EN

REF F-NCOV-01C

STANDARD F

COVID-19 IgM/IgG Combo FIA

STANDARD™ F COVID-19 IgM/IgG Combo FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Test device
(individually in a foli pouch with desiccant)

Buffer bottle

Capillary tube (20µl)

Instructions for use

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 stored 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 EDTA anti-coagulant tube 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. 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. Using a capillary tube, collect the 20µl of capillary whole blood to the black line of the capillary tube.
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 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 1 day after collection.
3. Do not use hemolyzed blood specimens.

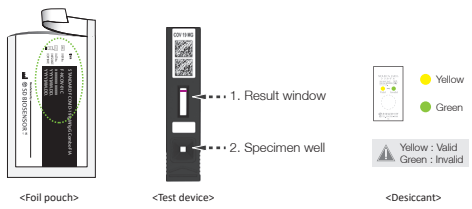
CAUTION

- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

TEST PROCEDURE

■ Preparation

1. Allow test device and collected specimen to room temperature (15-30°C / 59-86°F) prior to testing.
2. Carefully read instructions for using the STANDARD F COVID-19 IgM/IgG Combo FIA.
3. Take out the test device in foil pouch.
   * Check the valid expiry date at the back of the foil pouch. Do not use if the expiry date has passed.
   * The valid color of indicator in desiccant is yellow.



<Foil pouch> <Test device> <Desiccant>

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

CAUTION

CAUTION

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

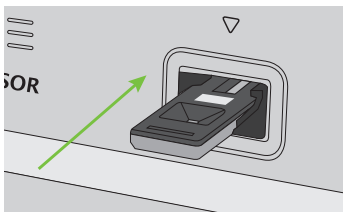
■ Analysis of specimen

• 'STANDARD TEST' mode — **STANDARD F100, F200 and F2400 analyzer**

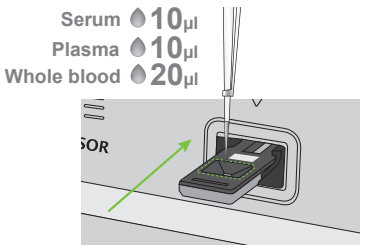
1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual.

STANDARD F2400 analyzer	'Standard Test' mode → 'Workplace' → 'Run Test' → Insert patient ID and / or operator ID on the analyzer
STANDARD F100 and F200 analyzer	'Standard Test' mode → Insert patient ID and / or operator ID on the analyzer

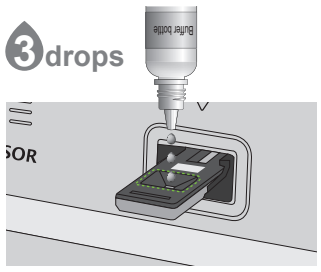
2. Take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device.
3. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.



4. Add the collected serum and plasma (10µl) or whole blood (20ul) to the specimen well of the test device.



5. Apply 3 drops of buffer to the specimen well in the test device.



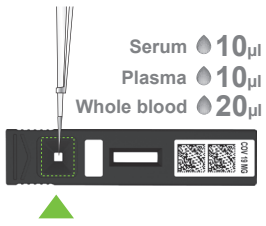
6. After applying the buffer, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

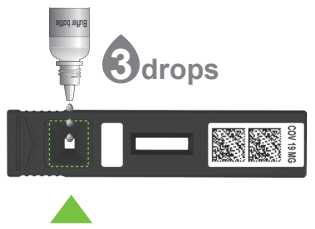
7. The analyzer will automatically display the test result in 15 minutes.

• 'READ ONLY' mode — **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 information on the label of test device.
2. Add the collected serum and plasma (10µl) or whole blood (20ul) to the specimen well of the test device.

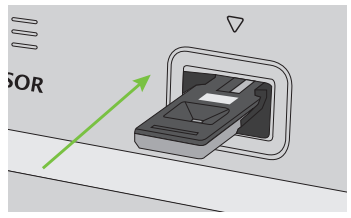


3. Apply 3 drops of buffer to the specimen well in the test device.



4. Incubate the test device for 15 minutes outside of the analyzer.

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. The analyzer automatically reads the barcode information of the test device and outputs the resulting values based on the test information.



