

KarmaCare™

COVID-19 IgM/IgG

Rapid Diagnostic Test for the Detection of SARS-CoV-2 IgM/IgG Ab

[REF] BT700

For use under Emergency Use Authorization only
For *in vitro* diagnostic use only
For prescription use only

Package Insert (Instructions for Use)

False positive results for the *KarmaCare*™ COVID-19 IgM/IgG 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 SARS-CoV-2 IgG or IgM assay.

The *KarmaCare*™ COVID-19 IgM/IgG is only for use under the Food and Drug Administration's Emergency Use Authorization.

Summary and Explanation of the Test

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. This antibody test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, the virus that causes COVID-19, indicating recent or prior infection, by detecting antibodies to SARS-CoV-2 in human blood specimens. Although not everyone who is infected will develop an antibody response, appropriately validated serology tests, when used broadly, can be useful in understanding how many people have developed an adaptive immune response to the virus and how far the pandemic has progressed. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Principles of the Test

The *KarmaCare*™ COVID-19 IgM/IgG test is an immunochromatographic assay for the detection and differentiation of SARS-CoV-2 IgM and/or IgG antibodies in human blood specimens. Control antibody, anti-human IgG, and streptavidin (test line for IgM) are immobilized onto a nitrocellulose membrane to form three distinct lines, the control line, the IgG test line, and the IgM test line. The nitrocellulose membrane is attached onto a plastic backing card and combined with the other reagents and pads to construct a test strip. The test strip is encased inside a plastic device. Blood samples, including human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA) and fingerstick whole blood. The *KarmaCare*™ COVID-19 IgM/IgG 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 for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The *KarmaCare*™ COVID-19 IgM/IgG should not be used to diagnose or exclude acute SARS-CoV-2 infection.

Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the detection of SARS-CoV-2 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the *KarmaCare*™ COVID-19 IgM/IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

The presence of two lines marked by "C" and "G" indicates a SARS-CoV-2 IgG positive result. The presence of two lines marked by "C" and "M", indicates a SARS-CoV-2 IgM positive result. The presence of three lines "C", "G," and "M", indicates positive results for both SARS-CoV-2 IgG and IgM. The appearance of only the control line "C" indicates negative. If the control line does not appear, regardless of the presence of "G" or "M" test lines, the test result is not valid. With an invalid result, it is recommended to repeat the test using a new, unopened device following the instructions.

Reagents and Materials Provided

Contents Name	Quantity (in a kit)	Description
Test device	25 each	Foil pouched test device containing one test strip which is encased on plastic devices cassette
Assay buffer	1 each	Na ₂ CO ₃ <0.1% sodium azide as a preservative.
Blood transfer pipette	25 each	For blood transfer.
Alcohol swab	25 each	Use to clean a collection site prior to sampling the fingerstick whole blood.
Sterile safety lancet	25 each	Single-use lancets intended for sampling fingerstick whole blood.
Package insert	1 each	Instructions for use
Quick Reference Instructions (QRI)	1 each	Quick reference instructions

*Materials not supplied

- Timer
- Pair of safety gloves
- External positive and negative controls (available for purchase separately)
- Optional materials:
 - 20 µl micropipette

Warnings and Precautions

- For prescription and in vitro diagnostic use only. For use under an Emergency Use Authorization Only.
- This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories
- This product has been authorized only for detecting the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Testing of serum, plasma and venous whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet requirements to perform high or moderate complexity tests.
- Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. Testing of fingerstick whole blood specimens is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Immediately use after opening the test device in the pouch.
- Immediately add the assay buffer to the test device after the specimen is applied.
- In order to obtain accurate results, the test must follow this package insert.
- Do not interpret the test result before 10 minutes and after 15 minutes following the addition of buffer to the sample well.
- Do not use if the test device package is damaged.
- Do not use the kit contents beyond the expiration date.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents.
- Dispose of used contents as biohazardous wastes in accordance with federal, state, and local requirements.
- Nitrile or latex gloves should be worn when performing this test.
- If the assay buffer contacts the skin or eye, flush with copious amounts of water.
- Handle all specimens as though they contain infectious agents.
- Adding additional blood sample volume to the sample well may cause false positive or invalid results.

- Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Reagents contain sodium azide, which is harmful if inhaled, swallowed, or exposed to skin. Contact with acids produces a very toxic gas. If there is contact with skin, wash immediately with plenty of water. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up.
- Do not interchange kit contents from different lots.
- Do not re-use any contents in the kit as they are single-use only.

Storage and Stability

- Store the test kit as packaged between 1- 30°C.
- The reagents and materials in the *KarmaCare*™ COVID-19 IgM/IgG are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date.
- The test device must remain in the sealed pouch until use.
- Do not freeze any contents of the kit.

Quality Control

Internal Quality Control:

The *KarmaCare*™ COVID-19 IgM/IgG contains a built-in internal procedural control in the test device. A red-colored line appearing in the control region "C" is designed as an internal procedural control. The appearance of the procedural control line indicates that sufficient flow has occurred, and the functional integrity of the test device has been maintained. If the procedural control line does not develop in 10 minutes, the test result is considered invalid, and retesting with a new device is recommended. If the internal procedural control line is still absent in the retest, please contact the manufacturer or distributor.

