



### OneStep Scrub Typhus IgM (Serum/WB/Plasma) RapiDip™ InstaTest

**REF** 146118

**PIC** ID146118XU1

**IVD** See External Label 20°C 30°C 25 Tests

Scrub Typhus IgM RapiDip™ InstaTest	
Principle	Immunochromatographic Immunoassay
Detection	Qualitative
Specimen	10 µl serum/plasma

#### PRODUCT FEATURES

**High Sensitivity and Specificity**

**Built in Internal Controls**

**Simplified Workflow, Non-invasive, and Safe**

**Rapid and Faster Results**

A rapid test for the qualitative detection of IgM antibodies to Scrub Typhus antigens in serum, plasma, or whole blood.

#### INTENDED USE

The OneStep Scrub Typhus IgM RapiDip™ InstaTest is a rapid immunochromatographic immunoassay for the qualitative detection of IgM antibodies to members of *O. tsutsugamushi* (OT) species in human serum, plasma or blood.

#### SIGNIFICANCE AND SUMMARY

Scrub Typhus (ST) is an infectious disease that is caused by *Orientia tsutsugamushi* (OT; formerly *Rickettsia*), a tiny parasite about the size of bacteria that belongs to the family Rickettsiaceae (1). A bite from the larval trombiculid mite, a parasite of rodents, will transmit the disease. An ulcer of the skin is characteristic of a bite from a trombiculid mite, followed by symptoms including fever, a spotted rash on the torso, and swelling of the lymph glands. After the onset of symptoms, the IgM antibody titers increased gradually over 2–3 weeks, peaked at about 4 weeks, and started to decrease rapidly between 4 and 5 weeks. Over the first 2 weeks, IgG antibody titers increases sharply, peaked at about 4 weeks and decreased rather gradually thereafter (1). Scrub typhus generally occurs after exposure to areas with secondary (scrub) vegetation, which is where its name is derived from. However, the disease can also be prevalent in sandy, mountainous, and tropical areas. Scrub Typhus is a worldwide illness, but particular to South East Asia and the Western Pacific. It accounts for approximately 20% of fever in some regions in South East Asia, where it is endemic. Illness lasts for a period of 10 to 12 days after the initial bite. With therapy, the fever will break within 36 hours, but if left untreated, complications or death may occur.

#### ASSAY PRINCIPLE

The OneStep Scrub Typhus IgM RapiDip™ InstaTest is a qualitative, membrane-based immunoassay for the detection of IgM. The membrane is pre-coated with a mixture of novel recombinants

(representing several geographical isolates; 2, 3) on the test line region and appropriate control antigen on the control line region. During testing, the sample reacts with the dye conjugate (anti-human IgM colloidal gold conjugate) which has been pre-coated in the test device. The mixture then migrates upward on the membrane chromatographically by capillary action to react with ST derived recombinant antigens on the membrane and generates a red line. Presence of this red line indicates a positive result, while its absence indicates a negative result. Independent of the presence or absence of antibody to scrub typhus antigens, a red line at the control line region will always appear when the sera-gold migrates to the immobilized control region. The presence of this red line verifies for sufficient sample volume and proper flow of reagents.

#### SPECIMEN COLLECTION

1. The Scrub Typhus IgM Test system can be performed using serum, plasma or whole blood. *Note: Do not use heat inactivated samples*
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. The plasma or serum may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
3. 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.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

#### MATERIALS AND COMPONENTS

The OneStep Scrub Typhus IgM RapiDip™ InstaTest strip's membrane is pre-coated with a mixture of ST derived recombinant r-56 antigens on the test line region and anti-human IgM (for IgM detection) reagents on the control line region. The Kit contains the following:



1. Twenty-five (25) individually pouched Test Strips or twenty-five (25) test strips in a vial with desiccant on the vial cap.
2. One (1) vial of Chase Buffer solution.

### ASSAY PROCEDURE

1. Allow the samples to reach room temperature prior to testing.
2. Remove the OneStep Scrub Typhus IgM RapiDip™ InstaTest from the foil pouch or vial.
3. Add 10µl of sera or 1µl whole blood to the test strip in the area beneath the arrow (sample pad area). For addition of the sera, the strip may be placed horizontally on a flat surface or vertically in a microtiter well or test tube.
4. If the test strip is placed horizontally on a flat surface, add 3 drops (or 90-120 µl) of the Chase Buffer solution into a test tube or plastic well (with a minimum capacity of 200 µl); then place the strip, facing downward (as indicated by arrows on the strip), into the well.
5. If the test strip is placed vertically in the well, then add 3 drops (90-120 µl) of the Chase Buffer solution directly into the well.
6. Read the results in 15 minutes.
7. To ensure the detection of all samples, including those yielding a weak signal in the test region, it is imperative that the testing period be complete and that the background on the strip cleared prior to reading the result. Results interpreted after 15 minutes can be inaccurate.

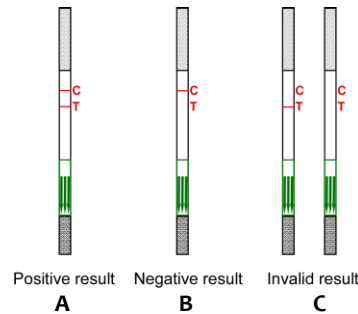
**Note:** Do not test this product with the Chase Buffer solution alone. 10 µl of human serum or 10 µl of whole blood must be added first.

