



SARS-CoV-2 Antibody Test – Informed Consent Form

Patient Name: _____

Date of Birth: _____

The test is designed to detect the presence of SARS-CoV-2 antibodies. In other words, it detects the likelihood of a prior SARS-CoV-2 (COVID-19) infection. The test has been made available from the FDA under an Emergency Use Authorization (EUA) order.

Antibodies are a protein created by the immune system to detect and defend against foreign tissues and pathogens. IgM and IgG antibodies respond to pathogens such as viruses and bacteria. The presence of antibodies in the bloodstream is detected typically around 5-15 days (IgM is within the first few days with IgG detected 7-15 days). Early testing may yield falsely negative results. This test is NOT used to diagnose a current COVID-19 infection and does not imply or confirm in any way immunity to SARS-CoV-2 (COVID-19) infection.

A positive test result indicates your immune system has had exposure to, or infection from, the SARS-CoV-2 (COVID-19) virus in the past.

A negative test result means that SARS-CoV-2 (COVID-19) specific antibodies were not present in the specimen, at a level above the limit of detection. A negative result does not rule out COVID-19.

An equivocal or borderline test result means that the test was unable to determine if SARS-CoV-2 (COVID-19) antibodies were or were not present in the sample. The test manufacturers recommend retesting in 2 weeks.

False negative results can occur. Risks of a false negative result could include but are not limited to: lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms. This may result in increased risk of spread of COVID-19 or other unintended adverse events.

False positive results can occur. Risks of false positive results could include, but are not limited to: delay in detection of the actual cause of symptoms, delaying care, management, and recommendation for actual causes of symptoms, recommendation of isolation which could include monitoring of household and other close contacts for symptoms, and limited contact with family or friends.

If you are exhibiting signs or symptoms of COVID-19 or have had a recent exposure, you may require additional and follow up testing. This test cannot be used as a sole basis for diagnosis, treatment, patient management decisions or to rule out active infection. Lab results must be considered in the context of clinical observations and epidemiological data to make final diagnosis.

Please initial the following:

Test without a visit:

_____ I request to have the SARS-CoV-2 Antibody Test performed, and do not wish to seek medical evaluation by a clinical provider.

Test with a visit:

_____ I request to have the SARS-CoV-2 Antibody Test performed and am also requesting medical evaluation by a clinical provider.

My signature constitutes acknowledgement and understanding of the above information as well as consent for Fry Laboratories, LLC to obtain a sample of my blood for the purpose of SARS-CoV-2 (COVID-19) antibody (serology) testing.

Patient (Guardian) Signature: _____ Date: _____