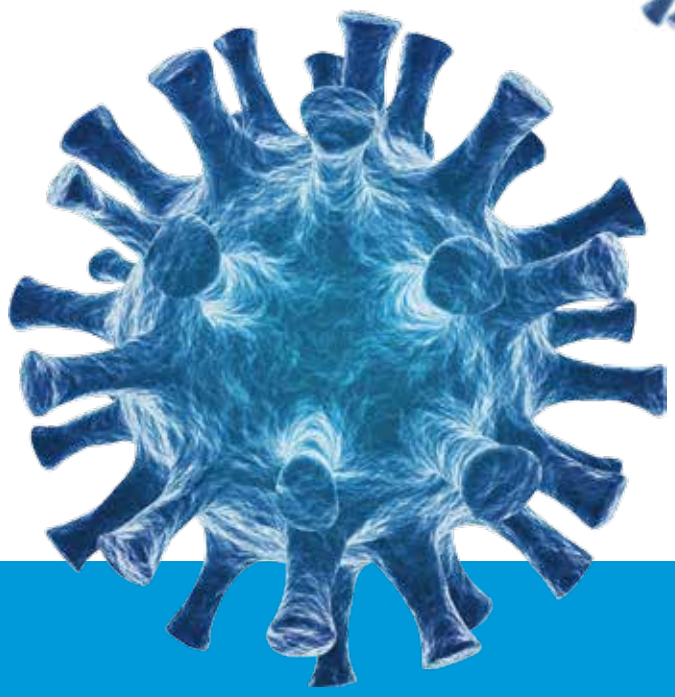
ACON®



SARS-CoV-2

IgG/IgM Rapid Test

The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.*

Reliable Performance

Easy to Use

User Friendly

SARS-CoV-2 IgG/IgM Rapid Test

The novel coronavirus belongs to the β genus. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of new infections; asymptomatic carriers can also be a source of infection propagation. Based on the current research, the incubation period is between 2 to 14 days after exposure to the virus. The main manifestations of the disease include fever, fatigue and dry cough. Nasal congestion, loss of smell, sore throat, myalgia and diarrhea as well as other less common symptoms can also be seen in patients.

General Information

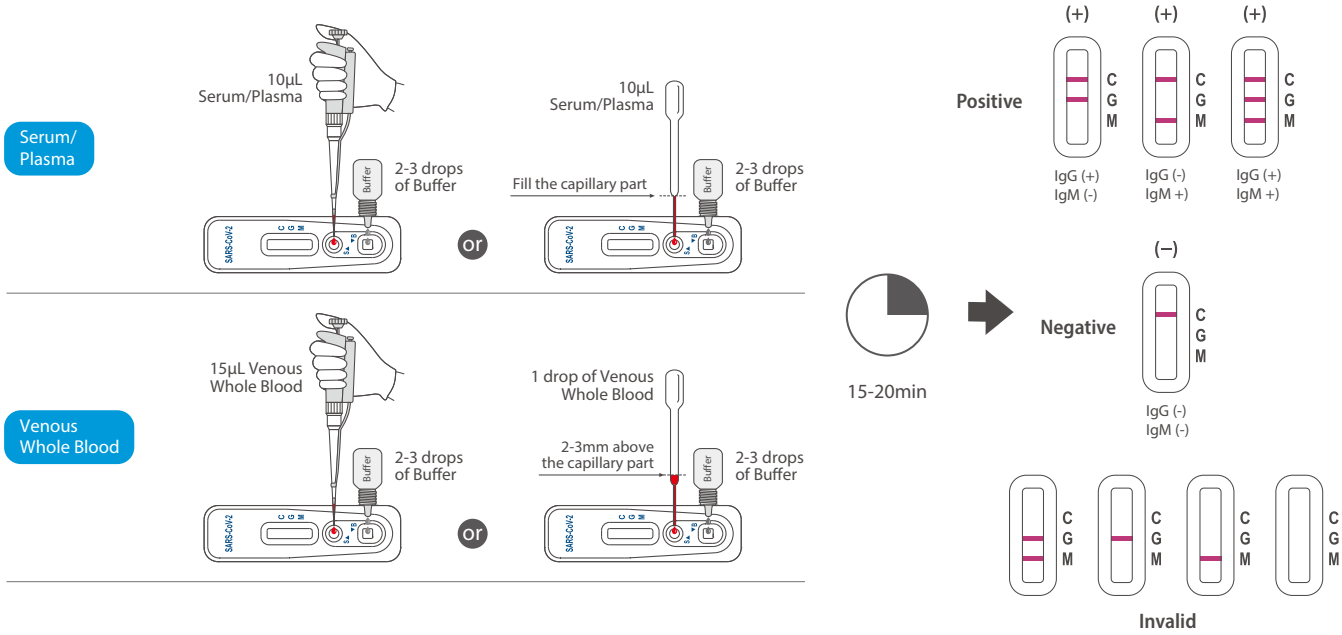
- Detection: IgM and IgG antibodies to SARS-CoV-2
- Combined Sensitivity: 100 % (95% CI: 88.7 %; 100 %)
- Combined Specificity: 96.2 % (95% CI: 89.5 %; 98.7 %)
- Specimen: Serum, Plasma or Venous Whole Blood
- Shelf life: 12 months
- Storage temperature: 2 - 30 °C

Materials Provided and Required

Provided: • Test cassettes • Disposable specimen applicator • Buffer • Package insert

Required: • ACON External Positive and Negative Controls

Test Procedure and Interpretation



Ordering Information

Product Name	Catalog No.	Format	Specimen	Package
ACON SARS-CoV-2 IgG/IgM Rapid Test	L031-11711	Cassette	S/P/WB	25 Tests/Kit
ACON External Positive and Negative Controls	L021-1011	Liquid	N/A	2 Vials/Kit

* Emergency use of this test is limited to authorized laboratories. Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate or high complexity tests.
This test 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 test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
The emergency use of 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
Results from the SARS-CoV-2 IgG/IgM Rapid Test should not be used as the sole basis for diagnosis.

aconlabs.com

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