EN | REF FDEN01B

STANDARD F

Dengue IgM/IgG FIA

STANDARD™ F Dengue 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)	Assay diluent	STANDARD™ Ezi tube+ (10 µl)	Instuctions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD F Analyzer
- Timer

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 centrifuge 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. It 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. It 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 disposable dropper 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 specimens.

- Anticoagulants such as heparin, EDTA or sodim citrate do not affect the test result.
- 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 at least 30 minutes before starting the test.
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 desiccant in the foil pouch.

Foil pouch

Test device

Desiccant

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. Prepare a STANDARD F Analyzer. 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' → Scan or type patient ID and/or operator ID
STANDARD F200 Analyzer	'Standard Test' mode → Insert patient ID and / or operator ID on the analyzer

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 10 µl 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 assay diluent to the assay diluent well of the test device.

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

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

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

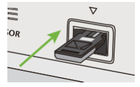
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a specimen information on the label of test device.
2. Collect the 10 µl of serum/plasma/whole blood to the black line of a the STANDARD Ezi Tube+.

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

4. Add 3 drops of 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 Dengue IgM/IgG antibody
Negative	COI < 1.0	Negative for Dengue IgM/IgG antibody
Invalid	Not show the COI value	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 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.

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 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 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 specimen. 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 specimen, 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 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 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.

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 specimen 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 specimen is below the detection limit of the test or if the specimen 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.

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. Theinvalidresultdenotesthatthefluorescencesignalisnotwithinthepre-setrange.Ifthescreenof STANDARD FAnalyzershows'Invalid Device', turnoffandturnonoftheanalyzeragainandre-testwithanewtestdevice.

PERFORMACE CHARACTERISTICS

CLINICAL PERFORMANCE

43 of Dengue IgM/IgG positive confi rmed specimens and 184 of Dengue IgM/IgG negative confi rmed specimens were tested internally. For **STANDARD™ F Dengue IgM/IgG FIA**, the result shows the 98.0%(42/43) sensitivity and 183/184 (99%) specifi city for plasma specimen.

1. Clinical Sensitivity

Dengue IgM/IgG		Reference test (ELISA)		
		POS	NEG	TOTAL
STANDARD™ F Dengue IgM/IgG FIA	POS	42	0	42
	NEG	1	0	1
	TOTAL	43	0	43
Sensibilidad: 42/43 (98%)				

2. Clinical Specificity

Dengue IgM/IgG		Reference test (ELISA)		
		POS	NEG	TOTAL
STANDARD™ F Dengue IgM/IgG Test	POS	0	1	1
	NEG	0	183	183
	TOTAL	0	184	184
Especificidad: 183/184 (99%)				

ANALYTICAL PERFORMANCE

1. Analytical Sensitivity (Limit of Detection)

The analytical sensitivity [Limit of Detection (LoD)] of **STANDARD™ F Dengue IgM/IgG FIA** are shown below;

STANDARD™ F Dengue IgM/IgG FIA	
Antibody	**Limit of Detection(ug/mL)**
Dengue IgM	**2.0**
Dengue IgG	**3.9**

2. Cross Reactivity

STANDARD™ F Dengue IgM/IgG FIA does not be aff ected by those potential cross-reactive microorganisms and viruses below;

