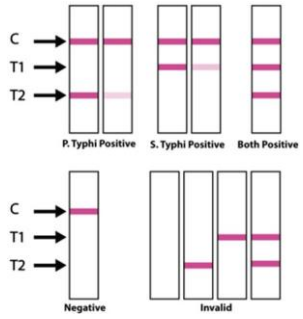
Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	
Remove the test cassette from the sealed pouchand use it as soon as possible. Caution: Do not touch the test window and themembrane inside.	
Hold the fecal specimen collection tube upright and break off the tip with hands. Invert the vial andadd 4 full drops (100 µl) of specimen without air bubbles into the sample well of the cassette.	
Read the result within 15 minutes, following instructions under the "Result Interpretations" section. NOTE: Specimens with high concentrations of analytes may produce positive results in as little as 1 minute and confirm negative results in 15-30 minutes.	 DO NOT INTERPRET RESULTS AFTER 30MINUTES

OR WHOLE BLOOD AND SERUM/PLASMA SAMPLES:

Remove the testing device from the sealed pouchby tearing at the notch and place the testing device on a leveled surface.	
Unscrew the cap of the specimen collection tubeand take out specimen collection stick.	
Hold the sample dropper vertically. Add one full drop (40 µl) of the specimen without air bubbles into the specimen collection tube.	

Insert the specimen collection stick into the tube and tighten the cap. Shake the tube vigorously to ensure thorough mixture of the specimen and the assay diluents reagent.	
Hold the specimen collection tube upright andbreak off the tip with hands. Invert the vial and add 4 full drops (100 µl) of specimen without air bubbles into the sample well of thecassette.	
Read the result in 15-20minutes, following instructions under the "Result Interpretations"section. NOTE: Strong positive specimens may producepositive results in as little time as 1 minute. Confirm negatives in 20 minutes.	DO NOT INTERPRET RESULTS AFTER30 MINUTES

RESULT INTERPRETATIONS



Negative
A pink colored band appears only at the control region (C), indicating a negative result for S. typhi and paratyphi infections.
Positive
S. Typhi Positive: a clear pink control line (C) and a detectable test line (T1) appears, indicating positive result for S. Typhi infection.
S. Paratyphi Positive: a clear pink control line (C) and a detectable test line (T2) appears, indicating positive result for Paratyphi A infection.
S. Typhi and S. Paratyphi Positive: a clear pink control line (C) and two detectable test line (T1 andT2) appears, indicating positive results for S. Typhi and Paratyphi A mixed infection.
Invalid
No visible band at the control region. Repeat with a new test device. If the test still fails, please contact the distributor with the lot number.

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QUALITY CONTROL

Although the testing device contains an internal control (pink colored line in the control region), good laboratory practice recommends the use of an outside control to ensure proper testing device performance. Quality control samples should be tested according to the standard quality control requirements established by your laboratory.

LIMITATION OF THE PROCEDURE

- This product is an *in vitro* diagnostic test designed for professional use only.
- Humidity and temperature can adversely affect results.
- The instructions for the use of the test should be followed during testing procedures.
- There is always a possibility that false results will occur due to the presence of interfering substances in the specimen or factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
- Although the test demonstrates superior accuracy in detecting *S. typhi and paratyphi* in fecal extract, a low incidence of false results can occur. Therefore, other clinically available tests are required in case of questionable results. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNING AND PRECAUTION

- For professional *in vitro* diagnostic use only.
- Do not reuse.
- Do not use if the pouch seal or its packaging is compromised.
- Do not use after the expiration date shown on the pouch.
- Do not mix and interchange different specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling potentially infectious materials and performing the assay.
- Wash hands thoroughly after finishing the tests.
- Do not eat, drink or smoke in the area where the specimens or kits are being handled.
- Clean up spills thoroughly with appropriate disinfectants.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and used devices in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
- Keep out of children's reach.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

AstraGene FZ LLC, Office No. 208 – 209, Dubai Science Park Building, Dubai, United Arab Emirates
+971-4-8781222, contact@astragene.com