CAUTION

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

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive result for Anti-SARS-CoV-2 IgM and/or IgG
Negative	COI < 1.0	Negative result for Anti-SARS-CoV-2 IgM and/or IgG
Invalid	Not show the COI value	Retest should be performed

NOTE

The test result of a specimen is given either Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. The COI is a numerical representation of the measured fluorescence signal.

- STANDARD F COVID-19 IgM/IgG Combo FIA may cross-react with antibody against SARS-Corona-1.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.

EXPLANATION AND SUMMARY

■ Introduction

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, such as fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, Severe Acute Respiratory Syndrome, kidney failure, and even death. The 2019 new coronavirus, or "2019-nCoV", was discovered because of Wuhan Viral Pneumonia cases in 2019, and was named by the World Health Organization on January 12, 2020, confirming that it can cause colds and the Middle East Respiratory Syndrome (MERS) and more serious diseases such as Severe Acute Respiratory Syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confi rming or excluding cases alone.

■ Intended use

STANDARD F COVID-19 IgM/IgG Combo FIA is the fluorescent immunoassay for the qualitative detection of specifi c antibodies to SARS-CoV-2 present in human serum, plasma and whole blood. STANDARD F COVID-19 IgM/IgG Combo FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. This test is for in vitro professional diagnostic use and intended as an aid to diagnosis of SARS-CoV-2 infection in convalescent phase of patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confi rmation of SARS-CoV-2 infection.

■ Test principle

STANDARD F COVID-19 IgM/IgG Combo FIA has three pre-coated lines, "C" Control line, "G" and "M" Test line for the device on the surface of the nitrocellulose membrane. Goat polyclonal anti-mouse IgG antibody is coated on the control line region and SARS-CoV-2 recombinant protein is coated on test lines region. Monoclonal anti-human IgG antibody conjugated with europium particles are used as detectors for "G" test line and monoclonal anti-human IgM antibody conjugated with europium particles are used as detectors for "M" test line. During the test, SARS-CoV-2 antibodies in the specimen interact with monoclonal anti-human IgG antibody conjugated with europium particles or monoclonal anti-human IgM antibody conjugated with europium particles making antibody-antibody-europium particle complex. This complex migrates on the membrane via capillary action until it reaches the test line, where it is captured by the SARS-CoV-2 recombinant protein. The intensity of the fl uorescence light will be generated on the test line if SARS-CoV-2 antibodies are present in the specimen. The intensity of the fl uoerescence light will vary depending upon the amount of SARS-CoV-2 antibodies present in the specimen. If SARS-CoV-2 antibodies are not present in the specimen, no fl uoerescence light appears on the test line. The control line is used for procedural control, and should always disappear if the test procedure is performed correctly and the reagents of the control line works properly.

KIT STORAGE AND STABILITY

Store the kit at 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 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 the buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Use the STANDARD F COVID-19 IgM/IgG Combo FIA at 15-30°C / 59-86°F, and 10-90%RH.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
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 biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from aff ecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
12. Immediately use the test device after taking out of foil pouch.
13. As the detection reagent is a fl uorescent compound, no visible results will form on the test device.
14. 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.
15. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again with the same analyzer.
16. Improper specimen collection, handling or transportation may yield inaccurate results.
17. Do not write on the barcode or damage the barcode of the test device.

PERFORMANCE CHARACTERISTICS

■ Clinical evaluation

Performance characteristic for the STANDARD F COVID-19 IgM/IgG Combo FIA for rapid detection of anti-SARS-CoV-2 antibodies was established in retrospective, single institute, randomized, single-blinded study conducted at a trial site in KOREA during the 2020 SARS-CoV-2 pandemic situation. A total of 336 retrospective specimens were tested using the STANDARD F COVID-19 IgM/IgG Combo FIA with STANDARD F Analyzer. These specimens consisted of serum from PCR positive or negative confirmed patients. The performance of the STANDARD F COVID-19 IgM/IgG Combo FIA were compared to a commercialized molecular assay. Although the STANDARD F COVID-19 IgM/IgG Combo FIA allows to test for IgM and IgG separately, due to the differing inter-patient time response to the virus, any individual with positive result for the IgM or the IgG test should be read as a positive for anti-SARS-CoV-2 antibodies. The combined test result (positive for IgM and/or IgG or negative for IgM and/or IgG) was used to calculate the total test sensitivity and specificity.

