EN REF IF-CVF-01

STANDARD F

Covi-FERON FIA (IFN-gamma)

STANDARD™ F Covi-FERON FIA (IFN-gamma)

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Test device
(individually in a foil pouch with desiccant)

Conjugate tablet

Sample Dilution Buffer

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Heparin blood collection tubes
- Calibrated micropipets (10µl to 1000µl) with disposable tips
- Incubator capable of maintaining temperature at 37±1°C/96.8~100.4°F
- Waste discard container with suitable fresh disinfectant
- Personal Protective Equipment (PPE)

SPECIMEN COLLECTION

■ Blood incubation and harvesting

1. Covi-FERON FIA (IFN-gamma) should use the following tubes.
   1) Covi-FERON Nil tube (Gray cap)
   2) Covi-FERON Original SP Antigen tube (Light blue cap)
   3) Covi-FERON Variant SP Antigen tube (Orange cap)
   4) Covi-FERON NP Antigen tube (Black cap)
   5) Covi-FERON Mitogen tube (Purple cap)
2. Take out the Covi-FERON Tubes at room temperature (15-25°C/59-77°F) for 15-30 minutes before using and inject the blood without cold air.
3. Collect blood from the patient and inject respectively 1ml into each Covi-FERON Tube (Nil tube, Original SP Antigen tube, Variant SP Antigen tube, NP Antigen tube, and Mitogen tube).
   1) Insert a needle into the tube for 2-3 seconds after the injection is completed to collect the correct volume.
   2) The black line on the side of the tube indicates 1.0ml.
   3) When using Butterfly needle, Purge tube must be used.
   4) If the tubes are not filled to the black line due to vacuum, open the cap and fill it up with additional blood up to the black line.
4. As soon as the tube is filled with blood, shake it 10 times gently or use a Roller-rocker to allow the entire surface of the tube to be immersed in blood so that it can mix well with the antigen on the tube wall. - DO NOT SHAKE THE TUBE EXCESSIVELY to prevent blood cells from breaking. Since it is an experiment that requires living lymphocytes, it should be mixed to the extent that cell damage does not occur. Also, Excessive shaking may cause gel disruption and could lead to inaccurate results.
5. Incubate the well-mixed blood tubes at 37°C for 16 to 24 hours. When incubating, the tubes should be inserted into a rack vertically.

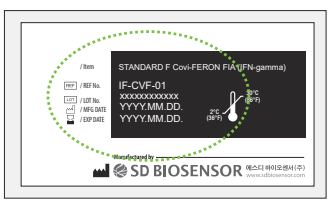
* When it is difficult to incubate right after blood collection, it should be stored at room temperature (15-25°C/59-77°F). The tubes must be incubated within 16 hours after collection.

If it is difficult to inject blood into each Covi-FERON Tube, collect blood in the blood collection tube containing heparin. For Covi-FERON Tubes 500, collect a least 5.5ml of blood in a heparin tube and shake it gently up and down blood to dissolve the heparin (4.5mL blood collection for Covi-FERON Tubes 400). It prevents blood from clotting. After blood collection, it should be stored at room temperature (15-25°C/59-77°F). Within 16 hours after collection, dispense 1ml into each Covi-FERON Tube with pipette, mix well and start incubating. When dispensing blood with pipette after opening the cap of the Covi-FERON Tubes, sterile tips must be used so that blood could be dispensed in an aseptic.

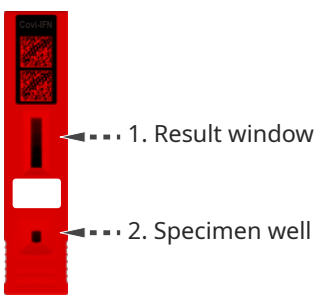
6. After incubation of the tubes at 37°C, collect plasma by centrifuging tubes for 15 minutes at RCF 2200 to 2300g. - When collecting plasma, DO NOT pipetting or plasma mixing in the tube and spearing the gel with pipette tip.

PREPARATION AND TEST PROCEDURE

■ Preparation



Foil pouch



Test device

Desiccant

1. Carefully 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 Covi-FERON FIA (IFN-gamma).
   * Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Check the test device and the desiccant.

