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

STANDARD F

Dengue IgM/IgG FIA

STANDARD™ F Dengue IgM/IgG FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]

Dengue viruses, transmitted by Aedes aegypti and Aedes albopictus mosquitoes, are widely distributed throughout the tropical and subtropical areas of the world. There are four known distinct serotypes of dengue virus (DEN-1, DEN-2, DEN-3 and DEN-4). Rapid and reliable tests for primary and secondary infections of Dengue are essential for patient management. An infected person experiences the acute symptoms of Dengue when there is a high level of the virus in the bloodstream. As the immune response fights the Dengue infection, the person's B cells begin producing IgMs and IgGs antibodies that are released in the blood and lymph fluid, where they recognize and neutralize the Dengue virus and viral molecules such as the Dengue non-structural protein 1 (NS1) antigen.

[Intended use]

STANDARD F Dengue IgM/IgG FIA is a fluorescence immunoassay for the detection of IgM/IgG antibodies against Dengue virus 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 analyze with appropriate analyzer, STANDARD F Analyzer, manufactured by SD BIOSENSOR.

[Test principle]

STANDARD F Dengue IgM/IgG FIA 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. Inactivated Dengue virus in the antigen pad and europium conjugated antibodies (monoclonal anti-Dengue Env-Ep and monoclonal anti-Dengue NS1-Ep) in the conjugation pad release by adding assay diluents and react with anti-Dengue IgM or IgG in patient sample. If human anti-Dengue IgM or IgG exist in patient serum, complexes with anti-human IgM/IgG on the test lines, human IgM/IgG in patient sample, inactivated Dengue virusin 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 Sample collector [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. Use the STANDARD F Dengue 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 bar code 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 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 Dengue 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

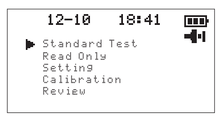
- Do not write on the bar code or damage the bar code of the test device.

[Analysis of sample]

- **Using a STANDARD F100 Analyzer**

- **'Standard Test' mode**

1. Prepare a STANDARD F100 Analyzer and set the 'Standard Test' mode according to the analyzer's manual.



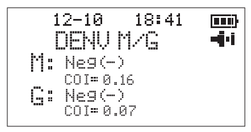
2. Take the test device out of the foil pouch.
3. Insert the test device to the Test Slot of the analyzer. The analyzer automatically reads the information of the bar code on the test device and releases the test device for adding sample.

4. Collect the 10μl of serum/plasma/whole blood to the black line of a sample collector.
5. Add the collected serum/plasma/whole blood to the sample well of the test device.

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

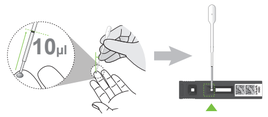
7. After applying the sample, immediately press the center button to start the test.

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

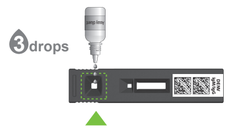


- **'Read Only' mode**

1. Take the test device out of the foil pouch and place it on a flat and dry surface.
2. Collect the 10μl of serum/plasma/whole blood to the black line of a sample collector.
3. Add the collected serum/plasma/whole blood to the sample well of the test device.

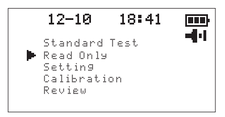


4. Add 3 drops of assay diluent into the assay diluent well of the test device.



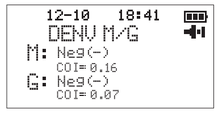
5. Leave the test device for 15 minutes. Notice that the test device should not leave for 20 more minutes.

6. Prepare a STANDARD F100 Analyzer and set the 'Read Only' mode according to the analyzers' manual.



7. Insert the test device to the Test Slot of the analyzer.

8. The analyzer will automatically display the test result.



- **Using a STANDARD F200 Analyzer**

- **'Standard Test' mode**

1. Prepare a STANDARD F200 Analyzer and select the `Standard Test' mode on the analyzer's screen.

2. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.
3. Take the test device out of the foil pouch.

4. Once the 'Insert Device' is displayed in the screen, insert the test device into the Test Slot of the analyzer.

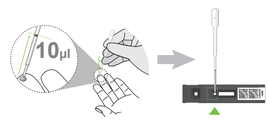
5. When inserting the test device to the analyzer, the analyzer automatically reads the information of bar code on the test device and releases the test device for adding sample.

6. Collect the 10μl of serum/plasma/whole blood to the black line of an Ezi tube+ and add the collected sample 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 start button.**

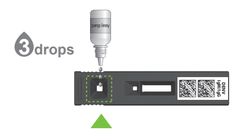
9. The analyzer will automatically display the test result after 15 minutes.

- **'Read only' mode**

1. Take the test device out of the foil pouch and place it on a flat and dry surface.
2. Collect the 10μl of serum/plasma/whole blood to the black line of a sample collector.
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. Leave the test device for 15 minutes. Notice that the test device should not leave for 20 more minutes.

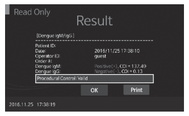
6. Prepare a STANDARD F200 Analyzer and select the 'Read Only' on the analyzer's screen.

7. Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.

8. Once the 'Insert Device' is displayed in the screen, insert the test device to the Test Slot of the analyzer.

9. When inserting the test device to the analyzer, the analyzer automatically reads the information of bar code on the test device.

10. The analyzer will automatically display the test result.



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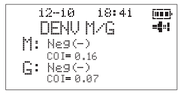
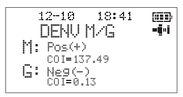
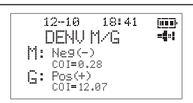
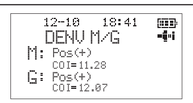
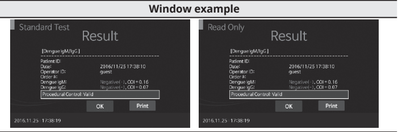
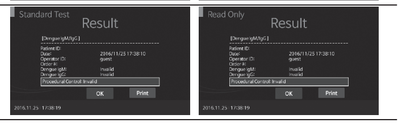
INTERPRETATION OF TEST RESULTS

[Displays of STANDARD F100 Analyzer]

Test result		Window example
Negative		
Positive	Dengue IgM positive	
	Dengue IgG positive	
	Dengue IgM/ IgG positive	
Invalid		

[Displays of STANDARD F200 Analyzer]

Test result		Window example
Negative		
Positive	Dengue IgM positive	
	Dengue IgG positive	
	Dengue IgM/ IgG positive	
Invalid		

CAUTION

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

CAUTION

The analyzer's test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. COI is calculated that a measured signal is divided by an appropriate cutoff value.
- Test results of a COI ≥ 1.00 are considered positive for Dengue IgM/IgG antibody.
- Test results of a COI < 1.00 are considered negative for Dengue IgM/IgG antibody.

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.

LIMITATION OF TEST

1. The contents of this kit are to be used the qualitative detection of anti-Dengue IgM/IgG from blood specimens of the symptomatic patients.
2. Failure to follow the test procedure or improper sample collection may adversely affect test performance or invalidate the test result.
3. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
4. A negative test result may occur if the level of antibody in a sample is below the detection limit of the test or if the sample was collected, transported, or stored improperly.
5. Negative test results do not rule out possible other infections.
6. Positive test results do not rule out co-infection with other pathogens.

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6. Guzman M. G. et al. Dengue: A continuing global threat, Nat Rev Microbiol, 8:S7 -S16, 2010.

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 REF FDEN01B

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L28DEN2ENR1
Issue date : 2017.11