Salmonella Typhi/Paratyphi A Antigen Test Kit

Instructions For Use

Format: Cassette

Specimen: Fecal Extract and Whole Blood
Catalog Number: A03-30-522

* Please read the instructions carefully before use
INTENDED USE

Artron One-Step Salmonella typhi (S. typhi)/paratyphi Test is a rapid and convenient immunochromatographic assay for the qualitative detection of S. typhi and paratyphi antigens in human fecal or whole blood samples. It is intended for professional use as an aid in the diagnosis of Salmonella typhi and paratyphi bacteria infection. This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test.

SUMMARY AND PRINCIPLE OF THE ASSAY

Typhoid fever is a serious illness caused by S. typhi, a Gram-negative bacterium. Typhoid fever is common in developing countries. About 12.5 million people are infected with the illness each year. The infection is contracted by eating or drinking contaminated food or water or by coming into contact with patients of typhoid fever. S. typhi bacteria are carried in the bloodstream and intestinal tract of infected persons. The incubation period of typhoid fever ranges from 3 days to 3 months, but is usually within 1 to 3 weeks after exposure. Around 2-5% of people who have contracted typhoid fever become chronic carriers and continues to carry the bacteria even after they have recovered from the symptoms. Both chronic carriers and those ill with Salmonella typhi release S. typhi bacteria in their stool.

Salmonella paratyphi A also causes an enteric illness called paratyphoid fever. Symptoms of both S. typhi and Serovar paratyphi bacteria infection include a slowly progressive fever that may reach 40°C, profuse sweating, and abdominal pain. As the disease gets worse, severe diarrhea often occurs. Diagnosis of typhoid and paratyphoid fever includes the isolation of the bacteria and the identification of antibodies.

Artron One-Step Salmonella typhi and paratyphi Test is an antigen-capture immunochromatographic assay, which detects the presence of S. typhi and paratyphi bacteria in fecal and whole blood samples. Monoclonal antibodies specifically against S. typhi and paratyphi A are 1) conjugated with colloidal gold and deposited on the conjugate pad and 2) immobilized on the test zone (T2 and T1) of the nitrocellulose membrane, respectively. When a fecal 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 (T2 and T1) where it will be captured by immobilized antibodies, forming a visible pink line (Test line), indicating a positive result. If S. typhi or paratyphi is absent in the sample, no pink line will appear in the Test Zone (T2 and T1), 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

- Pouch contents: test cassette, sample dropper, desiccant.
- Fecal Specimen Collection tube with sample buffer (2 ml/tube).
- Test instructions.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Gloves.
- Clock or timer.

WARNINGS AND PRECAUTIONS

- 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 or 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 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.

SPECIMEN COLLECTION AND STORAGE

FOR FECAL SAMPLES:
• Bacteria detection is improved by collecting the specimens at the onset of symptoms. It has been reported 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 immediately 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 for 6 months at -20°C if not tested within 1 hour after preparation.
• 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.

FOR WHOLE BLOOD SAMPLES:
• For whole blood samples, collect blood in a tube containing anticoagulant.
• Whole blood samples should be tested immediately after sample collection.
• The blood may be stored at 2º C to 8º C for up to three days if the tests cannot be performed immediately. Ensure that the blood samples should be allowed to attain room temperature prior to use.

TEST PROCEDURES

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

FOR FECAL SAMPLES:

<table>
<thead>
<tr>
<th>Use clean, dry containers for specimen collection. Best results will be obtained if the assay is performed within 6 hours after collection.</th>
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</thead>
<tbody>
<tr>
<td>Unscrew the cap of the fecal specimen collection tube and take out specimen collection stick.</td>
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<tr>
<td>For solid specimens: Stab the specimen collection stick into the fecal specimen in at least 3 different sites of the feces to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.</td>
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<tr>
<td>For liquid specimens:</td>
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<tr>
<td>Hold the pipette vertically, aspirate the fecal specimens, and then transfer 6 drops (approximately 300 μl) into the specimen collection tube containing the extraction buffer.</td>
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<tr>
<td>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.</td>
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<tr>
<td>Remove the test cassette from the sealed pouch and use it as soon as possible.</td>
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<tr>
<td>NOTE: The dropper provided is not used for fecal specimens.</td>
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<tr>
<td>Caution: Do not touch the test window and the membrane inside.</td>
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<tr>
<td>Hold the fecal specimen collection tube upright and break off the tip with hands. Invert the vial and add 2 full drops (80 μl) of specimen without air bubbles into the sample well of the cassette.</td>
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<tr>
<td>Read the result within 15 minutes, following instructions under the “Result Interpretations” section.</td>
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<tr>
<td>NOTE: Specimens with high concentrations of S. typhi bacteria may produce positive results in as little as 1 minute and confirm negative results in 15-30 minutes.</td>
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<tr>
<td><strong>DO NOT INTERPRET RESULTS AFTER 30 MINUTES</strong></td>
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**FOR WHOLE BLOOD SAMPLES:**

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<thead>
<tr>
<th><img src="image_url" alt="Image" /></th>
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<tr>
<td>Remove the testing device from the sealed pouch by tearing at the notch and place the testing device on a leveled surface.</td>
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</table>
Hold the sample dropper vertically. Add one full drop (40 µl) of the specimen without air bubbles into the sample well that is marked with an arrow on the testing device.

Wait for 20-30 sec, then add 1 to 2 drops (40-80 µl) of the assay buffer to the same Sample Well of the testing device.

Caution: Do not touch the test window and the membrane inside.

Read the result in 20 minutes, following instructions under the “Result Interpretations” section.

NOTE: Strong positive specimens may produce positive results in as little time as 1 minute. Confirm negatives in 20 minutes.

DO NOT INTERPRET RESULTS AFTER 30 MINUTES

RESULT INTERPRETATIONS

<table>
<thead>
<tr>
<th>C</th>
<th>T1</th>
<th>T2</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Typhi Positive</td>
<td>P. Typhi Positive</td>
<td>Both Positive</td>
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</table>

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 (T2) appears, indicating positive result for S. Typhi infections.
Paratyphi Positive: a clear pink control line (C) and a detectable test line (T1) appears, indicating positive result for Paratyphi A infections
S. Typhi and Paratyphi Positive: a clear pink control line (C) and two detectable test line (T2 and T1) 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

QUALITY CONTROL
Although the testing device contains an internal quality control (pink colored band in the control region), good laboratory practice recommends the daily 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.

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

- 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.

MANUFACTURER CONTACT INFORMATION

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