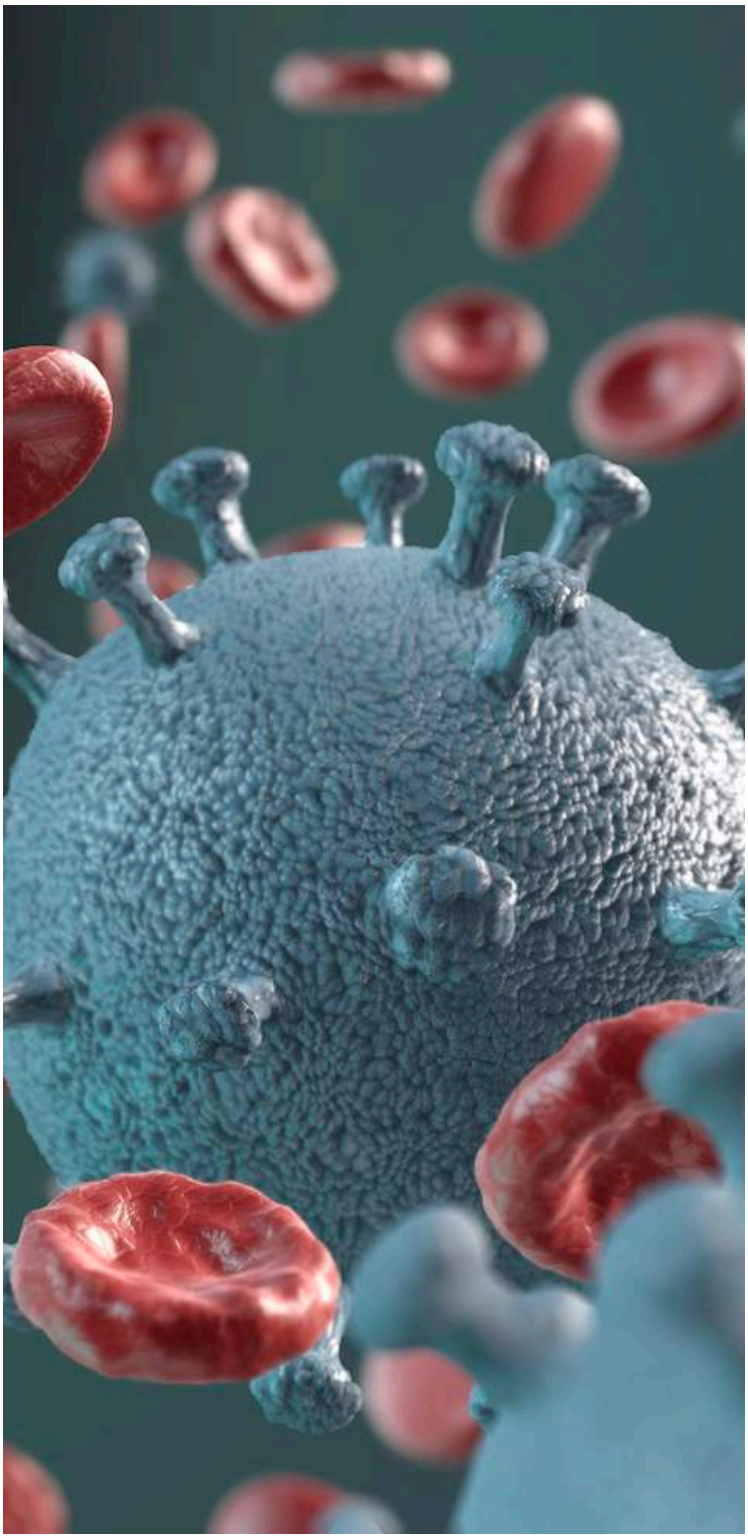
COVID-19 IgG/IgM Rapid Test Kit
(Whole Blood/Serum/Plasma)



INTENDED USE

COVID-19 IgG/IgM Rapid Test Kit (Whole Blood Serum/ Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test is intended for use by healthcare professionals.

