

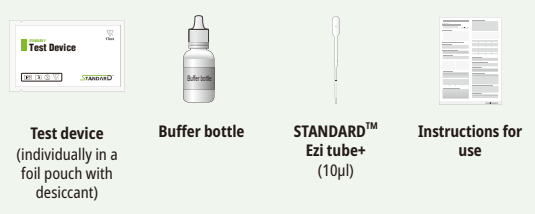
STANDARD F

Tsutsugamushi IgM/IgG FIA

STANDARD™ F Tsutsugamushi IgM/IgG FIA
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU
PERFORM THE TEST



KIT CONTENTS



MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD F Analyzer

SPECIMEN COLLECTION AND PREPARATION

Serum

- 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 centrifuge blood to get serum specimen of supernatant.
- 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 4 days after collection. For prolonged storage, it should be at below -40°C / -40°F.
- They should be brought to room temperature prior to use.

Plasma

- 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.
- 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.
- They should be brought to room temperature prior to use.

Whole blood

[Capillary whole blood]

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

[Venous Whole blood]

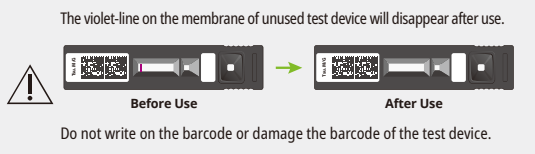
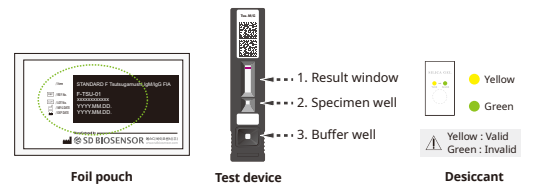
- Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin or EDTA by venipuncture.
- If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 3days after collection.
- Do not use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

- 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

- Allow kit components and collected specimen to room temperature at least 30 minutes before starting the test.
- Carefully read instructions for using the STANDARD F Tsutsugamushi IgM/IgG FIA.
- Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
- Open the foil pouch and check the test device in the foil pouch.



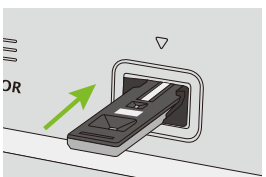
Analysis of specimen

STANDARD TEST mode STANDARD F200 and F2400 Analyzer

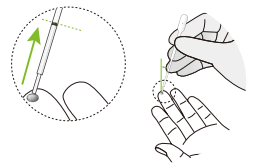
- Prepare a STANDARD F Analyzer and take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device. Select the 'STANDARD TEST' mode according to the analyzer's manual as below.

STANDARD F2400 analyzer	'Workplace' → 'Run Test' → Insert patient ID and / or operator ID on the analyzer
STANDARD F200 analyzer	'STANDARD TEST' mode → Insert patient ID and/or operator ID

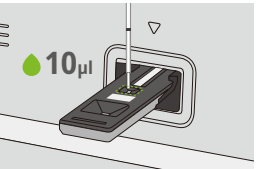
- Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.



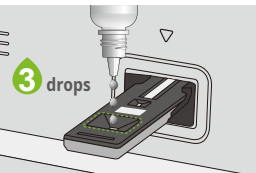
- Collect the 10 µl of serum/plasma/ whole blood to the black line of a the STANDARD Ezi Tube+.



- Add the collected serum/plasma/ whole blood to the specimen well of the test device.



- Add 3 drops of buffer bottle into the buffer bottle well of the test device.



- After applying the sample, immediately press the TEST START button.



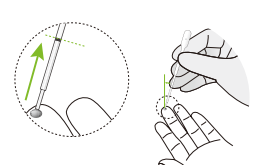
- The analyzer will automatically display the test result after 15 minutes.



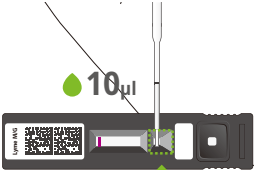
'READ ONLY' mode STANDARD F200 Analyzer

- Take the test device out of the foil pouch and place it on a flat and dry surface. Write a specimen information on the label of test device.

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



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



- Add 3 drops of buffer bottle into the buffer bottle well of the test device.

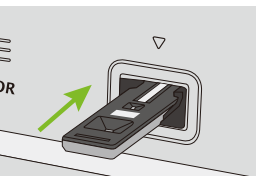


- Incubate the test device for 15 minutes outside of the analyzer. Incubation must not be more than 20 minutes.



- Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual.

- 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
	Tsutsugamushi IgM	Tsutsugamushi IgG	
Positive	COI ≥ 1.0	COI < 1.0	Positive for Tsutsugamushi IgM
Positive	COI < 1.0	COI ≥ 1.0	Positive for Tsutsugamushi IgG
Positive	COI ≥ 1.0	COI ≥ 1.0	Positive for Tsutsugamushi IgM/IgG
Negative	COI < 1.0	COI < 1.0	Negative for Tsutsugamushi IgM/IgG
Invalid	COI value is not displayed		Retest should be performed

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

The analyzer's 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 procedural control

- 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.
- The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F Analyzer shows 'Invalid Device', turn off and turn on of the analyzer again and re-test with a new test device.

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 detect 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 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

- Do not re-use the test kit.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not use assay diluent of another lot.
- Do not smoke, drink or eat while handling specimen.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing procedures.
- 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.
- Desiccant 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.
- 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.
- As the detection reagent is a fluorescent compound, no visible results will form on the test device.
- Improper specimen collection, handling or transport may yield inaccurate results.
- Do not write on the barcode or damage the barcode of the test device.

LIMITATION OF TEST

- The test should be used for the detection of anti-Tsutsugamushi IgM/IgG in human serum, plasma or whole blood specimens.
- Neither the quantitative value nor the rate of anti-Tsutsugamushi IgM/IgG concentration can be determined by this qualitative test.
- Failure to follow the test procedure or improper specimen collection may adversely affect test performance or invalidate the test result.
- A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test or if the specimen was collected, transported, or stored improperly.
- For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
- The test result must always be evaluated with other data available to the physician.

SYMBOL

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

EC REP

Authorized Representative

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