ImmunoScience INDIA

ImmunoQuick

Scrub Typhus IgM

Rapid Test for Detection of Scrub Typhus IgM Antibodies – Device

For *In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

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1. OVERVIEW

Scrub typhus, also known as bush typhus, is a disease caused by a bacteria called Orientia tsutsugamushi. Scrub typhus is spread to people through bites of infected chiggers (larval mites). The most common symptoms of scrub typhus include fever, headache, body aches, and sometimes rash. Scrub typhus is a zoonotic infection caused by the bacterium Orientia tsutsugamushi. It is transmitted to humans by the bite of the larval stage of trombiculid mites.

2. INTENDED USE

Scrub Typhus IgM test is an immunochromatographic assay for the qualitative Detection of Scrub Typhus specific IgM antibodies in human serum/plasma or whole blood.
This test is for in vitro diagnostic use only.

3. PRINCIPLE

After addition of the sample and the assay buffer to the sample well of the device containing a test strip, the sample moves on to the conjugate pad containing colloidal gold particles conjugated with recombinant Scrub typhus antigen and streptavidin. If the sample contains detectable levels of the Scrub Typhus specific IgM antibodies, it reacts with the colloidal gold particles conjugated with antigen to form a complex. This complex moves further reacts with Anti-Human IgM test line coated on the nitrocellulose membrane area to form colored band/s. The unbound complex and the Streptavidin conjugated colloidal gold particles move further to the Biotin coated control area to form a colored band (Control line). The appearance of test line and control line in respective area indicates the positive result. Appearance of only control line indicates a negative result. The control line acts as a procedural control. Control line should always appear if the test is performed as per the procedure and reagents are working properly.

4. CONTENTS OF KIT

1. Test device with desiccant and plastic dropper sealed in individual pouch.
2. Assay Buffer
3. Package Insert

5. OPTIONAL MATERIAL REQUIRED

1. Timer
2. Sample container
3. Micro pipette
4. Disposable Gloves

6. PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test. Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C. Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

7. WARNINGS

1. Do not reuse the test device.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose the used test & samples hygienically in Biohazard waste.
5. Do not touch the membrane.
6. Treat samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.

8. SPECIMEN COLLECTION

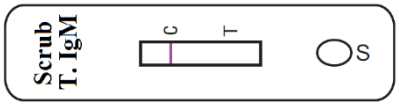
1. Blood sample shall be collected in EDTA or heparin tube. Fresh fingerpick blood can also be used for testing.
2. For serum, collect the blood sample in plain tube. Allow the blood to clot for few minutes. Centrifuge the tube and use supernatant as a serum sample. Testing should be performed as early as possible after collection. Do not leave samples at room temperature for prolonged periods.

9. TEST PROCEDURE

1. Allow the test device and sample reach to room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the test device, desiccant and plastic dropper from the pouch and use it as early as possible.
3. Put the device on plain surface and add 10 µl of serum / plasma or 20 µl whole blood sample in sample well and add 2 drops (Approx. 60 µl) of assay buffer in sample well.
4. Start the timer.
5. Read the result at 15 minutes. Do not read the result after 20 minutes.

10. INTERPRETATION OF RESULTS

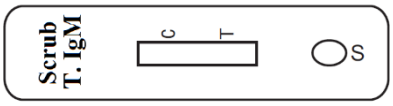
Negative: Only one colored line appears at the control line 'C' only



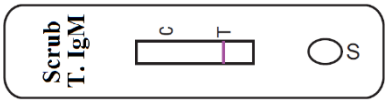
Positive: A distinct colored line appears at the control region 'C' and at the test line 'T'.

Invalid: The test should be considered invalid if,

A) no line appears at 'C' & 'T'



B) No line appears at 'C' and line appears at 'T'



NOTE: The intensity of the color of test lines will vary depending upon the levels of antibodies present in specimen.

11. LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.

12. 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 Rickettsial Infections. 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.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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