

COVID-19 ANTIBODY TESTING INFORMATION FOR PROVIDERS

General information:

A multitude of antibody-based tests for COVID-19 are commercially available and have highly variable test characteristics. The antibody response to COVID-19 is an active area of investigation and the clinical implications of antibody testing remain largely unknown. Serological (antibody) tests should not be used as the sole basis to diagnose COVID-19 infection but rather to provide information about whether a patient may have been exposed.

What antibody tests for COVID-19 are available at UCSF?

As of April 23rd, in house testing is available using the Abbot assay for plasma IgG antibodies directed against the nucleocapsid protein of SARS-CoV-2. An IgM antibody test is also available as a send out through Viracor but requires infectious diseases approval. The RNA PCR test remains the test of choice for acute infection; the main use of the IgM test currently is for neonatal diagnosis.

What are the test characteristics of the Abbot COVID-19 IgG assay?

Based on studies performed by the manufacturer (which used clinical samples from UCSF for validation), the specificity of the assay is >99%. Note that even with a high specificity assay, false positives are possible, and the positive predictive value depends on the pre-test probability of infection/prevalence of infection in the community (as with any antibody test). The sensitivity of the assay depends on the timing of testing from symptom onset with increasing sensitivity with longer durations from symptom onset. Sensitivity is approximately 70% at 7-14 days and 94-99% at >21 days post symptom onset based on internal validation data (includes samples from immunocompromised patients). Not all persons with COVID-19 infection, such as persons with immunocompromising conditions, may develop an antibody response. It is unknown whether severity of illness may correlate with presence of antibody response (e.g. if patients with asymptomatic or mild infections may be less likely to develop an antibody response).

Does a positive IgG indicate immunity in a patient who has recovered from COVID-19?

We do not yet know how antibody detection correlates with protective immunity. While developing a measurable immune response to the virus may confer some protection against re-infection, to date there is no direct evidence that the presence of antibodies to SARS-CoV-2 confers immunity. If it is established that protective immunity is conferred by prior infection, it will also be important to determine which antibodies reflect protective immunity (different assays detect antibodies to different viral proteins) as well as to what extent and for how long. For other viral infections, including other coronavirus strains that cause the common cold, immunity may wane over time. Until more is known about protective immunity, serologic testing results should not be used to make decisions regarding social distancing and other public health interventions, safety to return to work, or the use of personal protective equipment.

Does having a detectable COVID-19 IgG antibody indicate a patient is no longer infectious?

Having a detectable IgG antibody does not necessarily mean a patient with COVID-19 infection is no longer infectious. The period of infectivity/shedding of infectious viral particles may overlap with the period of detectability of IgG antibodies, so a positive antibody test should not be used to determine whether transmission-based isolation precautions can be discontinued.

What is the clinical utility of the COVID-19 antibody test based on our current understanding?

The primary clinical use at present for the IgG test is to support the diagnosis of COVID-19 infection in patients in whom COVID-19 infection is highly suspected and PCR based testing is negative, and when symptoms have been present for at least 7 days. Given the limitations of serological testing, results should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection. Test results may also aid in determining who may donate blood for convalescent plasma. Routine testing of patients who think they may have previously had COVID-19 infection is not recommended as ***a detectable antibody does not guarantee immunity or lack of infectiousness.***

How can an IgG antibody test be ordered?

The COVID-19 IgG antibody test is currently available to order through Apex and does not require infectious diseases approval. If testing is being ordered for a symptomatic patient with suspected COVID-19 infection, the test should be collected in a setting where appropriate transmission-based precautions can be followed (e.g. the respiratory screening clinic).