CareStart™

COVID-19 IgM/IgG

Rapid test for antibodies to the SARS-CoV-2 Virus

The CareStart™ COVID-19 IgM/IgG antibody test provides a critical new resource in the fight against COVID-19 with results in 10 minutes.

The CareStart™ COVID-19 IgM/IgG antibody test is the first American-made lateral flow IgM/IgG authorized by the FDA.

The CareStart™ COVID-19 IgM/IgG serology test is an FDA authorized (EUA) antibody test for use by healthcare professionals and health systems conducting COVID-19 testing in a CLIA certified laboratories for medium complexity and high-complexity testing.

℞ Only CE

Features

- Fast and easy to use
- Detect and differentiate IgM/IgG antibody specific to SARS-CoV-2
- Requires a small sample volume (10 uL of whole blood, serum, or plasma)
- No special equipment or training required
- Results in 10 minutes.

Clinical Features

- Identify and monitor individual's previous infection history and immune response to COVID-19
- Clinical performance (NIH/NCI) of 100% sensitivity and 97.5% specificity

The CareStart™ COVID-19 IgM/IgG antibody test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratoires. 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.

Manufactured by Access Bio
In partnership with Intrivo™

65 Clyde Rd. Suite A Somerset, NJ 08873

AccessBio
www.accessbio.net

Intrivo
www.intrivo.com

Test Principles

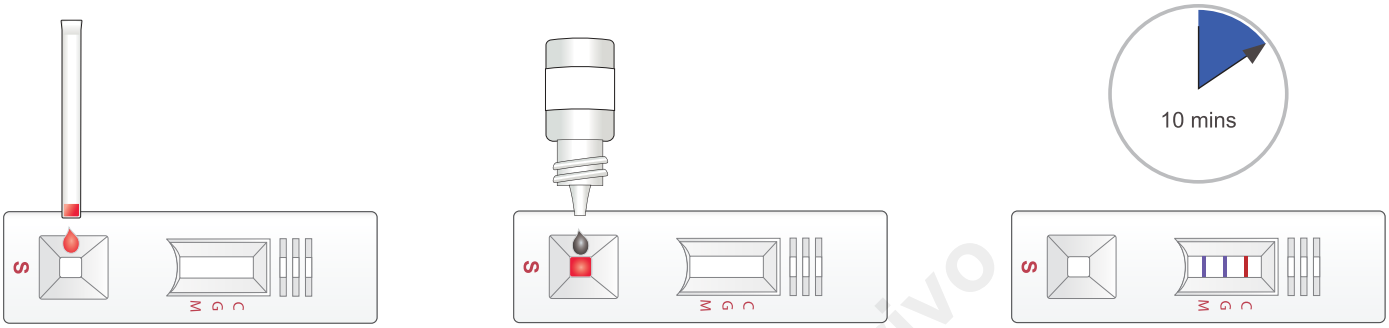
The CareStart™ COVID-19 IgM/IgG test is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 IgM/IgG antibodies in human blood specimens. This test differenciate IgM and IgG specific to SARS-CoV-2 in a single test within 10 minutes.

Procedure

01
Add 10 ul of the sample
(whole blood, serum or plasma)

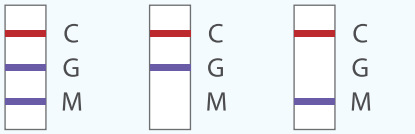
02
Add 1 drop of Assay Buffer.

03
Read the test results
after 10 min



Results Interpretation

Positive



Negative

Invalid

Order Information

Cat No.	RCLM-02571
Package Unit	25 tests/kit
Kit Component	25 Test devices 1 Assay buffer 25 Blood transfer pipettes Instructions for Use

MADE IN USA

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