SARS-CoV-2 IgG/IgM Rapid Test
Package Insert

REF L031-11711	English

A rapid test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 in serum, plasma, venous whole blood, or capillary fingertip blood.
For professional in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma, venous whole blood, or capillary fingertip blood. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARS-CoV-2 IgG/IgM Rapid Test should not be used to diagnose acute SARS-CoV-2 infection.

Results are for the detection of antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the SARS-CoV-2 IgG/IgM Rapid Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG or IgM assay.

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 SARS-CoV-2 IgG/IgM Rapid Test is a qualitative membrane based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma or whole blood. The membrane is pre-coated with anti-human IgM antibody and anti-human IgG antibody. During testing, SARS-CoV-2 antibodies, if present in the specimen, will react with the SARS-CoV-2 antigen-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action, reacting with anti-human IgM antibody on the IgM Test Line region (M) and/or with anti-human IgG antibody on the IgG Test Line region (G), forming a colored line in IgM line region (M) and/or IgG line region (G). The absence of the colored lines in IgM line region (M) and IgG line region (G) indicates that the specimen does not have any SARS-CoV-2 antibodies. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test cassette contains SARS-CoV-2 recombination antigens coated particles, anti-human IgM and anti-human IgG are coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations. The used test should be considered potentially infectious and be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The SARS-CoV-2 IgG/IgM Rapid Test can be performed using serum, plasma or whole blood specimen.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for long-term storage. Serum and 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 not tested immediately. The specimens must be tested within 2 days of collection. Do not freeze whole blood specimens.
- Whole blood collected by fingerstick should be tested immediately. Fingerstick blood collection method:
  Step 1: Wash both hands with soap and warm water and disinfect the puncture site with a topical skin antiseptic such as an alcohol swab.
  Step 2: Puncture the skin with a single use auto-disabling safety lancet.
  Step 3: Gently massage from the surrounding area toward the puncture site to get a drop a blood.
  Step 4: Collect the required blood volume using the Dropper.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- Anticoagulants such as heparin, EDTA and sodium citrate do not affect the test result.

MATERIALS

Materials Provided

- Test Cassettes
- Buffer
- Droppers
- Package insert

Materials Required But Not Provided

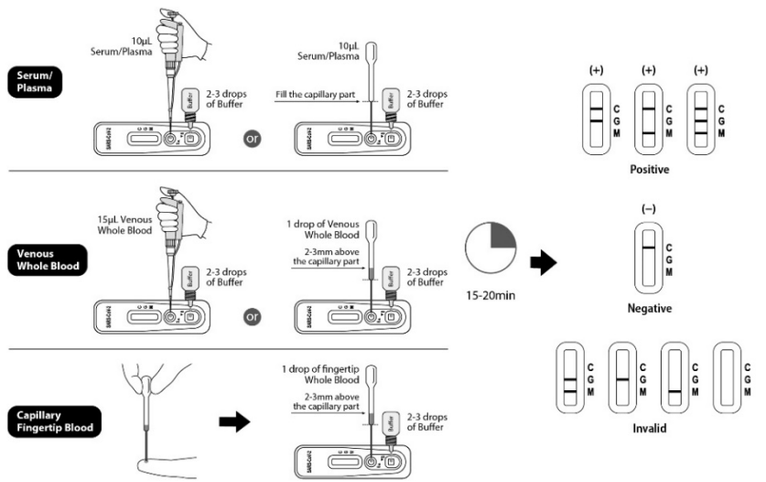
- Pipette and disposable tips
- Centrifuge
- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow the test, specimen and buffer to room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.

2. Place the test on a flat and clean surface. Transfer the specimen by a Pipette or a Dropper:
   - To use a **Pipette** for Serum, Plasma or venous Whole blood:
     Transfer 10 µL of Serum, Plasma, or 15 µL of venous Whole blood specimen into the Sample Well (S), then add 2~3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for Serum or Plasma:
     Hold the dropper vertically and fill the capillary part of the dropper (not to exceed the capillary part) with Serum or Plasma (approximately 10 µL), then carefully dispense the specimen into the Sample Well (S), immediately add 2~3 drops of buffer into the Buffer Well (B), and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for venous Whole blood or fingertip Capillary blood:
     Hold the dropper vertically, draw the specimen about 2-3mm above the capillary part and then transfer 1 full drop (approximately 15 µL) of specimen into the Sample Well (S). Immediately add 2~3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE: Only colored control line appears in the control region (C).

