

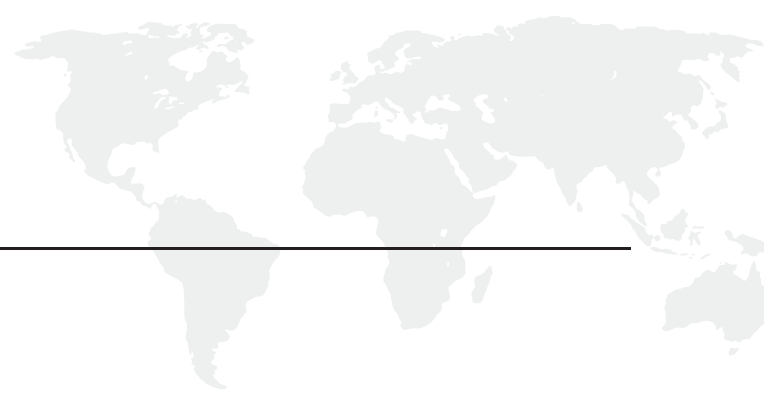
Coronavirus (SARS-CoV-2) IgG/IgM Nucleocapsid (N) Protein Rapid Test Cassette

Whole Blood/Serum/Plasma



- **Suitable for large-scale screening** •
- **Simultaneous detection of both IgM and IgG antibodies** •





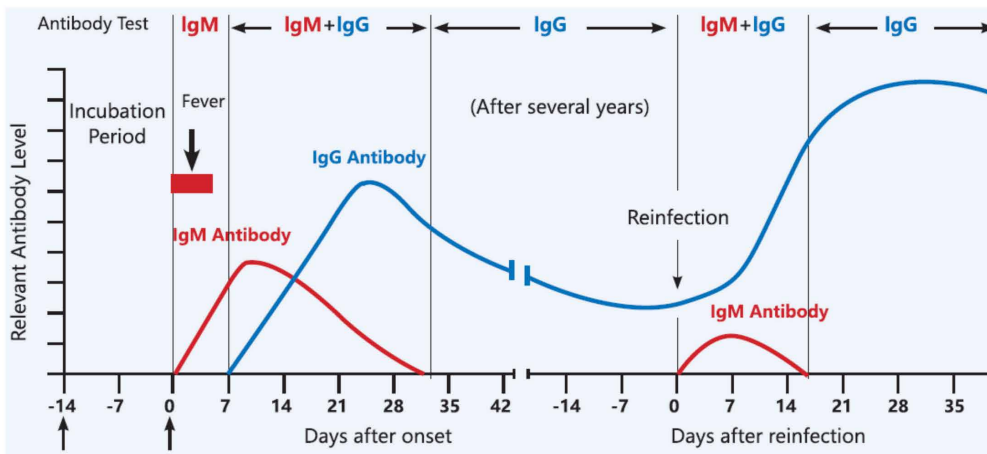
Why use a Serology Test for COVID-19?

As reported on the US-CDC web page, "... CDC is currently working to develop a new laboratory test to assist with efforts to determine how much of the U.S. population has been exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19. The antibodies detected by this test indicate that a person had an immune response to SARS-CoV-2, whether symptoms developed from infection or the infection was asymptomatic. Antibody test results are important in detecting infections with few or no symptoms.

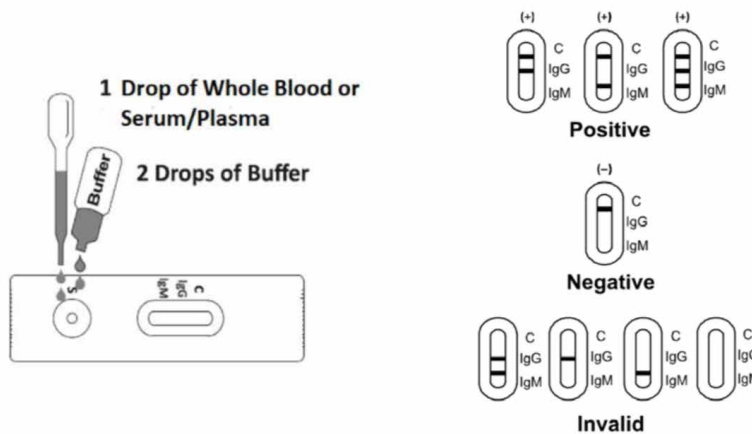
<https://www.cdc.gov/coronavirus/2019-ncov/about/testing.html>