No.	Type	Potential Cross-reacting Microorganism/Virus	Concentration
1	Bacteria	Acinetobacter baumannii	2.0x10⁸ cfu/mL
2		Bacteriodes fragilis	
3		Bordetella pertussis	
4		Candida albicans	
5		Chlamydia pneumoniae	
6		Escherichia coli	
7		Fusobacterium nucleatum	
8		Haemophilus influenzae	
9		Kingella kingae	
10		Klebsiella pneumoniae	
11		Lactobacillus plantarum	
12		Legionella pneumophila	
13		Moraxella catarrhalis	
14		Mycobacterium avium	
15		Mycobacterium tuberculosis	
16		Mycoplasma pneumoniae	
17		Neisseria gonorrhoeae	
18		Neisseria meningitides	
19		Neisseria mucosa	
20		Neisseria sicca	
21		Peptostreptococcus anaerobius	
22		Prevotella oralis	
23		Propionibacterium acnes	
24		Proteus mirabilis	
25		Pseudomanas aeruginosa	
26		Serratia marcescens	
27		Staphylococcus aureus	
28		Staphylococcus epidermidis	
29		Streptococcus mutans	
30		Streptococcus pneumoniae	
31		Streptococcus pyogenes	
32		Streptococcus salivarius	
33		Streptococcus sanguis	
34		Veillonella parvula	
35	Viruses	Adenovirus 3	2.0x10⁵ TCID₅₀/mL
36		Adenovirus 4	
37		Adenovirus 5	
38		Adenovirus 11	
39		Coranavirus 229E	
40		Coranavirus OC43	
41		Cytomegalovirus AD-169	
42		Cytomegalovirus Towne	
43		Echovirus Type 3	
44		Enterovirus	
45		Herpes Simplex virus 1	
46		Herpes Simplex virus 2	
47		HSV Type 1	
48		Human Coronavirus OC43	
49		Human Metapneumovirus A1	
50		Human Metapneumovirus A2	
51		Human Metapneumovirus B1	
52		Human Metapneumovirus B2	
53		Human Parainfluenza	
54		Influenza A H1N1 (Denver/1/57)	
55		Influenza A H1N1 (FM/1/47)	
56		Influenza A H1N1 (Mexico/4108/2009)	
57		Influenza A H1N1 (New Jersey/8/76)	
58		Influenza A H1N1 (PR/8/34)	
59		Influenza A H3N2	
60		Influenza B Hong Kong	
61		Influenza B Panama	
62		Influenza C Taylor	
63		Measles virus	
64		Mumps virus	
65		Parainfluenza virus 1	
66		Parainfluenza virus 2	
67		Parainfluenza virus 3	
68		Parainfluenza virus 4A	
69		Parainfluenza virus 4B	
70		Rhinovirus Type 2	
71		Rhinovirus Type 3	
72		Rhinovirus Type 7	
73		Rhinovirus Type 15	
74		Rhinovirus Type 18	

3. Interference Substances

The following substances do not interfere the test result up to the indicated concentrations;

No.	Interfering Substances	Concentration
1	Acetamidophenol	20 mg/mL
2	Acetylsalicylic acid	20 mg/mL
3	Albuterol	20 mg/mL
4	Beclomethasone	10 ug/mL
5	Bilirubin	200 ug/mL
6	Budesonide	10 ug/mL
7	Chlorpheniramine	5 mg/mL
8	Dextromethorphan	10 mg/mL
9	Diphenhydramine	4 mg/mL
10	Flunisolide	500 ng/mL
11	Fluticasone	500 ng/mL
12	Guaiacol	30 mg/mL
13	Hemoglobin	10 mg/mL
14	Homeopathic Allergy Medicine	20 mg/mL
15	Ibuprofen	20 mg/mL
16	Mucin	10 mg/mL
17	Oxymetazoline	0.05 mg/mL
18	Phenylephrine	10 mg/mL
19	Ribavirin	1 ug/mL
20	Rimantadine	500 ng/mL
21	Synagis	4 µg/mL
22	Tobramycin	500 ng/mL
23	Triamcinolone	500 ng/mL
24	Triglyceride	9 ng/mL

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4. Ludolfs D. et al., Serological differentiation of infections with dengue virus serotypes 1 to 4 by using recombinant antigens, J Clin Microbiol, 40(11):4317-4320, 2002.
5. Matthew T. R. et al. Dengue virus pirates human platelets, Blood, 126(3):286-287, 2015.
6. Guzman M. G. et al. Dengue: A continuing global threat, Nat Rev Microbiol, 8:S7 -S16, 2010.

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		

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CE IVD

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