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

STANDARD F

Zika IgM FIA

STANDARD™ F Zika IgM FIA

REF FZKA02B

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

EXPLANATION AND SUMMARY

[Introduction]

Zika virus is a single-stranded RNA virus of the flaviviridae family, genus flavivirus. It is transmitted to humans primarily through the bite of certain infected mosquitoes, mainly Aedes aegypti in tropical and sub-tropical regions. The disease usually causes mild febrile symptoms with maculo-papular rash lasting for several days to a week and then can be cured completely. However, there is now growing concern following reports from several countries including Brazil that Zika virus infection may be linked to fetal and newborn microcephaly and serious neurological complications, such as Guillain-Barré syndrome. Moreover, Zika virus disease is currently considered as an emerging infectious disease around the world. Prior to 2015, there had been no outbreaks of Zika outside of Africa, Asia and the Pacific Islands. But now, it is sweeping through Latin America infecting thousands. This prompted the World Health Organization to declare a Public Health Emergency of International Concern (PHEIC) in 2016. To date, there is no prophylaxis, treatment or vaccine to control and to protect against its infection. Therefore, great efforts to establish best practice to detect it promptly are required in order to treat in time and to prevent further spread and recurrence of the infection. STANDARD F Zika IgM FIA, using immunofluorescent assay with STANDARD F analyzer, provides significantly fast, easy and accurate test result to identify the Zika IgM antibody from human serum, plasma or whole blood specimens. The test may aid in the reliable clinical diagnosis of Zika virus infection and enables supportive treatment decisions.

[Intended use]

STANDARD F Zika IgM FIA uses the fluorescence immunoassay to detect specific Zika IgM present in human serum, plasma or whole blood specimens from patients with symptoms of Zika virus infection. This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of Zika virus infection. It provides only an initial screening test result. Alternative diagnosis methods recommended by the WHO, CDC algorithm or laboratory testing from the regulatory authorities should be performed in order to obtain the final confirmation.

[Test principle]

When patient's specimen is applied into the sample well of the test device, the specimen migrates through the membrane with the added assay diluant. If Zika IgM antibody is present in the sample, it will be conjugated with inactivated Zika virus antigen and europium fluorescent microparticle on the conjugation pad. The formed antibody complex will migrate through the membrane to the test line where the complex will be immobilized. The STANDARD F Analyzer will scan the intensity of the fluorescent light generated from the test line to detect the Zika IgM antibodies in the sample. It will process the measured fluorescent light signal using pre-programmed algorithms then display the test result on the screen. If Zika IgM antibody is not present in the sample, there will be no conjugation of antibody complex so that test line does not capture any antibody complex.

[Kit contents]

① Test Device ② Assay diluent ③ Sample collector [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. Use the STANDARD F Zika IgM FIA at 15-32°C / 59-90°F and 10-90%RH.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all specimens as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. 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.
11. 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.
12. 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.
13. As the detection reagent is a fluorescent compound, no visible results will form on the test device.
14. Improper specimen collection, handling or transport may yield inaccurate results.
15. 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

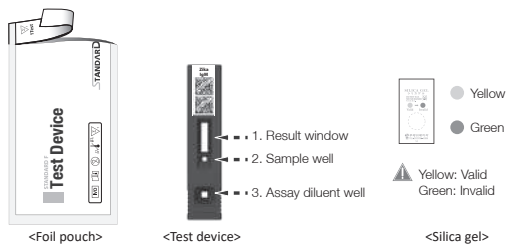
- Anticoagulants such as heparin, EDTA or sodim citrate do not affect the test result.
- As known relevant interference, hemolytic sample, rheumatoid factors-contained sample and lipaemic, icteric sample can lead to impair the test results.
- Use separate disposable materials for each sample in order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

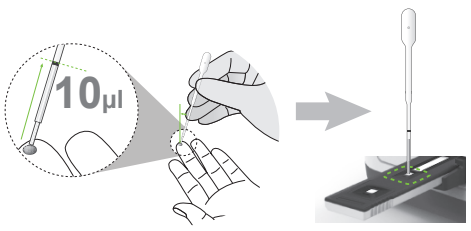
- Do not write on the bar code or damage the bar code of the test device.

[Analysis of sample]

- **Using a 'STANDARD TEST' mode**
  - **Applied STANDARD F100, F200 and 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. Using a sample collector, collect the 10μl of serum, plasma or whole blood to the black line of the sample collector. Add the collected sample to the sample well of the test device.



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

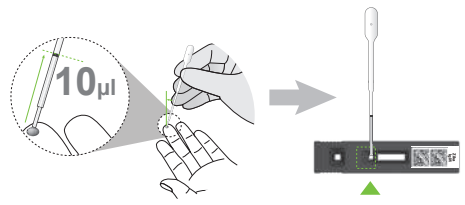
7. After applying the sample, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

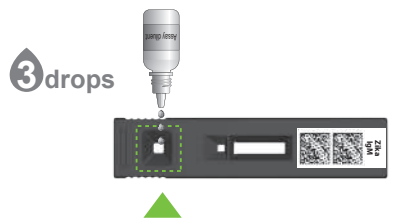
8. The analyzer will automatically display the test result within 15 minutes.

- **Using a 'READ ONLY' mode**
  - **Applied STANDARD F100 and 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. Using a sample collector, collect the 10μl of serum, plasma or whole blood to the black line of the sample collector. Add the collected sample to the sample well of the test device.



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



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

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

6. Insert the test device to the test slot of the analyzer.

7. 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 ≥ 1.00	Positive for Zika IgM antibody
Negative	COI < 1.00	Negative for Zika IgM antibody
Invalid	Not show the COI value	Retest should be performed

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI(cutoff index) value.
- Test result of a COI ≥ 1.0 is considered as positive
- Test result of a COI < 1.0 is considered as negative

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 STANDARD F analyzers show '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-Zika IgM in human serum, plasma or whole blood specimens.
2. Neither the quantitative value nor the rate of anti-Zika IgM 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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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