Quality approved by SD BIOSENSOR / For *In vitro* use only

STANDARD F
Tsutsugamushi IgM/IgG FIA

REF F-TSU-01

STANDARD™ F Tsutsugamushi IgM/IgG FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

EXPLANATION AND SUMMARY

[Introduction]

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. Most cases of scrub typhus occur in rural areas of Southeast Asia, Indonesia, China, Japan, India, and northern Australia. Anyone living in or traveling to areas where scrub typhus is found could get infected.

The distribution of *O. tsutsugamushi* extends north to Japan, Russia, and the Primorske Karai region in the Russian Far East, south to northern Australia and the western Pacific islands, and west to Afghanistan, Pakistan, and areas bordering the Central Asian Republics. Human *O. tsutsugamushi* occurs widely in these regions, but not everywhere. Scrub typhus is probably one of the most underdiagnosed and underreported febrile illnesses requiring hospitalization in the region. The absence of definitive signs and symptoms combined with a general dependence upon serological tests make the differentiation of scrub typhus from other common febrile diseases such as murine typhus, typhoid fever and leptospirosis quite difficult.

[Intended use]

STANDARD F Tsutsugamushi IgM/IgG Test is a fluorescent immunoassay for the detection of IgM/IgG antibodies against *Orientia tsutsugamushi* in human serum, plasma, or whole blood samples. This test kit is for *in vitro* use only. This is intended for professional use only for an initial screening test. Test results of this kit have to be analyzed with appropriate analyzer, STANDARD F, manufactured by SD BIOSENSOR.

[Test principle]

STANDARD F Tsutsugamushi IgM/IgG Test Kit has “M”, “G” test lines and “C” control line. Monoclonal anti-human IgM and monoclonal anti-human IgG are immobilized at two individual test lines respectively (M, G line) on the nitrocellulose membrane. The IgM line in the result window is closer to the sample well and followed by IgG line. Orientia tsutsugamushi recombinant antigen-Europium in the conjugate pad release by adding assay diluent and react with anti-tsutsugamushi IgM or IgG in patient sample. If human anti-tsutsugamushi IgM or IgG exist in patient serum, complexes with anti-human IgM/IgG on the test lines, human IgM/IgG in patient sample, inactivated *Orientia tsutsugamushi* in the antigen pad, and europium conjugated antibodies in the conjugation pad make fluorescence signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the analyte in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]

① Test Device ② Assay diluent ③ STANDARD™ Ezi Tube+ (10μl) ④ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer

KIT STORAGE AND STABILITY

Store the kit at 2-30°C/36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use assay diluent of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
11. The barcode of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
12. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
13. Improper specimen collection, handling or transport may yield inaccurate results.
14. Do not write on the bar code or damage the bar code of the test device.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA or sodium citrate, by venipuncture and leave to settle for 30 minutes for blood coagulation and then centifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen of supernatant.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Whole blood]

- **Capillary whole blood**

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Collect the capillary whole blood to the black line of the Sample collector for the testing.
5. The capillary whole blood must be tested immediately after collection.

- **Venous Whole blood**

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood samples.

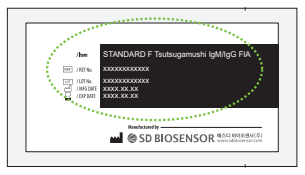
CAUTION

- Anticoagulants such as heparin, EDTA or sodim citrate do not affect the test result.
- As known relevant interference, hemolytic sample, rheumatoid factors-contained sample and lipaemic, icteric sample can lead to impair the test results.
- Use separate disposable materials for each sample in order to avoid cross-contamination which can cause erroneous results.

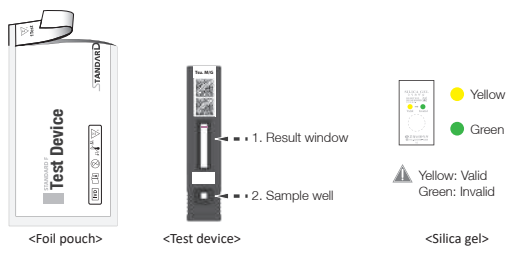
TEST PROCEDURE

[Preparation]

1. Allow kit components and collected sample to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Carefully read instructions for using the STANDARD F Tsutsugamushi IgM/IgG FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



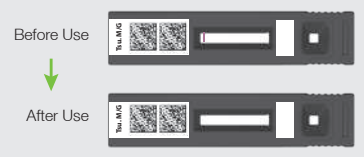
4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.