Principle of the test

- **COVID-19 IgG/IgM Rapid Test** is an immunochromatographic assay for the differential determination of anti-2019-nCoV IgG/IgM antibodies in human serum or plasma. Viral antigens (rN-protein) are fixed in the T zone (test) on a nitrocellulose membrane.
- IgM and IgG are the first antibodies appearing in the human system during infection. When detecting acute 2019-nCoV infection, IgM and IgG antibodies have the advantages of high sensitivity, early diagnosis, and the ability to judge whether a suspect is infected.
- IgM and IgG antibodies can only be produced after several days of infection, and the specific time may vary between individuals.



Instruction for use and interpretation of results



- **NEGATIVE:** If only the C band is present, the absence of any burgundy color in the both T bands (IgG and IgM) indicate that no anti-COVID-19 antibodies are detected in the specimen. The result is negative.
- **IgM POSITIVE:** In addition to the presence of the C band, if only IgM band is developed, the test indicates for the presence of IgM anti-COVID-19 in the specimen. The result is IgM anti-COVID-19 positive.
- **IgG POSITIVE:** In addition to the presence of the C band, if only IgG band is developed, the test indicates for the presence of IgG anti-COVID-19 in the specimen. The result is IgG anti-COVID-19 positive.
- **IgG and IgM POSITIVE:** In addition to the presence of the C band, both IgG and IgM bands are developed, the test indicates for the presence of both IgG and IgM anti-COVID-19 in the specimen. The result is IgG and IgM anti-COVID-19 positive.
- **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedure techniques are most likely reasons of control line failure. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

IMPORTANT! A POSITIVE result obtained with this test is not sufficient to diagnose COVID-19 syndrome. Any POSITIVE result must be interpreted in clinical context and confirmed by superior laboratory methods.

Disposable finger prick devices (lancet, capillary tube and alcohol pad) are available separately. Ask for CODES **C61LD1001, C61LD1002.**

Sensitivity and specificity

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was compared with a leading commercial PCR:

IgG	IgM
Relative sensitivity: 97.4% (95%CI*: 86.2%~99.9%);	Relative sensitivity: 86.8% (95%CI*: 71.9%~95.6%);
Relative specificity: 99.3% (95%CI*: 96.2%~99.9%);	Relative specificity: 98.6% (95%CI*: 95.0%~99.8%);
Accuracy: 98.9% (95%CI*: 96.1%~99.9%).	Accuracy: 96.1% (95%CI*: 92.2%~98.4%).

*Confidence Interval

The results show that the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood /Serum /Plasma) has a high sensitivity and specificity.

Cross reactivity studies

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for anti-influenza A virus, anti-influenza B virus, anti-RSV, anti-Adenovirus, HBsAg, anti-Syphilis, anti-H. Pylori, anti-HIV and anti-HCV positive specimens. The results showed no cross-reactivity.

Application scenarios

- **Center of Disease Control and Prevention:** test on high-risk groups such as quarantined person, contacts, and returned workers of developed cities
- **Primary Health Care Institution:** test on suspect person and/or person with fever and cold on site, which is a candidate for immediate reporting and transfer to suitable facilities for infection-positive patients
- **Government Department/Public Institution State-Owned Enterprise/Large Company:** on duty inspection/regular screening of government staff
- **Industrial Production Enterprise:** start-up inspection and regular screening.
- **School:** start-up inspection and regular screening
- **Prison/Detention Center/Drug Rehabilitation Center:** regular screening



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