External Control:

It is recommended to follow the laboratory regulations or quality control procedures to perform external controls in the *KarmaCare*™ COVID-19 IgM/IgG. Controls are available through Access Bio under catalog number: SCLM-02571 or SCLM-10071.

NOTE: The external controls are available for separate purchase.

- Positive External Control: Mixture of human chimeric SARS-CoV-2 IgM and IgG spike S1 antibodies in heat inactivated SARS-CoV-2 antibody-negative confirmed serum.
- Negative External control: Heat inactivated SARS-CoV-2 antibody -negative confirmed serum.

Specimen Type

Acceptable specimen types for testing with the *KarmaCare*™ COVID-19 IgM/IgG are human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood. Proper specimen collection methods must be followed. Inadequate specimen collection and/or improper specimen handling may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

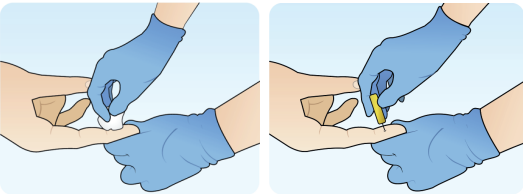
Specimen Collection and Handling Procedures

Procedural Notes

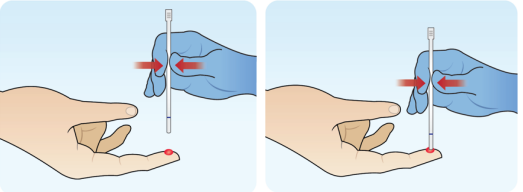
1. The *KarmaCare*™ COVID-19 IgM/IgG can be performed using human serum, plasma (sodium citrate, sodium heparin, or dipotassium EDTA), venous whole blood (sodium citrate, sodium heparin, or dipotassium EDTA), and fingerstick whole blood.
2. Allow test devices, reagents, and specimens to equilibrate up to room temperature (15~30°C) prior to testing.
3. Remove the *KarmaCare*™ COVID-19 IgM/IgG test device from its foil pouch immediately before testing.

Fingerstick whole blood

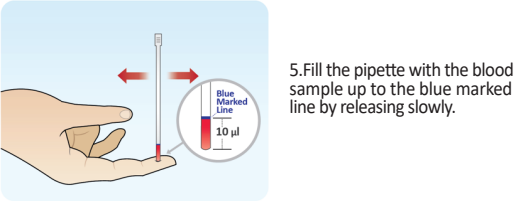
1. Collect the specimen wearing safety gloves to avoid contact and contamination.
2. Use only the provided blood lancet, alcohol swab, and blood transfer pipette for human fingerstick whole blood specimen collection.
3. Process the fingerstick sample immediately after collection.
4. Testing should be performed immediately after specimen collection.



1. Clean the fingertip to be pierced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce the cleaned area using a blood lancet. Properly discard the blood lancet.



3. Press the top part of the provided blood transfer pipette.
4. Touch the blood using the pipette tip while still pressing the pipette.



■ Venous Whole Blood:

Draw venous whole blood following the general laboratory procedures by a trained operator. Collect the blood sample in a commercially available blood collection tube containing anticoagulants including sodium citrate, sodium heparin, or dipotassium EDTA. Swirl the tube gently as needed. It is recommended to test whole blood specimens immediately after blood collection.


■ Serum:

Collect venous whole blood into a container NOT containing anticoagulants. Wait for the blood clot and separate the serum by centrifugation.


■ Plasma:

Collect venous whole blood into a container containing anticoagulants (sodium citrate, sodium heparin, or dipotassium EDTA). Separate the plasma by centrifugation.


- Use only the provided blood transfer pipette or micropipette for sample loading to the test device.
- 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 serum and plasma specimens at room temperature beyond 8 hours. Serum and plasma specimens may be stored at 2-8°C for up to 48 hours. For long term storage, serum and plasma specimens should be kept below -20°C for up to one month. It is recommended to test whole blood specimens immediately after blood collection.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens cannot be frozen and thawed more than once.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

**IVD**


In vitro diagnostic medical device
Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device

**LOT**

Batch code
Indicates the manufacturer's batch code so that the batch or lot can be identified


**Consult instructions for use**


Indicates the need for the user to consult the instructions for use

**Manufacturer**


Indicates the medical device manufacturer

Description of Symbols


**Prescription-only**

**Catalog number**


Indicates the manufacturer's catalog number so that the medical device can be identified

**Caution**


Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself

**Date of manufacture**


Indicates the date when the medical device was manufactured

**Temperature limit**

Indicates the temperature limits to which the medical device can be safely exposed

**Do not use if the package is damaged**

Indicates a medical device that should not be used if the package has been damaged or opened

**Contains sufficient for <n> tests**

Indicates the total number of *in vitro* diagnostic tests that can be performed with *in vitro* diagnostic medical device

**Manufactured by:**

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