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

STANDARD F

Zika Ag FIA

STANDARD™ F Zika Ag FIA

REF FZKA01G

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™

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 from the Aedes mosquitoes, mainly Aedes aegypti in tropical and sub-tropical region. 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 the 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 protect against its infection. Therefore, great efforts to establish best practice to be recognized it promptly are required in order to treat in time and to prevent further spread and recurrence of the infection. STANDARD F Zika Ag FIA, employing immunofluorescent detection system with STANDARD F analyzer, provides significantly fast, easy and accurate system to identify the Zika antigen 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 Ag FIA is the fluorescence immunoassay to detect specific Zika antigen 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 algorithm, the CDC guideline or laboratory testing from the regulatory authorities should be performed in order to obtain the final confirmation.

[Test principle]

When a patient specimen is applied into the sample well of the test device, the specimen migrates through the membrane from the sample well. If Zika antigen is present, it will be bound to by detector coupled to europium microparticle that migrates through the membrane. The europium microparticle complex will be captured by capture antibody on the test line where it is detected by STANDARD F analyzer. If Zika antigen is not present, the europium microparticle will not be trapped by the capture antibody nor detected by STANDARD F Analyzer. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer. STANDARD F Analyzer can analyze the presence of the Zika antigen 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 Disposable dropper (100µl) ③ Assay diluent ④ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

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 Ag 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-coagulant 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 whole blood into the commercially available anti-coagulant tube such as heparin, EDTA or sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
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 samples.

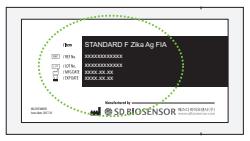
CAUTION

- Anticoagulants such as heparin, EDTA or sodium citrate do not affect the test result.
- As known relevant interference, haemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples 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.

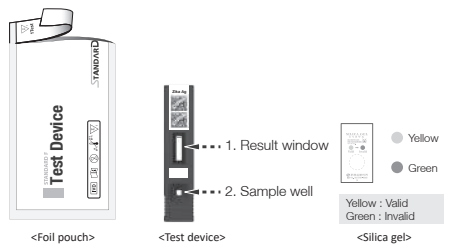
TEST PROCEDURE

[Preparation]

1. Allow kit components and collected sample to room temperature (15-30°C/59-86°F) a minimum of 30minutes prior to testing.
2. Carefully read instructions for using the STANDARD F Zika Ag 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

- **If a violet colored band (check band) does not appear in the result window of the test device, do not use it.**

CAUTION

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

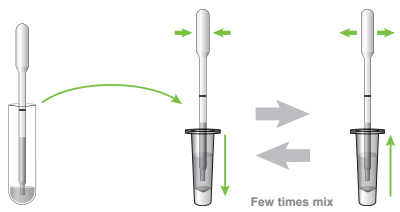
[Analysis of sample]

- **Using a 'STANDARD TEST' mode**
  - **Applied STANDARD F100, F200 and F2400 analyzer**

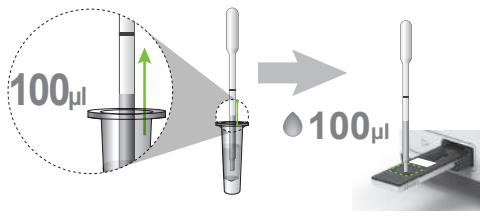
1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
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 disposable dropper, collect the 100µl of the serum, plasma or whole blood to the black line of the disposable dropper. Add the collected sample into the assay diluent and mix thoroughly.



6. Apply the 100µl of sample mixture to the sample well of the test device.



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

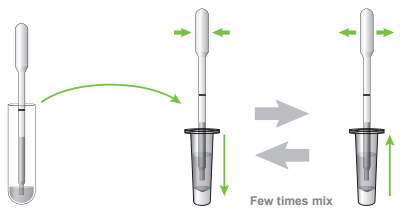
<F100> <F200> <F2400>

8. The analyzer will automatically display the test result within 15 minutes. Strong positive sample can be detected early at 5 minutes by F100 and F200 analyzers.

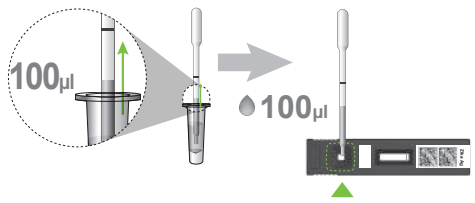
- **Using a 'READ ONLY' mode**
  - **Applied STANDARD F100 and F200 analyzer**

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 disposable dropper, collect the 100µl of the serum, plasma or whole blood to the black line of the disposable dropper. Add the collected sample into the assay diluent and mix thoroughly.



3. Apply the 100µl of sample mixture to the sample well of the test device.



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

5. Prepare the STANDARD F analyzer and set the 'READ ONLY' mode following the instructions in the manual.
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.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive for Zika antigen
Negative	COI < 1.0	Negative for Zika antigen
Invalid	Not show the COI value	Retest should be performed

CAUTION

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

NOTE

The 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 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 analyzer shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

LIMITATION OF THE TEST

1. The test should be used for the detection of Zika antigen in human serum, plasma or whole blood specimens.
2. Neither the quantitative value nor the rate of Zika antigen 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
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CE IVD

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

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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