INTRODUCTION

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Seven coronavirus species are known to cause human disease. Four viruses - 229E, OC43, NL63, and HKU1 - are prevalent and typically cause common cold symptoms in immunocompetent individuals.4 The three other strains - severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory syndrome coronavirus (MERS-CoV) and 2019 Novel Coronavirus (COVID-19) - are zoonotic in origin and have been linked to sometimes fatal illness. IgG and IgM antibodies to 2019 Novel Coronavirus can be detected with 2-3 weeks after exposure. IgG remains positive, but the antibody level drops overtime.

PRINCIPLE

The COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) is a lateral flow immunochromatographic assay. The test uses anti-human IgM antibody (test line IgM) , anti-human IgG (test line IgG) and goat anti-rabbit IgG (control line C) immobilized on a nitrocellulose strip. The burgundy colored conjugate pad contains

colloidal gold conjugated to recombinant COVID-19 antigens conjugated with colloid gold (COVID-19 conjugates) and rabbit IgG-gold conjugates. When a specimen followed by assay buffer is added to the sample well, IgM &/or IgG antibodies if present, will bind to COVID-19 conjugates making antigen antibodies complex. This complex migrates through nitrocellulose membrane by capillary action. When the complex meets the line of the corresponding immobilized antibody (anti-human IgM &/or anit-human IgG) the complex is trapped forming a burgundy colored band which confirm a reactive test result. Absence of a colored band in the test region indicates a non-reactive test result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti rabbit IgG/rabbit IgG-gold conjugate regardless of the color development on any of the test bands. Otherwise, the test result is invalid, and the specimen must be retested with another device.

MATERIALS SUPPLIED

25 sealed pouches each containing a test cassette, a plastic dropper and a desiccant.
1 bottle Diluent
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1.lancet 2. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated 35.6-86°F (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

WARNINGS AND PRECAUTIONS

1. For professional "FOR In Vitro Diagnostic Use Only". Do not use after expiration date.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the pouch is damaged orbroken.
4. Test is for single use only. Do not re-use under anycircumstances.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

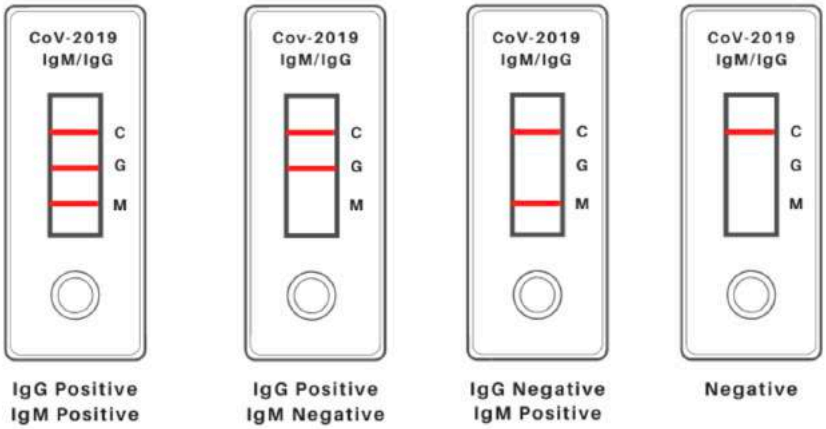
SPECIMEN COLLECTION

1. COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
3. Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6º- 46.4ºF (2-8ºC) for up to 3 days. For long term storage, specimens should be kept below -4.0ºF (-20ºC). Whole blood collected by venipuncture should be stored at 35.6º- 46.4ºF (2-8ºC) if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be testedimmediately.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

TEST PROCEDURE

Allow test cassette, specimen, and/or controls to equilibrate to room temperature 59-86°F (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results willbe obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface.
3. Add 1 drop blood/serum/plasma (10ul) sample into the sample well and add 2 drops (70-100ul)of diluent.
4. Wait for the colored line(s) to appear. The result should be read at 10minutes.



INTERPRETATION OF RESULTS

NEGATIVE:

If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates
that no anti-COVID-19 antibodies are detected in the specimen. The result is negative.

IgM POSITIVE:

In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID-19 in the specimen. The result is IgM anti-COVID-19 positive.

IgG POSITIVE:

In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-COVID-19 in the specimen. The result is IgG anti-COVID-19 positive.

IgG and IgM POSITIVE:

In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti-COVID-19 positive.

