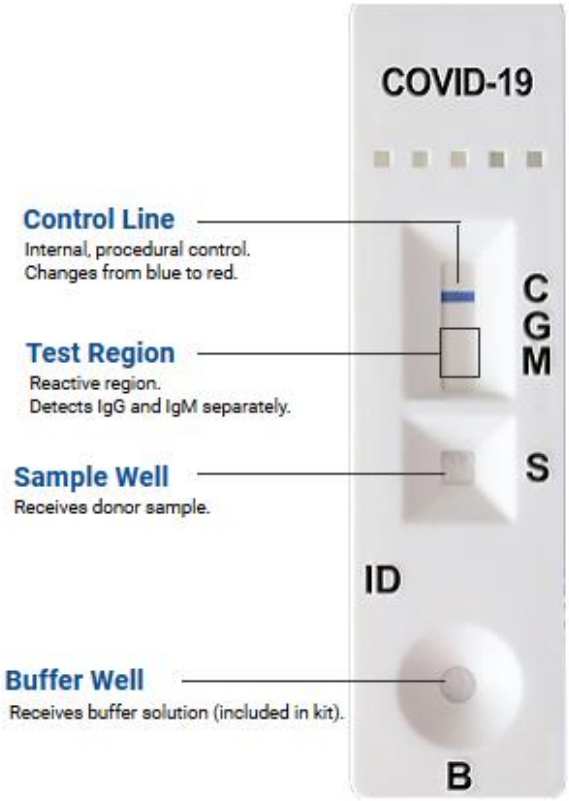
The COVID-19 IgG/IgM (Whole Blood/Serum/Plasma) Rapid Test Device utilizes lateral flow technology that is used for the qualitative, differential detection of both anti-*SARS-CoV-2* IgM and IgG antibodies. In general, antibodies can be detected 1-3 weeks after infection. This test is intended to screen 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 authorized by FDA under an EUA for use by authorized laboratories.

This test has not been FDA cleared or approved.

This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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.

This product is intended for professional use and not for home use.

Not for the screening of donated blood.

Clinical Evaluation

Positive Percent Agreement (PPA): IgG 96.7%; IgM 86.7%; Overall 96.7%
Negative Percent Agreement (NPA): IgG 98.0%; IgM 99.0%; Overall 97.0%

Clinical Agreement with Characterized Samples

Sensitivity: IgG 96.7%; IgM 100%; Combined 100%
Specificity: IgG 97.5%; IgM 100%; Combined 97.5%

Specimen: Whole Blood, Serum, Plasma - Time to Results: 10 minutes - Shelf Life: 24 months from the date of manufacture

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.