• Test sensitivity

The seroconversion time of IgM and IgG antibodies varies from person to person, but it was estimated to be around 7 days after onset of symptom. The STANDARD F COVID-19 IgM/IgG Combo FIA showed **94.41% of sensitivity** using specimens from patients 7 days after symptom onset (combined IgM+IgG).

Table 1. Summary of the sensitivity of the STANDARD F COVID-19 IgM/IgG Combo FIA compared to PCR using specimens **7 days after symptom onset**

≥ 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	135	0	135
	Negative	8	0	8
	Total	143	0	143
Sensitivity		**94.41% (135/143, 95% CI, 89.27% - 97.55%)**		

Table 2. Summary of the sensitivity of the STANDARD F COVID-19 IgM/IgG Combo FIA compared to PCR using specimens **within less than 7 days after symptom onset**

< 7 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	24	0	24
	Negative	9	0	9
	Total	33	0	33
Sensitivity		72.73% (24/33, 95% CI, 54.48% - 86.70%)		

Table 3. Summary of the sensitivity of the STANDARD F COVID-19 IgM/IgG Combo FIA compared to PCR using specimens in **the period of 7 days to 14 days after symptom onset**

7-14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	51	0	51
	Negative	5	0	5
	Total	56	0	56
Sensitivity		87.50% (49/56, 95% CI, 75.93% - 94.82%)		

Table 4. Summary of the sensitivity of the STANDARD F COVID-19 IgM/IgG Combo FIA compared to PCR using specimens **14 days after symptom onset**

> 14 days after symptom onset		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	86	0	86
	Negative	1	0	1
	Total	87	0	87
Sensitivity		98.85% (86/87, 95% CI, 93.76% - 99.97%)		

• Test specificity

The STANDARD F COVID-19 IgM/IgG Combo FIA showed 90.62% of specificity (combined IgM+IgG).

Table 5. Summary of the specificity of the STANDARD F COVID-19 IgM/IgG Combo FIA compared to PCR

		PCR		
		Positive	Negative	Total
STANDARD F COVID-19 IgM/IgG Combo FIA	Positive	0	15	15
	Negative	0	145	145
	Total	0	160	160
Sensitivity		90.62% (145/160, 95% CI, 85.01% - 94.66%)		

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate of SARS-CoV-2 concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV.
10. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

QUALITY CONTROL

■ STANDARD F Analyzers calibration check

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzer's manual.

- **When to use calibration set**
  1. Before using the analyzer for the first time
  2. When you drop the analyzer
  3. Whenever you do not agree with your result
  4. When you want to check the performance of an analyzer and test device
- **How to use calibration set**

  Calibration set test is a mendatory function that ensures optimal performance by checking the internal analyzer optics and functions.
  1. Select the 'Calibration' menu.
  2. The specific calibration set is included with the analyzer.
  3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.

CAUTION

- The STANDARD F Analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

■ Procedural control

1. The internal procedural control zone is in the end of 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 analyzers shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

■ External quality control

1. Positive and negative controls may be supplied with each kits or can be purchased from the distributors.
2. It is recommended that positive and negative controls be run:

- once for each new lot.
- once for each untrained operator.
- as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
2. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
3. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E or past or present infection with SARS virus (no. 6).
4. This test is not for screening of donated blood.
5. The test procedure should be conducted in ambient temperature and pressure.
6. Results of these tests should be appropriately recorded in a test report.

BIBLIOGRAPHY

1. Clinical management of severe acute respiratory infection when novel coronavirus(nCoV) infection is suspected. Interim guidance. WHO.2020
2. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020
4. Guo L et al. Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19). Clinical Infectious Disease. 2020
5. Zhao J et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Clinical Infectious Disease. 2020

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 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

L28COV5ENR2
Issue date : 2020.06

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
Note
Do not re-use.
To indicate the temperature limitations in which the transport package has to be kept and handled.
Use by
LOT Batch code
CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices
Manufacturer
Date of manufacture
Indicate that you should keep the product dry
Keep away from sunlight
Do not use if packaging is damaged