SCREEN®

SCREEN IFA TEST COVID-19 IGG-IGM (Whole Blood/Serum/Plasma) Package Insert

REF: SC-1309-20	English

A Fluorescence Immunoassay qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma with the use of SCREEN® Fluorescence Immunoassay Analyzer as an aid in the diagnosis of COVID-19 infection.
For professional in vitro diagnostic use only.

INTENDED USE

The COVID-19 IgG/IgM Test Cassette is a fluorescence immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human whole blood, serum or plasma specimen.The COVID-19 IgG/IgM Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the COVID-19 IgG/IgM Test should not be used as the sole basis for diagnosis.
Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.
Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the COVID-19 IgG/IgM Test early after infection is unknown.
False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based fluorescence immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in whole blood, serum or plasma specimen. During testing, the specimen which contain IgG or/and IgM antibodies to SARS-CoV-2 reacts with SARS-CoV-2 antigens conjugated with fluorescence particles in the label pad of test cassette. Then the mixture migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG or/and IgM in IgG or/and IgM test line region of NC membrane. The concentration of IgG or/and IgM to SARS-CoV-2 in the specimen correlates with the fluorescence signal intensity captured on the Test line, which can be scanned by SCREEN® Fluorescence Immunoassay Analyzer. The testing result of COVID-19 IgG and IgM will display on the SCREEN® Fluorescence Immunoassay Analyzer screen.

REAGENTS

The test contains anti-human IgM and anti-human IgG as the capture reagent on the NC membrane, SARS-CoV-2 antigens which conjugated with fluorescence particles as the detection reagent on the label pad, goat anti-chicken IgY and chicken IgY conjugated fluorescence particles as the control system.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The COVID-19 IgG/IgM Test Cassette should only be used with the SCREEN® Analyzer by trained medical professionals.

STORAGE AND STABILITY

1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze**.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

- **Preparation**
- Before performing the test, please make sure that all components are brought to room temperature (15-30 °C). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
- **Sample Handling**
- Collect the specimen according to standard procedures.
- Do not leave specimens at room temperature for prolonged periods. Serum/Plasma specimens may be stored at 2-8 °C for up to 3 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2-8 °C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.
- EDTA K2, Heparin sodium, Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

MATERIALS

Materials Provided

• Test Cassettes • Buffer • ID Card • Package Insert

Materials Required But Not Provided

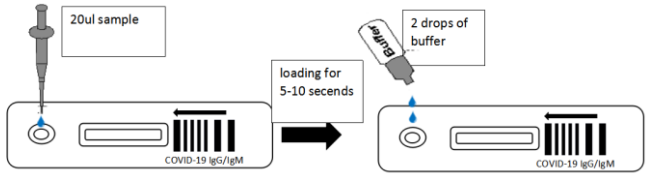
• Timer • Centrifuge • SCREEN® Fluorescence Immunoassay Analyzer
• Pipette • Specimen Collection Containers

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Turn on the Analyzer power. Take out the ID card and insert it into the Analyzer ID Card Slot.
2. Then according to the need, select **test mode to standard test or quick test, and sample type to whole blood or serum/plasma (S/P)**.
3. Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
4. Transfer **20µl of specimen** into the sample well.
5. After the sample absorbed evenly (about 5-10secends), add **2 drops of buffer** (about 80µl) into the sample well. Start the timer at the same time.
6. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.

"Quick test" mode: After **15 minutes** of adding buffer, Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
"**Standard test**" mode: Insert the test cassette into the Analyzer immediately after adding buffer, click "**STANDARD TEST**", fill the test information and click "**NEW TEST**" at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.
Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for COVID-19 IgG/IgM is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.
- Test results of a Value ≥ 1.00 are considered positive for COVID-19 IgG and/or IgM.
- Test results of a Value < 1.00 are considered negative for COVID-19 IgG and/or IgM.
The Reference Value is not a quantitative value or the rate of gG or IgM antibodies to SARS-CoV-2 concentration. This is only a qualitative test.

QUALITY CONTROL

Each COVID-19 IgG/IgM Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated.[1] An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 specific antibodies in the serum, plasma or whole blood specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro*

diagnostic use only. This test should be used for detection of IgG and IgM antibody to SARS-CoV-2 in whole blood, serum or plasma specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. The quantitative value of IgG or IgM antibodies to SARS-CoV-2 can not be determined by this qualitative test.

3. The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of IgG and IgM antibodies to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist, It is recommended to re-sample the patient a few days later or test with a molecular diagnostic device to rule out infection in these individuals.
6. The test will show negative results under the following conditions: The titer of the SARS-CoV-2 antibodies in the sample is lower than the minimum detection limit of the test, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody utilized in the test, or the SARS-CoV-2 antibody has not appeared at the time of sample collection (Asymptomatic stage).
7. In the early infection, anti-SARS-CoV-2 antibodies concentrations may be below detectable level. Therefore it is not recommended to use the test in early diagnosis of COVID-19.
8. The continued presence or absence of antibodies cannot be used to determine the success or failure of therapy.
9. Results from immunosuppressed patients should be interpreted with caution.
10. At this time, it is unknown how long IgM or IgG antibodies may persist following infection.
11. 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.
12. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains (e.g.,HKU1,229E,NL63,OC43) or other interference factors.
13. Not for the screening of donated blood.
14. The hematocrit level of the whole blood can affect the test results. Hematocrit level needs to be between 25% and 65% for accurate results.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The COVID-19 IgG/IgM Test Cassette(Whole Blood/Serum/Plasma)was compared with a leading commercial RT-PCR; the results were tabulated as below.

Table: Clinical Study from COVID-19 IgG/IgM

Method			**PCR**		**total**
	Results		**Positive**	**Negative**	
COVID-19 IgG/IgM Test	Positive	IgM+/IgG-	2	1	32
		IgM-/IgG+	5	2	
		IgM+/IgG+	22	0	
	Negative	IgM-/IgG-	1	95	96
total			30	98	128

Relative Sensitivity: 96.7% (95%CI*: 82.8%-99.9%) *Confidence Interval
Relative Specificity: 96.9% (95%CI*: 91.3%-99.4%)
Accuracy: 96.9% (95%CI*: 92.1%-99.1%)

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of three specimens: a negative, a IgG positive, and a IgM positive wtih 3 consecutive days and 3 operators. The negative, IgG positive, and IgM positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by using three specimens of a negative, a IgG positive and a IgM positive in 10 replicated. Three different lots of the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) have been tested. The specimens were correctly identified >99% of the time.

Cross-reactivity

The COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, Anti-Measles, HAMA, RF, non-specific IgG, non-specific IgM, anti-EV71, anti-Parainfluenza virus, HBsAg, anti-Syphilis, anti-H.Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have been tested using the COVID-19 IgG/IgM Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed.

Triglyceride: 100 mg/dL Ascorbic Acid: 20mg/dL Hemoglobin: 1000mg/dL
Bilirubin: 60mg/dL Total cholesterol : 15mmol/L

BIBLIOGRAPHY

1. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501.

INDEX OF SYMBOLS

	Consult Instructions for Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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