

FAQs for COV-ID™ Diagnostic Kit (Colloidal Gold) for IgG/IgM Antibody to SARS-CoV-2

What is the U.S. FDA status of the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 kit has been validated and notification provided to the U.S. FDA without being reviewed.

What is the storage requirement of Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 kit can be stored at room temperature (2-30°C or 35.6-86°F).

Does Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 differentiate IgM from IgG?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 will detect and differentiate IgM and IgG antibodies to SARS-CoV-2. In most people, IgM antibody is produced 5-10 days after disease onset in the acute infection stage. IgG antibody is produced secondary to IgM and indicates that the patient is at a later stage or previous infection.

When should patients be tested with Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2?

IgM antibody to SARS-CoV-2 is produced in the acute infection stage and should ideally be tested any time after 15 days of disease onset.

Can Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test be used to diagnose acute infection?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test **cannot** be used for the diagnosis of active SARS-CoV-2 infection because the IgM antibody produced in the acute infection can only be reliably demonstrated 15 days after disease onset.

What patient samples can be used on Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 can be tested with serum, plasma, venous blood (EDTA, heparin, sodium citrate) or finger stick blood samples.

When can the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test results be interpreted?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 test results can be read between 10-15 minutes. Positive results can be read as early as 10 minutes. Do not read the test results after 15 minutes.

The test line is quite weak.

Does this affect the interpretation of results?

Even if the test line is faint in color or incomplete it should be interpreted as positive. A positive result indicates the presence of antibodies to SARS-CoV-2.

The test(s) line is visible but the control line is absent.

Can I still report the results?

A burgundy control line must appear in the result window for the test to be valid. The absence of the control line indicates an invalid result and the patient must be retested with a new test.

What is the clinical performance for the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2?

Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 was demonstrated to be 99.4% sensitive and 98.8% specific compared to confirmed clinical diagnosis of SARS-CoV-2 when testing serum samples from patients 20 days out.

Has the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 undergone third party validation testing?

Across three validation studies, using both fingerstick and serum samples, the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 demonstrated sensitivities of 92-98% and specificities of 97-100% –all meeting U.S. FDA minimum requirements of 90% sensitivity and 95% specificity. Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 was demonstrated to be 99.4% sensitive and 98.8% specific when compared to confirmed clinical diagnosis of patients with SARS-CoV-2.

Does a positive result on the Diagnostic Kit for IgG/IgM Antibody to SARS-CoV-2 determine immunity?

Although having antibodies usually, but not always, provides immunity from further infection, there is not sufficient evidence at this time to conclude that people who have developed antibodies against SARS-CoV-2, the virus that causes COVID-19, are protected against future infections from the virus. Despite this, the presence of IgG responses in most other coronavirus family infections as SARS-CoV correlates to some level of protective immunity up to 2-3 years. Further, a study on rhesus monkeys re-challenged with the SARS-CoV-2 virus, after a history of being infected and recovered, showed no recurrence of COVID-19, suggesting that exposure to SARS-CoV-2 confers some level of immunity.