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

STANDARD F
COVID-19 Ag FIA

REF F-NCOV-01G

STANDARD™ F COVID-19 Ag FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

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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, 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 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 confirming or excluding cases alone.

[Intended use]

STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay to detect COVID-19 infection in human nasopharyngeal swab specimen, identifying existence of COVID-19 viral nucleoprotein antigens. STANDARD F COVID-19 Ag FIA should be used with the STANDARD F Analyzers manufactured by SD BIOSENSOR. STANDARD F COVID-19 Ag FIA is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD F COVID-19 Ag FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect COVID-19 nucleoproteins. STANDARD F COVID-19 Ag FIA has a test line which is coated with monoclonal anti-COVID-19 antibody. The patient's specimen is applied into the specimen well of the test device and the specimen migrates through the membrane. If COVID-19 viral antigen is present in patent specimen, it will react with europium conjugated monoclonal anti-COVID-19 antibody in the conjugation pad and form antibody-antigen fluorescence particle complex. This complex move along to the membrane to be captured by the anti-COVID-19 antibody on the test line and 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 COVID-19 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(individually in a foil pouch with desiccant) ② extraction buffer tube ③ Filter cap ④ Sterile swab A
⑤ Sterile swab B (option) ⑥ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

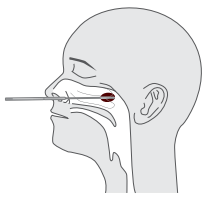
Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

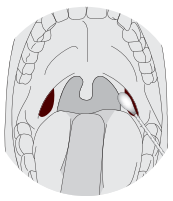
1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the extraction buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Use the STANDARD F COVID-19 Ag FIA at 15-32°C / 59-90°F, and 10-90%RH.
6. Wear personal 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 affecting 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 aluminum foil pouch.
13. As the detection reagent is a fluorescent 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 in the same analyzer.
16. Improper specimen collection, handling or transport may yield inaccurate results.
17. Do not write on the barcode or damage the barcode of the test device.

SPECIMEN COLLECTION AND PREPARATION

[Methods of specimen collection]



<Sterile swab A>
Nasopharyngeal Swab



<Sterile swab B (option)>
Throat swab

[Specimen preparation]

• Nasopharyngeal swab

1. To collect a nasopharyngeal swab specimen, insert the sterile swab A into the nostril that present the most secretion under visual inspection.
2. Using gentle rotation, push the sterile swab A until resistance is met at the level of the turbinate.
3. Rotate the sterile swab A a few times against the nasopharyngeal wall.
4. Remove the sterile swab A from the nostril carefully.
5. Specimen should be tested as soon as possible after collection.
6. Specimens may be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48 hours in a clean, dry, closed container prior to testing.

• Throat swab (option)

1. Open the mouth widely.
2. Depress the tongue with a tongue based or spoon.
3. Insert the sterile swab B completely from the mouth into the throat.
4. Swab the posterior pharynx, tonsils and other inflamed areas 3 times with moderate force.
5. Remove the sterile swab B avoid touching to tongue and teeth with the swab.
6. sterile swab B can be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48 hours after collection in a clean and dry plastic tube.

CAUTION

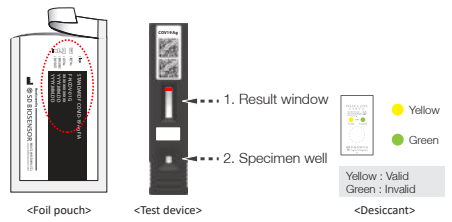
• **DO NOT USE** a viral transport medium as a specimen. It may cause inaccurate result.

TEST PROCEDURE

[Preparation]

1. A llow test device and collected specimen to room temperature(15-32°C / 59-86°F) prior to testing.
2. Carefully read instructions for using the STANDARD F COVID-19 Ag FIA.
   *Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.

3. Open the foil pouch and check the test device and the desiccant.



CAUTION

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

CAUTION

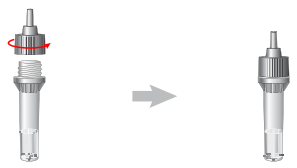
• Do not write on the bar code or damage the bar code of the test device.

[Extraction of specimen]

• Nasopharyngeal / Throat swab (option)

1. Insert nasopharyngeal swab/ throat swab specimen of patient into an extraction buff er tube. Swirl the swab at least five times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

3. Tightly screw the filter cap onto the tube.



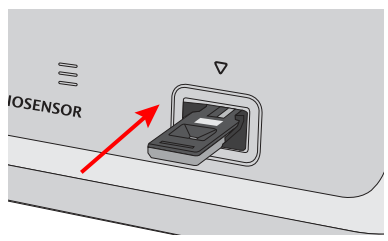
[Analysis of specimen]

• Using a 'STANDARD TEST' mode

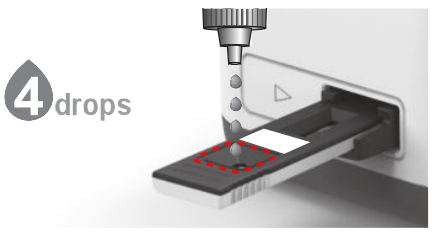
- **STANDARD F100, F200 and F2400 analyzer**

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. 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. Apply 4 drops of mixed sample to the Specimen well in the test device.



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

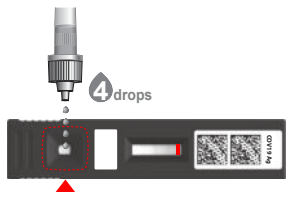
7. The analyzer will automatically display the test result within 30 minutes.

• Using a '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 a information on the label of test device.

2. Apply 4 drops of mixed sample to the Specimen well in the test device.



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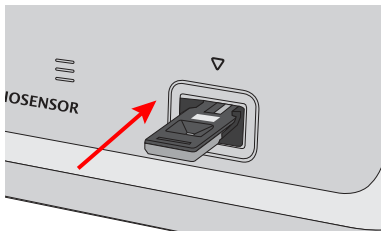
3. Incubate the test device for 30 minutes outside of the analyzer.

4. Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual. Insert the test device to the test slot of the analyzer.

5. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.



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 for COVID-19 Ag
Negative	COI < 1.0	Negative for COVID-19 Ag
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient specimen.

NOTE

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

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 required 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 F100 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.

[Internal 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.

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 CODVID-19 in the specimen and should not be used as the sole criteria for the diagnosis of COVID-19 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 CODVID-19 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.

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

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