

PROPOSED SARS-COV-2 TESTING PROTOCOL

Proposed Guideline for Serological Testing as Provided by WellTree Molecular Group

COURSE OF COVID-19/SARS-COV-2 INFECTION

When a person is exposed to SARS-CoV-2, the virus causing COVID-19, they may become infected. This means that the virus gets inside the body, starts to replicate, and may cause symptoms. Individuals may remain asymptomatic, or they may develop symptoms, ranging from mild to severe, even death. Regardless of symptoms, the immune system will respond and will start generating two types of antibodies (protective proteins): IgM may be produced within days and IgG may be produced within a week or two after exposure. Antibodies may last up to 90 days or perhaps more.

TYPES OF SARS-COV-2 TESTS

Currently, there are 2 types of SARS-CoV-2 tests commercially available: (1) a diagnostic study using PCR and (2) antibody/serology tests. The diagnostic PCR test answers the question: "Is the virus present in the patient TODAY?", which may be relevant in patients with active symptoms. The PCR test looks for the virus itself (more precisely, the RNA from the virus) in the patient, typically from a nasopharyngeal swab. The test needs to be performed in a laboratory and results may take a week or two to receive. The antibody/serology test answers the question: "Has the person been exposed to the virus IN THE PAST?". The test looks for the antibodies (IgM and IgG) in the person's blood. The test may be performed through a blood draw or finger stick test that can be analyzed in a laboratory or at a Point-of-Care (POC) application. Results for POC antibody tests are available in minutes.

WHY ANTIBODY TESTING?

Antibodies most commonly become detectable within days to weeks after exposure. Depending on the strength of and the blood levels of the antibodies, their presence may indicate reduced risk of infection or getting sick again. However, it is unknown whether the presence of antibodies actually provides protection against infection or re-infection, and the duration of the antibody response is also unknown at this time. There is evidence in the literature that antibody levels significantly decline by 90 days after exposure.

WHO SHOULD BE TESTED?

The diagnostic PCR test may be appropriate in people with active symptoms. The antibody test may be appropriate in those who would like to know if they had been exposed to the virus, regardless of symptoms.

WHEN TO TEST?

If person is asymptomatic, testing should occur 5-7 days after suspected exposure, then again at 10-14 days after exposure. This may determine if asymptomatic infection has occurred. If the person is symptomatic and presents within 9-14 days after illness onset, testing may be offered during that 9-14 day period and again 5 days later.

WHAT DO THE RESULTS MEAN?

Positive Antibodies' results

If antibodies are found, then prior exposure with possible infection by SARS-CoV-2.

Antibodies develop as a body response to the Virus regardless if any symptoms are experienced.

Note: Symptoms can take a week to appear.

Antibody tests are not to be used for diagnosis. They are an Indicator test.

Negative Antibodies' results

If no antibodies are found, then there are several possible meanings:

1. No infection.
2. Infection occurred, but the body's immune system was not able to, or strong enough to produce antibodies.
3. Not enough time for the body to produce a measurable level of antibodies.

References:

1. Centers for Disease Control and Prevention, Interim Guidelines for COVID-19 Antibody Testing. Last Updated July 30th, 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html#anchor_1590264293982
2. Centers for Disease Control and Prevention, COVID-19 Serology Surveillance Strategy. Last Updated June 25, 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html>