EN REF F-LYM-01

STANDARD F

Lyme IgM/IgG FIA

STANDARD™ F Lyme IgM/IgG FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Test Device
(individually in a foil pouch with desiccant)

Buffer bottle

STANDARD™ Ezi tube+
(10µl)

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD F Analyzer

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 4 days after collection. 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 or EDTA 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 4 days after collection. 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 is recommended by puncturing the side of the finger, rather than the finger-pad. This is because it is less painful and still yields satisfactory whole blood specimens.
2. Clean the area to be lanced with an alcohol swab.
3. Pierce with a sterile lancet. The finger should NOT be squeezed. The finger should be gently rubbed warm, to stimulate the blood circulation.
4. Collect the capillary whole blood to the black line of the STANDARD Ezi tube+ (10µl) for the testing.
5. The capillary whole blood must be tested immediately after collection.

[Venous whole blood]

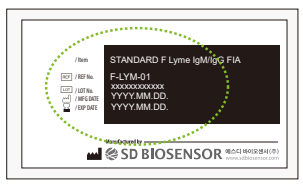
1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin or EDTA by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 3days after collection.
3. Do not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

⚠
- As known relevant interference, hemolytic specimen, rheumatoid factors-contained specimen and lipaemic, icteric specimen can lead to impair the test results.
- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

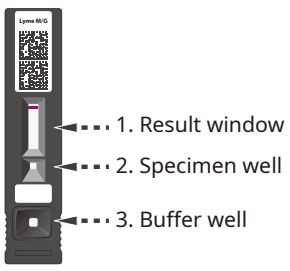
TEST PROCEDURE

■ Preparation

1. Allow kit components and collected specimen 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 Lyme 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 in the foil pouch.



Foil pouch



Test device

Desiccant

The violet-line on the membrane of unused test device will disappear after use.

Before Use **After Use**

Do not write on the barcode or damage the barcode of the test device.

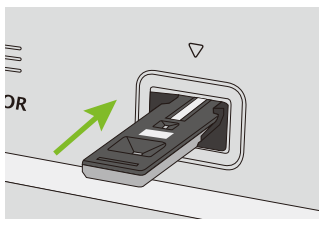
■ Analysis of specimen

'STANDARD TEST' mode — **STANDARD F200 and F2400 Analyzer**

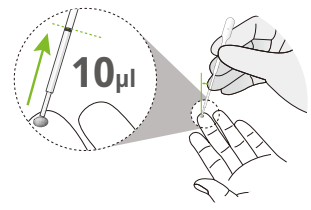
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device.

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

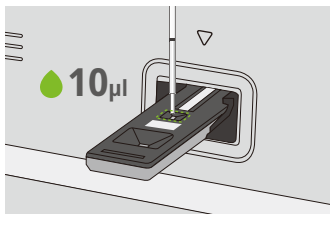
2. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.



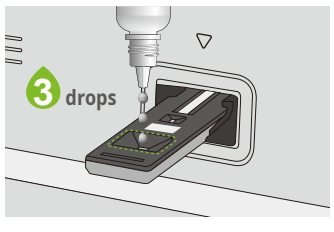
3. Collect the 10µl of serum/plasma/whole blood to the black line of a the STANDARD Ezi Tube+.



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



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



6. After applying the specimen, immediately press the '**TEST START**' button.

F200 **F2400**

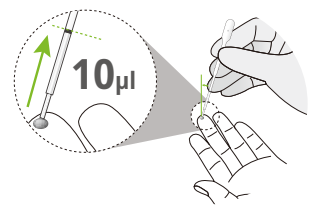
7. The analyzer will automatically display the test result after 15 minutes.

Incubate
For 15 mins

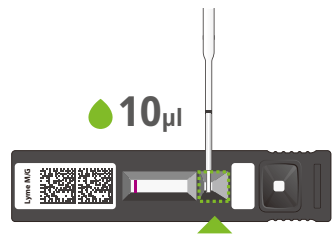
'READ ONLY' mode — **STANDARD F200 and F2400 Analyzer**

1. 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.