INVALID:

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. This test has not been reviewed by the FDA.
2. 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.
3. 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.
4. 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.
5. Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.
6. Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.
7. A negative result can occur if the quantity of the anti-COVID-19 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
8. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
9. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTER

1. Clinical Performance for IgM Test

The samples from susceptible subjects were tested by the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and by a commercial IgM EIA kit. Relative Sensitivity: 95.7%, Relative Specificity: 97.3%, Overall Agreement: 96.8%

2. Clinical Performance for IgG Test

The samples from susceptible subjects were tested by the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) and by a commercial IgG EIA kit. Relative Sensitivity: 91.8%, Relative Specificity: 96.4%, Overall Agreement: 95.0%

REFERRENCE

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81: 85-164.
2. Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24: 490-502.
4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.

Manufacture by: BEIJING KEWEI CLINICAL DIAGNOSTIC REAGENT INC.
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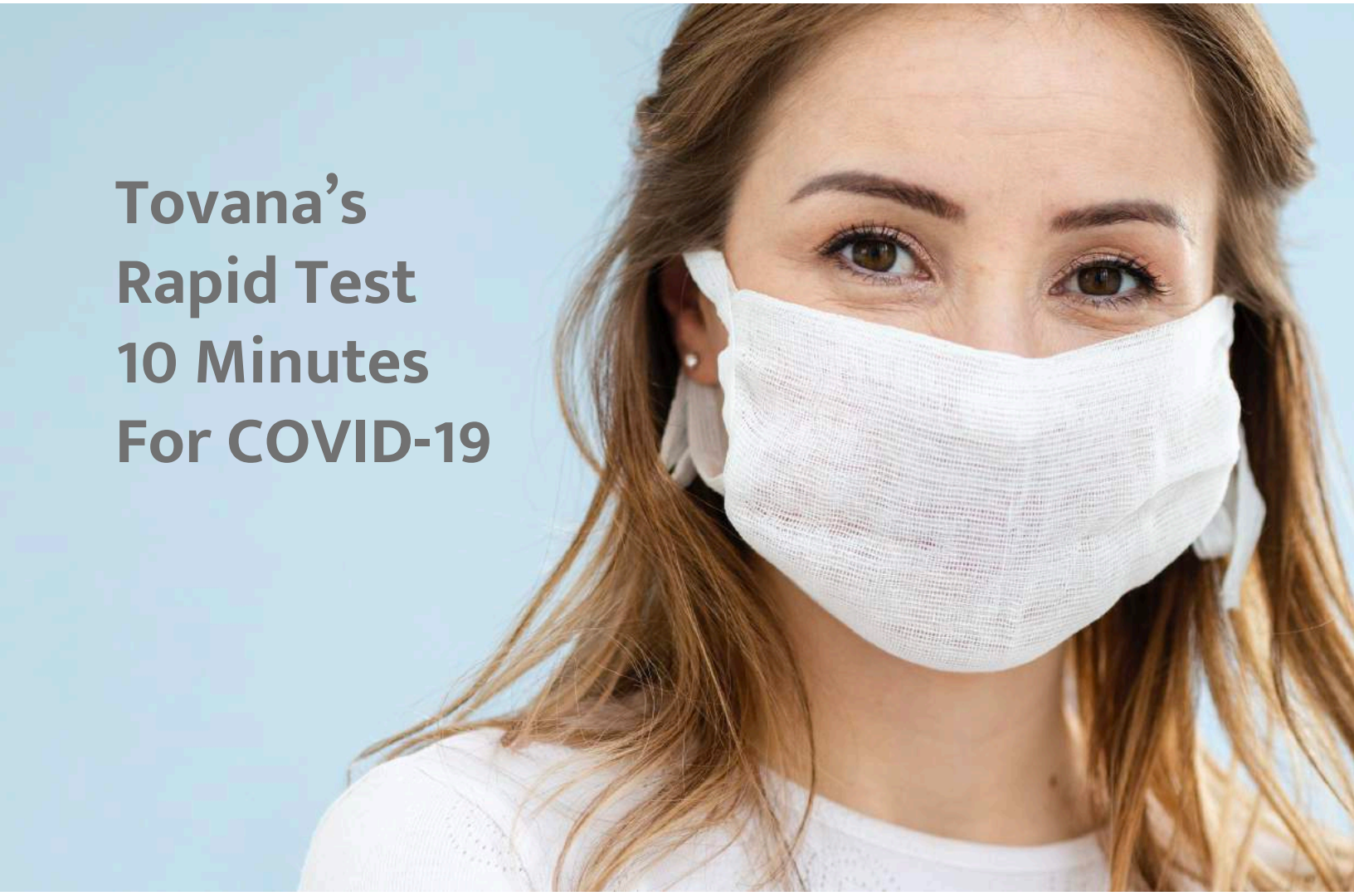
Nimbus PPE

