The COVID-19 IgG/IgM (Whole Blood/Serum/Plasma) Rapid Test Device utilizes lateral flow technology that is used for the qualitative, differential detection of both anti-*SARS-CoV-2* IgM and IgG antibodies. In general, antibodies can be detected 1-3 weeks after infection. This test is intended to screen patients for COVID-19. Combining RNA and Antibody tests can significantly raise the sensitivity for detecting COVID-19 in infected individuals.

Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals and birds that cause respiratory, enteric, hepatic and neurologic diseases. Four viruses - 229E, OC43, NL63 and HKU1 are prevalent and typically cause common cold symptoms in immunocompromised individuals. Three other strains SARS-CoV, MERS-CoV and SARS-CoV-2 (COVID-19) are can be transmitted from between non-human vertebrates to humans.

Warning

This test has been validated but independent review by the FDA is not yet complete.

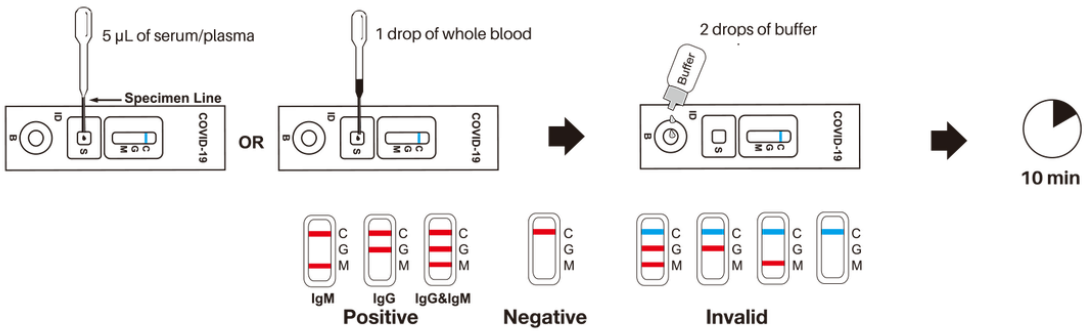
This product is intended for professional use and not for home use. Results from antibody testing are presumptive and should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

A negative result may appear and not correlate with symptoms. A medical professional is required to consider various factors, including confirmation testing, when receiving a presumptive result.

Instructions for Use:

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible.
2. Lay device on flat surface and add specimen (see specific instructions for each specimen type below):
a. For Serum or Plasma Specimen: With the plastic dropper provided, draw serum/plasma specimen to exceed the specimen line, as shown in the diagram

below. Hold the dropper vertically and transfer drawn serum/plasma specimen into the sample well (S). Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.
b. For Whole Blood Specimen: Hold the plastic dropper vertically and transfer 1 drop of whole blood (about 10 µL) to the sample well (S) of the test device. Immediately add 2 drops (about 80 µL) of sample buffer to the buffer well (B) ensuring that buffer vial tip does not touch the sample. Avoid air bubbles.
3. Wait for the control line (C) to change from blue to a red color. If, after 2 minutes, the sample has not moved across the test window or if blood is still present in the sample well (S), add 1 additional drop of sample buffer to the buffer well (B).
4. The results should be read in 10 minutes. Do not interpret the result after 15 minutes.



- Detection Window (IgM): 3-5 days after incubation
- Dual band results for simple interpretation
- Multivariable analysis of immunoglobin IgG & IgM
- Room temperature storage or refrigerated (2-30ºC / 36-86ºF)
- Procedural internal control included
- Buffer included

- Sensitivity: IgG 97.2%; IgM 87.9%
- Specificity: IgG 100%; IgM 100%
- Specimen: Whole Blood, Serum, Plasma
- Time to Results: 10 minutes
- Shelf Life: 24 months from the date of manufacture

ITEM CODE	DESCRIPTION	FORMAT	SPECIMEN	UOM
GCCOV-402a (CE)	COVID-19 IgG/IgM Rapid Test	Cassette	Whole Blood /Serum/Plasma	25 Tests/Kit