### INTERPRETATION OF RESULTS

#### A Positive Result

The test is positive when a control line (C) and test line (T) appears in the test area (Figure 1A). A positive result indicates that the OneStep Scrub Typhus IgM rapid dipstick detected antibodies to mixture of OT derived recombinant antigens. A faint line is considered a positive result. As a guide for interpretation, the red color in the test region (T) will vary depending on the concentration/affinity of antibodies present.

**Figure 1**  
**Schematic representation of the OneStep Scrub Typhus IgM RapiDip™ InstaTest reactivity**



#### A Negative Result

The test is negative when only the control line appears (Figure 1B). A negative result indicates that the OneStep Scrub Typhus IgM RapiDip™ InstaTest did not detect antibodies to members of OT derived recombinant antigens.

#### An Invalid Result

1. No lines appear at either the control or test line areas.
2. No control line appears, but a test line is seen (Figure 1C).

### LIMITATIONS

1. The OneStep Scrub Typhus IgM RapiDip™ InstaTest Device is for in vitro diagnostic use. The test should be used for the detection of antibodies to *O. tsutsugamushi* in specimen.
2. The OneStep Scrub Typhus IgM RapiDip™ InstaTest Device will only indicate the presence of antibodies to OT antigens in the specimen and may not imply active infection.

3. Do not use serum samples containing any glycerol or other viscous materials. This will decrease the sensitivity of the assay.
4. The OneStep Scrub Typhus IgM RapiDip™ InstaTest assays have not been tested in persons with advanced HIV infection or other immunocompromised diseases that are known to have low or undetectable specific antibodies.
5. Rheumatoid Factor containing (RF) sera may produce false positive results when OneStep Scrub Typhus IgM RapiDip™ InstaTest is used.

### PRECAUTIONS

1. For in vitro diagnostic use.
2. All human source materials used in the preparation of controls have tested negative for antibodies to HIV 1&2, Hepatitis C and Hepatitis B surface antigen. However, no test method can ensure 100% efficiency. Therefore, all human controls and antigen should be handled as potentially infectious material. The Center for Disease Control and the National Institute of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.
3. Avoid drinking and/or eating in testing areas.
4. A thorough understanding of this package insert is necessary for successful use of the product. Reliable results will only be obtained by using precise laboratory techniques and accurately following the package insert.
5. Do not mix various lots of any kit component within an individual assay.
6. Do not use any component beyond the expiration date shown on its label.
7. Avoid exposure of the reagents to excessive heat or direct sunlight during storage and incubation.
8. Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly afterwards.
9. Use a clean disposable pipette tip for each reagent, Standard, Control or specimen.
10. Cover working area with disposable absorbent paper.
11. Avoid all possible contact with skin and mucous membranes.



**STORAGE**

The sealed pouch or vial containing the test strip and the bottle containing the Chase Buffer is designed to be stored at room temperature (20-28°C) for the duration of its shelf life. Exposure to temperatures over 30°C can impact the performance of the test and should be minimized. The strips should not be frozen. The test should be used within 1 hour after removal from the pouch or vial to prevent exposure to humidity.

**REFERENCES**

1. Seong SY, Choi MS, Kim IS, 2001. Orientia tsutsugamushi infection: overview and immune responses. *Microbes Infect* 3(1): 11-21.
2. Land MV, Ching WM, Dasch GA, Zhang Z, KellyDJ, Graves SR, Devine PL, 2000. Evaluation of a Commercially Available Recombinant-Protein Enzyme-Linked Immunosorbent Assay for Detection of Antibodies Produced in Scrub Typhus RickettsialInfections. *J Clin Microbiol July 2000*: 2701-2705
3. Coleman RE, Sangkasuwan V, Suwanabun N, Eamsila C, Mungviriya S, Devine P, Richards AL, Rowland D, Ching WM, Sattabongkot J, Lerdthusnee K, 2002. Comparative Evaluation of Selected Diagnostic Assays for the Detection of IgG and IgM Antibody to *Orientia Tsutsugamushi* in Thailand. *Am J Trop Med Hyg* 67(5): 497-503.

**MANUFACTURER AND BRAND DETAILS**

 <p><b>ISO 13485:2016</b>          bsi          ISO 13485          Quality Management for Medical Devices          CERTIFIED</p>	
 <p><b>Diagnostic Automation/Cortez Diagnostics, Inc.</b>          21250 Califa Street, Suite 102 and 116,          Woodland Hills, California 91367 USA</p>	
<b>Date Adopted</b>	<b>2024-06</b>
<b>Brand Name</b>	<b>RapiDip™ InstaTest</b>
<b>REF</b> 146118	<b>OneStep Scrub Typhus IgM (Serum/WB/Plasma) RapiDip™ InstaTest</b>
<b>PIC</b>	<b>ID146118XU1</b>
<b>EU REP</b>	<b>AR Experts BV, Boeingavenue 201-219 1119 PD Schiphol-Rijk, The Netherlands <a href="mailto:info@ar-experts.eu">info@ar-experts.eu</a></b>
<b>Revision Date: 2018-05-01</b>	