TOVANA HEALTH

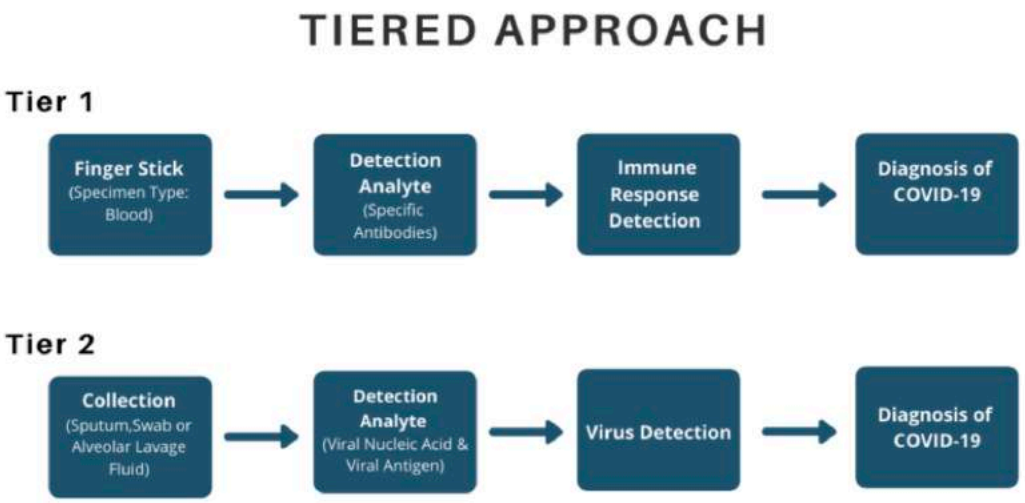


Early Detection = Early Intervention

• Rapidly accurate, low cost screening is required in order to identify all individuals in the population that are infected with the novel coronavirus SARS-CoV-2 causing COVID-19.
• This will allow the government and healthcare industry to quickly respond by placing the people that are infected in isolation and give them the treatment they need without placing the rest of the population at risk.
• This will aid in preventing further spread of the virus in the population and will ease the burden on the healthcare system.

Strategy/Solution

A Two-Tiered Approach should be implemented in order to effectively identify infected individuals and stop the virus from spreading.



Tier-1 Testing:

• The first-tier testing is the COVID-19 IgG/IgM Rapid Test Kit

• This a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma.

• Any reactive specimen with the COVID-19 IgG/IgM Rapid Test kit (Whole Blood/ Serum/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

• Best strategy is to test the entire population using Tier-1 testing twice two weeks apart to detect IgM (which appears within 5-7 days of infection) and IgG (which appears at ~14 days after infection) and enable identification of affected individuals that would require further confirmatory testing and possibly treatment.

Tier-1 Testing Details:

Test Attributes

Whole blood, serum, or plasma may be used for testing (drop of blood from finger stick)

- Easy to use, no need for an analyzer and results available in minutes
- Cost effective method for assisting in diagnosing COVID-19 disease.

Materials Supplied

- 25 sealed pouches each containing a test cassette
- (1 test per patient, 25 tests per box and 80 boxes per container)
- a plastic dropper and a desiccant.
- 1 bottle Diluent (for 25 tests)
- 1 package insert

Material Required but not Provided

- Lancet: 2x2 gauge
- Timer
- Alcohol swab

Storage and Stability

- The kit can be stored at room temperature or refrigerated 35.6-86°F (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

Test Procedure

1. Allow test cassette, specimen, and/or controls to equilibrate to room temperature 59-86°F (15-30°C) prior to testing.
2. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
3. Place the test device on a clean and level surface.
4. Add 1 drop of blood/serum/plasma (10ul) into the sample well and then add 2 drops (70-100ul) of the diluting agent.
5. Wait for the colored line(s) to appear. The result should be read at 15 minutes.