<Foil pouch> <Test device> <Silica gel>

CAUTION

- If there is no violet colored Check Band on the membrane of the test device, do not use it.



CAUTION

- Do not write on the bar code or damage the bar code of the test device.

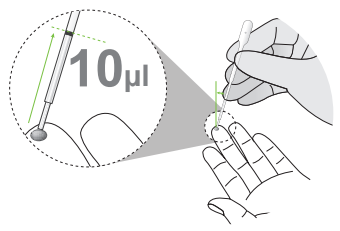
[Analysis of sample]

- **Using a ‘STANDARD TEST’ mode**

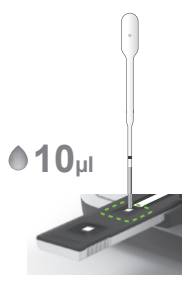
- **Applying STANDARD F100, F200, or F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the ‘Standard Test’ mode according to the analyzer’s manual. In case of STANDARD F2400 analyzer, go to the ‘Workplace’ in the main screen. And select the ‘Run Test’
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.
4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

5. Collect the 10μl of serum/plasma/whole blood to the black line of the STANDARD Ezi Tube+.



6. Add the collected serum/plasma/whole blood to the sample well of the test device.



7. Add 3 drops of assay diluent into the assay diluent well of the test device.

8. After applying the sample, immediately press the **‘TEST START’** button.

<F100> <F200> <F2400>

9. The analyzer will automatically display the test result within 15 minutes.

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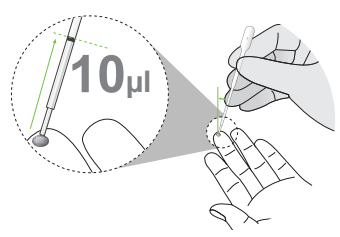
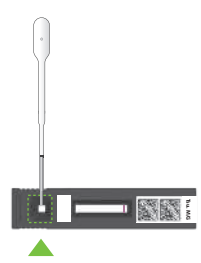
- **Using a 'READ ONLY' mode**

- **Applying STANDARD F100 or F200 analyzer**

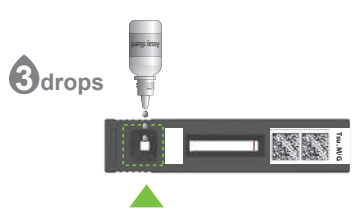
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a sample information on the label of test device.
2. Collect the 10µl of serum/plasma/whole blood to the black line of the STANDARD Ezi Tube+.



3. Add the collected serum/plasma/whole blood to the sample well of the test device.



4. Add 3 drops of assay diluent into the assay diluent well of the test device.



5. Incubate the test device for 15 minutes outside of the analyzer. Incubation must not be more than 20 minutes.

6. Prepare the STANDARD F analyzer and set the 'READ ONLY' mode following the instructions in the manual.

7. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive for Tsutsugamushi IgM/IgG
Negative	COI < 1.0	Negative for Tsutsugamushi IgM/IgG
Invalid	Do not display COI value	Retest should be performed

CAUTION

Results should be considered in conjunction with the clinical history and other data available to the physician.

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. Cut-off index (COI) is based on the ratio of assay signal to cut-off value.

QUALITY CONTROL

[Internal quality control]

1. The internal procedural control zone is on the membrane of the test device. STANDARD F analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F analyzers. shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

LIMITATION OF TEST

1. The test should be used for the detection of anti- Tsutsugamushi IgM/IgG in human serum, plasma or whole blood specimens.
2. Neither the quantitative value nor the rate of anti- Tsutsugamushi IgM/IgG concentration can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A negative test result may occur if the level of extracted antibody in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

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2. Silpasakorn, Saowaluk et al. "Development of New, Broadly Reactive, Rapid IgG and IgM Lateral Flow Assays for Diagnosis of Scrub Typhus." The American Journal of Tropical Medicine and Hygiene 87.1 (2012): 148–152. PMC.
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4. Blacksell SD, Jenjaroen K, Phetsouvanh R, Wuthiekanun V, Day NP, Newton PN, Ching WM. Accuracy of AccessBio Immunoglobulin M and Total Antibody Rapid Immunochromatographic Assays for the Diagnosis of Acute Scrub Typhus Infection. Clin Vaccine Immunol. 2010;17(2):263–6.
5. WHO Recommended Surveillance Standards, Second edition, World Health Organization.

Product Disclaimer
Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning
The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

CE IVD

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IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
Indicate that you should keep the product dry
Keep away from sunlight
Do not use if packaging is damaged