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



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



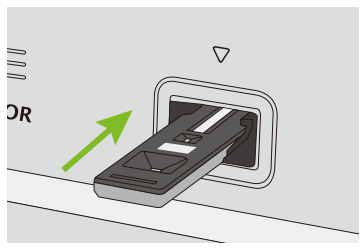
4. Add 3 drops of buffer bottle into the buffer bottle well of the test device.

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

Incubate
For 15 mins

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



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INTERPRETATION OF TEST RESULTS

COI (Cutoff index) value	Result	Interpretation
IgM: COI ≥ 1.0, IgG: COI ≥ 1.0	IgM: Positive IgG: Positive	Presumptive detection of anti-*B. burgdorferi* IgM & IgG antibodies.
IgM: COI ≥ 1.0, IgG: COI < 1.0	IgM: Positive IgG: Negative	Presumptive detection of anti-*B. burgdorferi* IgM antibodies.
IgM: COI < 1.0, IgG: COI ≥ 1.0	IgM: Negative IgG: Positive	Presumptive detection of anti-*B. burgdorferi* IgG antibodies.
IgM: COI < 1.0, IgG: COI < 1.0	IgM: Negative IgG: Negative	No detectable anti-*B. burgdorferi* IgM antibodies detected.
N/A	Invalid	Retest should be performed.

The analyzer's test result of a specimen 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

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 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

Lyme disease is caused by bacteria, Borrelia burgdorferi that are transmitted to humans through a bite from an infected black-legged or deer tick. It's usually easier to treat if it's diagnosed early. Early antibiotic treatment of Lyme disease can resolve clinical symptoms and prevent progression of the disease to later stages. Lyme disease causes more than 300,000 illnesses each year in the United States. It is the most commonly occurring vector-borne disease and the sixth most commonly reported notifiable infectious disease. Lyme disease can produce a wide range of symptoms, including fever, rash, facial paralysis, and arthritis. The humoral immune response to Borrelia burgdorferi has been well characterized and involves the production of both IgM and IgG antibodies. As a result, assessing the presence of IgM and IgG antibodies may offer information on the disease progression. Furthermore, simultaneous use of assays for IgM antibodies only or IgG antibodies only may provide specific information for the clinician allowing better patient management.

■ Intended use

STANDARD F Lyme IgM/IgG FIA is a fluorescent immunoassay for the detection of IgM/IgG antibodies against Borrelia burgdorferi in human serum, plasma, or whole blood specimens. 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 Lyme IgM/IgG FIA has "M", "G" test lines and "C" control line. Monoclonal anti-human IgM and monoclonal antihuman IgG are immobilized at two individual test lines respectively (M, G line) on the nitrocellulose membrane. Inactivated borrelia in the antigen pad and europium conjugated antigens (OspC(outer surface protein C) and VlsE (Variable like sequence expressed) in the conjugation pad release by adding buffer bottles and react with human anti-Lyme IgM or IgG in patient specimen. If Human anti-Lyme IgM or IgG exist in patient serum, complexes with anti-human IgM/IgG on the test lines. 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 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. Use the STANDARD F Lyme IgM/IgG FIA at 15-32°C / 59-90°F and 10-90% RH.
3. Do not use the kit if the pouch is damaged or the seal is broken.
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 after you experiment.
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 biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. 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.
11. Immediately use the test device after taking out of a foil pouch.
12. As the detection reagent is a fluorescent compound, no visible results will form on the test device. The STANDARD F Analyzers authorized by SD BIOSENSOR must be used for result interpretation.
13. Improper specimen collection, handling or transport may yield inaccurate results.
14. Do not write on the barcode or damage the barcode of the test device.

BIBLIOGRAPHY

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2. BARBOUR A. Laboratory aspects of Lyme Borreliosis. Clinical microbiology reviews. 1988, 1:399-414. 4.
3. DESSAU R. Simultaneous use of serum IgG and IgM for risk Scoring of suspected early Lyme borreliosis: Graphical and bivariate Analyses. APMIS.2010, 118: 313-323
4. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Vector-Borne Diseases (DVBD),CDC, December 21, 2018

CE IVD

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