Warnings and Precautions

For professional In Vitro diagnostic use only. Do not use after expiration date.

• This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.

• Do not use it if the pouch is damaged or broken.

• Test is for single use only. Do not re-use under any circumstances.

• Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.

• Wear protective clothing such as laboratory coats, disposable gloves, masks and eye protection when specimens are assayed.

• Humidity and temperature can adversely affect results.

• Do not perform the test in a room with strong air flow, i.e. electric fan or strong air-conditioning.

Specimen Collection

• COVID-19 IgG/IgM Rapid Test kit (Whole Blood/Serum/Plasma) can be performed using either whole blood, serum or plasma.

• Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

• Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 35.6-46.4°F (2-8°C) for up to 3 days. For long term storage, specimens should be kept below -4°F (-20°C). Whole blood collected by venipuncture should be stored at 35.6-46.4°F (2-8°C) if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.

• 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.

Interpretation Results

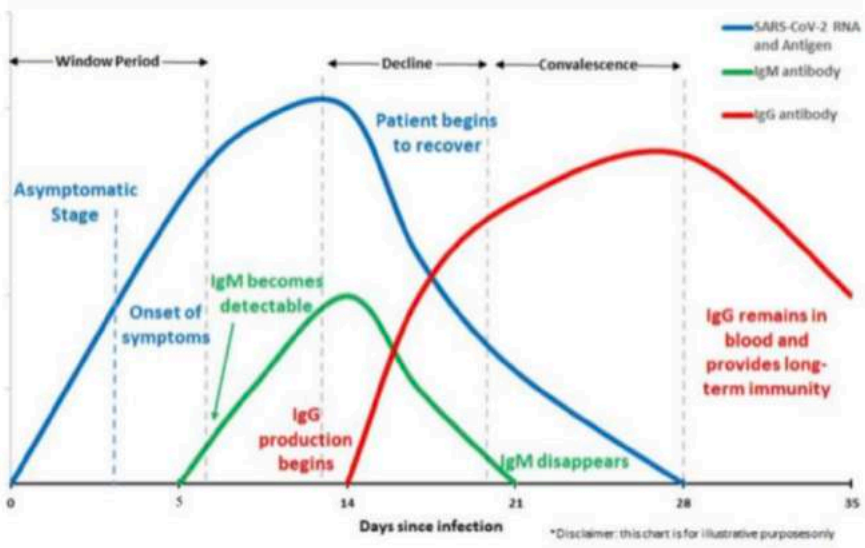
• **NEGATIVE:** If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicates that no anti-COVID-19 antibodies are detected in the specimen. The result is negative.

• **IgM POSITIVE:** In addition to the presence of C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID19 in the specimen. The result is IgM anti-COVID-19 positive.

• **IgG POSITIVE:** In addition to the presence of C band, if only IgG band is developed, the test indicates for the presence of IgG anti-COVID19 in the specimen. The result is IgG anti-COVID-19 positive.

• **IgG and IgM POSITIVE:** In addition to the presence of C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti- COVID-19 positive.

• **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



• The median incubationcperiod is estimated to be 5.1 days.

• Specific IgM antibodies to SARS-CoV-2 become detectable 5-7 days after onset of symptoms.

Test results			Clinical Significance
PCR	IgM	IgG	
+	–	–	Patient may be in the window period of infection.
+	+	–	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	–	+	Patient may be in the late or recurrent stage of infection.
–	+	–	Patient may be in the early stage of infection. PCR result may be false-negative.
–	–	+	Patient may have had a past infection, and has recovered.
–	+	+	Patient may be in the recovery stage of an infection, or the PCR result may be false-negative.

Limitations

• Use fresh samples whenever possible. Frozen and thawed samples (especially repeatedly) contain particles that can block the membrane. This slows the flow of reagents and can lead to high background color, making the interpretation of results difficult.

• Optimal assay performance requires strict adherence to the assay procedure described in this insert sheet. Deviations may lead to aberrant results.

• A negative result for an individual subject indicates absence of detectable anti-COVID-19 antibodies.

• However, a negative test result does not preclude the possibility of exposure to or infection with COVID-19.

• A negative result can occur if the quantity of the anti-COVID-19 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.

• Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect

• As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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