Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

OneStep Salmonella Typhi Antigen in Human Stool/Whole Blood/Plasma/Serum RapiCard™ InstaTest

REF 118565-25-23

IVD See external Label 4 - 30°C 25 Tests

Sensitivity	25 ng/ml

INTENDED USE

Cortez Diagnostics, Inc. OneStep S. Typhi Antigen RapiCard™ InstaTest is an *in vitro* qualitative immunochromatographic assay for the rapid detection of *S. Typhi* antigens in human stool or whole blood/plasma/serum specimen. The test results are intended to help in the diagnosis of *S. Typhi* infection and, to monitor the effectiveness of therapeutic treatment.

INTRODUCTION

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. 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 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. 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. The diagnosis of typhoid consists of isolation of the bacilli and the demonstration of antibodies. The isolation of the bacilli is very time consuming and antibody detection is not very specific. Other tests include the Widal reaction which lacks both sensitivity and specificity. Cortez Diagnostics, Inc. OneStep S. Typhi Antigen RapiCard™ InstaTest takes only 10-20 minutes and requires only a small quantity of stool or one drop of serum* to perform. It is the easiest and most specific method for detecting S. typhi infection.

TEST PRINCIPLE

Cortez OneStep S. Typhi Antigen RapiCard™ InstaTest is a qualitative one step immunochromatographic assay. The test employs antibodies specific to S. typhi lipopolysaccharide (LPS) to selectively identify S. typhi (typhoid) infection with a high degree of sensitivity and specificity.

As the specimen flows through the absorbent pad in the sample well and through the antibody/colloidal gold conjugate S. typhi antigen present in the sample binds to the conjugate forming an antigen/antibody complex. The complex continue to migrate along the membrane to the test band region where S.typhi specific LPS antibody is immobilized. In the presence of S. typhi, the antibody captures the complex. This forms a visible pink/purple band in the test line zone area (T). If no antigen is present, there is no line formation in the (T) area. The remaining complex continues to migrate on the membrane to the control line zone area (C) and forms a pink/purple band. The appearance of the control band indicates the proper performance of the test.

SPECIMEN COLLECTION AND PREPARATION

Cortez Diagnostics, Inc. OneStep S. Typhi Antigen RapiCard™ InstaTest can be run on stool or whole blood/plasma/serum samples. The test works best on fresh samples. If testing cannot be done immediately, they should be stored at 2-8°C after collection for up to 3 days. If testing cannot be done within 3 days, serum can be stored frozen at –20°C or colder.
Shipment of samples should comply with local regulations for transport of etiologic agents.Stool and whole blood/plasma/serum specimens should be collected in containers that do not contain media, preservatives, animal serum or detergents as any of these additives may interfere with the Cortez S. Typhi Antigen Test.

MATERIALS AND COMPONENTS

Materials provided with the test kits

Each kit contains:

1. Cortez S. Typhi Antigen Test - 25 each.
   Each cassette contains a test strip with S. Typhi specific antibody on the test region of the membrane and colored S. Typhi antibody-gold conjugate pad.
2. Fecal sample buffer – 2 bottles, 8 mL each.
3. Instruction for use.

Materials required but not provided

1. Specimen collection container
2. Timer.

REAGENT PREPARATION

Bring all reagents, including test device, to room temperature (15-30°C) before use.

STOOL SPECIMEN PREPARATION

Add about 1/4 gram to approximately 500µl of the extraction reagent provided (about 12 drops from the dropper vial provided). Mix well and allow to sit for 5 minutes or so to allow the large particles to settle.

ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature (8 – 30°C).
2. Remove the test card from the sealed foil pouch.
3. For stool samples: use the provided pipet to transfer sample from the upper layer of the stool extract and add 3 drops to the sample well (marked as “S”). For whole blood/plasma/serum samples: use the provided pipet to transfer the serum sample and add 3 drops to the sample well (marked as “S”).
4. Read the result at 20 minutes. A strong positive sample may show test band earlier. However, to confirm a result is negative, it must wait 20 minutes to read the results.

Note: The amount of S. typhi antigens present in whole blood/plasma/serum is typically less than that in stool. This may

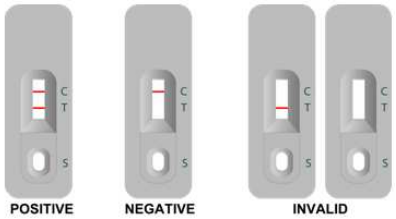
Diagnostic Automation/ Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367 USA Phone: 818-591-3030, Fax : 818-591-8383
Email: onestep@rapidtest.com Website: www.rapidtest.com

decrease the sensitivity of the test when using whole blood/plasma/serum specimens, depending how soon after the onset of the infection the test is performed. Early infection typically exhibits greater levels of the antigen in the whole blood/plasma/serum than in later infection.

To confirm whole blood/plasma/serum results: The use of a stool sample is recommended if whole blood/plasma/serum is used first and a negative result is obtained and typhoid is still suspected.

RESULTS

- **Positive result**: A distinct pink colored band appears on test line regions, in addition to a pink line on the control line region.
- **Negative result:** No line appears in the test line region. A distinct pink line shows on the control line region.
- **Invalid result:** The control line next to the test line does not become visible within 20 minutes after the addition of the sample.



PERFORMANCE CHARACTERISTICS

Sensitivity

The analytical sensitivity of S. typhi test was determined at 25 ng/ml of LPS.

Specificity

S. typhi test is specific to Salmonella O (somatic) antigen, group D and has no cross with other groups of O antigen tested.

Salmonella O antigen	S. typhi
A	Negative
B	Negative
C1	Negative
C2	Negative
D	Positive
E2	Negative
E4	Negative
G1	Negative
H	Negative
I	Negative
VI	Negative

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials, which are not provided with this test kit, may be commercially available.

LIMITATIONS OF PROCEDURE

1. The test is for qualitative detection of S.Typhi antigen in stool or whole blood/plasma/serum sample and dose not indicate the quantity of the antigens.
2. The test is for *in vitro* diagnostic use only.
3. For samples that test positive (reactive) by Cortez S. Typhi Antigen Test, more specific confirmatory testing should be done. A definitive clinical diagnosis should only be made by the physician after all clinical and laboratory finding have been evaluated.. The use of a rapid test alone is not sufficient to diagnose S. typhi infection even if antigen is present. Also, a negative result does not preclude the possibility of infection with S. typhi.

PRECAUTIONS

1. This kit is for ***In Vitro*** diagnostic use only.
2. This kit is for ***Professional*** use only.
3. Read the instructions carefully before performing the test.
4. This product does not contain any human source materials.
5. Do not use kit contents after the expiration date.
6. Handle all specimens as potentially infectious.
7. Follow standard Lab procedure and biosafety guidelines for handling and disposal of potentially infective material. When the assay procedure is completed, dispose specimens after autoclaving them at 121°C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.
8. Do not pipette reagent by mouth and no smoking or eating while performing assays.
9. Wear gloves during the whole procedure.

STORAGE INSTRUCTION

1. The expiration date is indicated on the package label.
2. Test device can be stored at 4-30°C

REFERENCES

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. Bng. J. Med. 2002, 347:1770-82.

ISO 13485
ISO 9001

Diagnostic Automation/
Cortez Diagnostics, Inc.
21250 Califa St, Suite 102 and 116,
Woodland Hills, California 91367 USA

Date Adopted	**2016-02-04**
REF **118565-25-23**	**CORTEZ- OneStep Salmonella Typhi Antigen in Human Stool/Whole Blood/Plasma/Serum RapiCard™ InstaTest - 2016**
Revision Date: 2013-11-12	