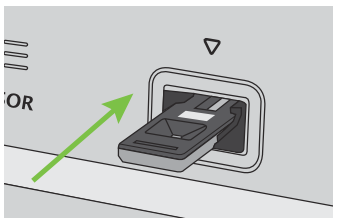
■ Test Procedure
[Analysis of specimen]

'STANDARD TEST' mode — **STANDARD F200 and F2400 analyzer**

1. 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.

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

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. Prepare a Nil sample according to the sample preparation method, and inject it into the sample spot of the test device.

Nil tube (Gray cap)	Original SP Antigen tube (Light blue cap)	Variant SP Antigen tube (Orange cap)	NP Antigen tube (Black cap)	Mitogen tube (Purple cap)
				
This is used to adjust for background noise INF-γ as negative control.	This is used to assess INF-γ response to specific SARS-CoV-2 Spike Protein (SP) antigen derived from SARS-CoV-2 and 20I/501Y.V1 variant.	This is used to assess INF-γ response to specific SARS-CoV-2 Spike Protein (SP) antigen derived from 20H/501.V2 and 20J/501Y.V3 variants.	This is used to assess INF-γ response to specific SARS-CoV-2 Nucleocapsid Protein (NP) antigen.	This can be useful as positive control to check the patient's immune status.

4. On the screen, you can see "Nill Tube" and insert the device for inspection.
5. Take 100µl of Sample Dilution Buffer by using a pipette, and add it into a conjugate tablet vial.
6. Collect 100µl of plasma sample from Nil tube using a pipette, and mix the sample and a dissolved conjugate tablet by pipetting.
7. After applying the specimen, immediately press **'TEST START'** button.
8. The analyzer will automatically display the test result within 15 minutes.

F200 F2400

Repeat the following steps in the order Nil sample, Original SP Antigen sample, Variant SP Antigen sample, NP Antigen sample and Mitogen sample.

INTERPRETATION OF TEST RESULT

Result of each sample is automatically calculated in the analyzer.
A concentration of IFN-gamma is provided as IU/mL.

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 "COVID-19", was discovered due to Wuhan Viral Pneumonia cases in 2019 and was named by the World Health Organization on January 12, 2020. WHO confirmed that the COVID-19 virus (i.e., SARS-CoV-2) can cause colds, 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 confirming or excluding cases alone.

■ Intended use

Covi-FERON FIA (IFN-gamma) is a fluorescence immunoassay for detecting cell-mediated immune responses to SARS-CoV-2 specific proteins in heparinized whole blood. Plasma from the stimulated samples in Covi-FERON tubes can be used for detection of IFN-gamma (IFN-γ) using Covi-FERON FIA (IFN-gamma).

■ Test principle

Covi-FERON FIA (IFN-gamma) uses specialized blood collection tubes, which are antigen-sensitized. Incubation of the blood occurs in the tubes for 16 to 24 hours, after which, plasma is harvested and tested for the presence of IFN-γ produced in response to the specific antigens. The test is performed in two stages. First, whole blood is collected into each of Covi-FERON tubes, which include Nil tube, Original SP Antigen tube, Variant SP Antigen tube, NP Antigen tube, and Mitogen tube. The Mitogen tube can be used with the test as a positive control. This tube may also serve as a control for correct blood handling and incubation. All Covi-FERON tubes should be incubated at 37°C as soon as possible after blood collection, and within 16 hours of collection. Following 16 to 24 hours incubation period, the tubes are centrifuged, the plasma is collected and the amount of IFN-γ (IU/ml) measured by FIA (Fluorescence Immunoassay). FIA testing of plasma sample is the second stage of IGRA test. Details are mentioned on the following "Test procedure" part.

KIT STORAGE AND STABILITY

■ Covi-FERON Tubes 400, 500

1. Store Covi-FERON Tubes 400, 500 at 2~8°C.
2. Covi-FERON Tubes are stable through the expiration date printed on the package.

■ Covi-FERON FIA (IFN-gamma)

1. 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 buff er tube of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Use the Covi-FERON FIA (IFN-gamma) 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 biohazard 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 aluminum 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 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.

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.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results sections for this test kit must be followed closely when testing.
2. Testing could be performed on patients with clinical symptoms on when exposure is suspected.
3. Unreliable or indeterminate results may occur due to:
   1) Excessive levels of circulating IFN-γ or presence of heterophile antibodies.
   2) The Covi-FERON tubes must be incubated within 16 hours after blood collecting.
4. Test results must be considered with other clinical data available to the physician.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended

CE IVD

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L28COVF2ENR0
Issue date: 2021.08

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