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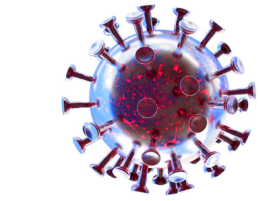
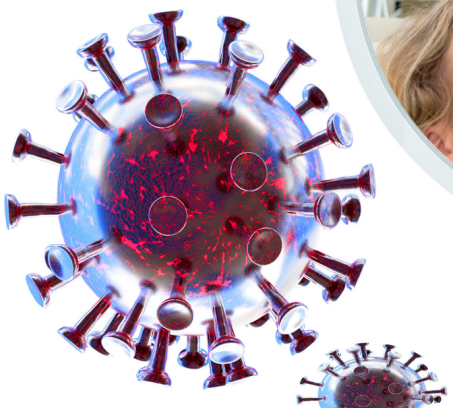
SARS-CoV-2 IgM Test # 6229
SARS-CoV-2 IgG Test # 6227

Background:

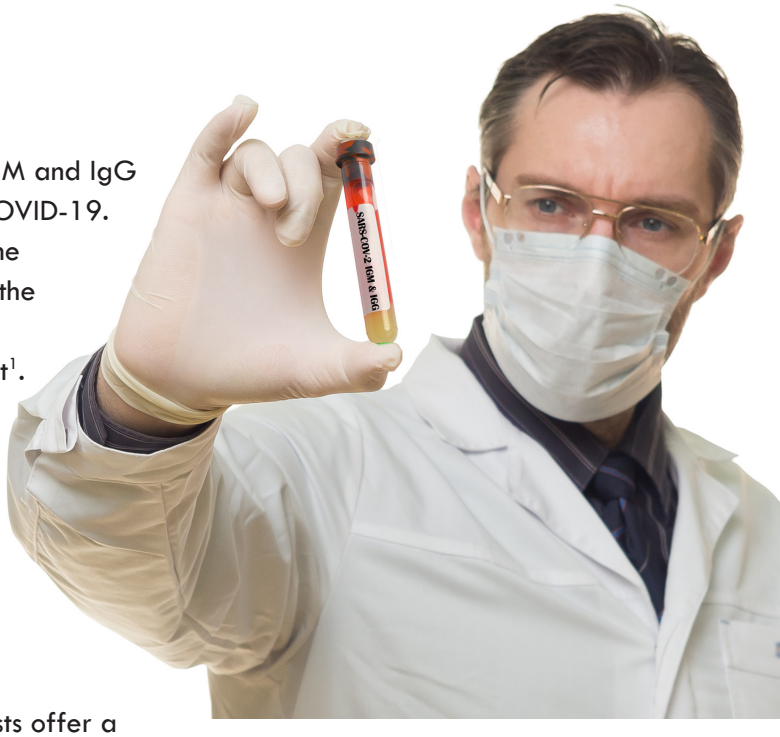
A recently discovered Syndrome Coronavirus 2 (SARS-CoV-2) is causing an epidemic of respiratory disease known as COVID-19. The most common symptoms of COVID-19 are fever, shortness of breath, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat, or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell. SARS-CoV-2 is transmitted through respiratory droplets and contact. When an infected person coughs or sneezes, droplets land on objects and surfaces. Other people may acquire SARS-CoV-2 by touching objects or surfaces, then touching their eyes, nose, or mouth.

Diagnosing COVID-19 currently relies on two major methodologies: Reverse Transcription Quantitative Polymerase Chain Reaction (RT-qPCR) and serological immunoassays that detect viral-specific antibodies (IgM and IgG).





What are SARS-CoV-2 Antibody Tests?



SARS-CoV-2 antibody tests provide qualitative detection of IgM and IgG antibodies against SARS- CoV-2 in individuals suspected of COVID-19. After infection with SARS-CoV-2, the virus antigen stimulates the immune system to produce antibodies that can be detected in the blood. Among these antibodies, SARS-CoV-2 IgM antibodies appears early and are mostly positive after 3-5 days of onset[1]. The SARS-CoV-2 IgM titers then decrease while the SARS-CoV-2 IgG antibody potency starts to rise rapidly. During the recovery phase, the titer of the SARS-CoV-2 IgG antibody may increase four times or more compared to the acute phase[1].

Why SARS-CoV-2 Antibody Tests?

Combined with RT-qPCR, SARS-CoV-2 serological antibody tests offer a valuable diagnostic tool in identifying infected patients. According to recent studies, SARS-CoV-2 antibodies are not detectable before 3 days after onset of symptoms (or at least 7 to 10 days after infection)[2-3]. However, antibody tests can detect past infection because virus-specific antibodies can persist in the blood for several weeks/months after onset of symptoms. Since the exact time of infection is often unknown, combining RT-qPCR and IgM/IgG testing can improve the accuracy of the COVID-19 diagnosis.

Who can be tested?

SARS-CoV-2 antibody tests are recommended to be used on patients with at least 3 days after onset of symptoms or 7-10 days after infection with the virus [2-4].

Interpretation of Results

SARS-CoV-2 antibody assays are designed to complement RT-qPCR in the diagnosis of SARS-CoV-2 infections. Table1 shows the clinical interpretation of all possible scenarios that can be encountered when testing a patient with both RT-qPCR and an IgM/IgG serological test.

TEST RESULTS			CLINICAL SIGNIFICANCE
RT-qPCR	IgM	IgG	
+	-	-	Patient may be in the window period of infection.
+	+	-	Patient may be in the early stage of infection.
+	+	+	Patient is in the active phase of infection.
+	-	+	Patient may be in the late or recurrent stage of infection.
-	+	-	Patient may be in the early stage of infection. RT-qPCR may be false negative.
-	-	+	Patient may have had a past infection and has recovered.
-	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative.

* **Table1**

This table is based on the current knowledge about the rise and fall of SARS-CoV-2 RNA and IgM/IgG antibodies and the correlation of these level variations with the initial time of infection, onset of symptoms and recovery phase[2-4].




Limitations:

- This test has not been reviewed by the FDA. For use in clinical laboratories by health care professionals following FDA guidance “Policy for Diagnostic Tests for Coronavirus Disease-2019 (COVID-19) during the Public Health Emergency”.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic assay should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- 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.
- Not for the screening of donated blood.

Specimen Requirements:

Submit one (1) SST.

Transport/Stability:

Refrigerated specimen is stable for 3 days.

References:

1. Diagnosis and treatment program of novel coronavirus pneumonia (Trial version 7).
2. Lauer, S. et al., 2020. The Incubation Period of Coronavirus Disease 2019 (COVID-19) From Publicly Reported Confirmed Cases: Estimation and Application. Annals of Internal Medicine.
3. National Health Commission of the People's Republic of China, New Coronavirus Pneumonia Diagnosis and Treatment Program (Trial Version 7).
4. To KK, Tsang OT, Leung WS, Tam AR, Wu TC, Lung DC et al. (2020). Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. Lancet Infect Dis. 2020 Mar 23. pii: S1473-3099(20)30196-1.