POSITIVE:* Colored control line appears in the control region (C) and colored test line(s) appears in the test line region (G) and/or (M).

IgG positive: Colored control line appears in the control region (C) and one colored line appears in the IgG line region (G).

IgM positive: Colored control line appears in the control region (C) and one colored line appears in the IgM line region (M).

IgG and IgM positive: Colored control line appears in the control region (C), one colored line appears in the IgG line region (G), and one colored line appears in the IgM line region (M).

***NOTE:** The color intensity of the IgM and IgG test line(s) may vary depending on the concentration of the SARS-CoV-2 IgM antibodies and SARS-CoV-2 IgG antibodies present in the specimen.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, do not use the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The SARS-CoV-2 IgG/IgM Rapid Test is for *in vitro* diagnostic use only. The test should be used for the detection of SARS-CoV-2 antibodies in serum, plasma, or whole blood specimens only. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
2. The test will only indicate the presence of SARS-CoV-2 IgM and IgG antibodies in the specimen and should not be used to diagnose acute SARS-CoV-2 infection.
3. A positive result may not indicate previous SARS-CoV-2 infection. False positive results for IgG and IgM may occur due to cross reactivity from some pre-existing antibodies or other possible causes. Consider other information, including clinical history, physical findings, local disease prevalence, and other diagnostic procedures in assessing the need for a second but different serology test to confirm an immune response.
4. A negative or non-reactive result can occur if the blood collection is within 7 days of symptom onset with the quantity of antibodies for the SARS-CoV-2 virus below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
5. If symptoms persist and the result from the SARS-CoV-2 IgG/IgM Rapid Test is negative or nonreactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
6. Results from immunosuppressed patients should be interpreted with caution.
7. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of Buffer may yield erroneous results.
8. This test should not be used for screening of donated blood.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The SARS-CoV-2 IgG/IgM Rapid Test has been tested with specimens obtained from a population of symptomatic and asymptomatic individuals. The positive population were confirmed with commercial RT-PCR product. The results are summarized with the positive specimens collected >7 days after onset of symptoms and the negative specimens were collected before November, 2019. The results show that the relative sensitivity and the relative specificity are as following:

Clinical Performance for SARS-CoV-2 Rapid Test

Method		**RT-PCR**		**Total**
SARS-CoV-2 IgG/IgM Rapid Test	**Results**	Positive	Negative	**Results**
	Positive	111	5	116
	Negative	1	295	296
Total Results		112	300	412

Relative Sensitivity: 99.1% (95.1%-100%)* Relative Specificity: 98.3% (96.2%-99.5%)*

Accuracy: 98.5% (96.9%-99.5%)* *95% Confidence Intervals

Cross-Reactivity and Interference

The SARS-CoV-2 Rapid Test is specific to SARS-CoV-2 IgG and IgM. No cross reactivity was observed with specimens from patients infected with HIV, Hepatitis B virus, Hepatitis C virus, Treponema pallidum, EB virus, Mycoplasma pneumoniae, Varicella-zoster virus, Influenza A/B, Chlamydiae pneumonia, Legionella pneumophila, Adenovirus, Measles virus, Cytomegalovirus, Herpes simplex virus-1/2 or Respiratory syncytial virus. And there is no cross reactivity with Rheumatoid factor positive and ANA positive samples.

The following interfering substances with a certain concentration have no interference on the test of SARS-CoV-2 Rapid Test.

Analytes	Conc.
Bilirubin	342 μmol/L
Hemoglobin	9 g/L
Triglyceride	15 mmol/L
Albumin Human	6 mg/dl
Anti-Mitochondrial Antibody (AMA)	80 U/mL
Mouse IgG	1000 μg/mL

PRECISION

Intra-Assay

Within-run precision has been determined by using 10 replicates of specimens: negative specimen, SARS-CoV-2 IgM positive specimen, and SARS-CoV-2 IgG positive specimen. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same specimen: negative specimen, SARS-CoV-2 IgM positive specimen, and SARS-CoV-2 IgG positive specimen. Three different lots of the SARS-CoV-2 Rapid Test have been tested using these specimens. The specimens were correctly identified >99% of the time.

Index of Symbols

	Manufacturer		Contains sufficient for <*n*>	30°C 2°C	Temperature limit
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
	Consult instructions for use	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community				

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