



## SARS-CoV-2 IgM/IgG Antibody Test Informed Consent

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 Emergency Use Authorization (EUA) order.

Antibodies are a protein created by the immune system to detect and defend against foreign tissue 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** results indicates your immune system has had exposure to, or infection from, the SARS-CoV-2 (Covid-19) 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.

**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 result could include but is not limited to: delay in detection of the actual cause of symptoms, delaying care, management, and recommendations for actual cause 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 a 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 The Center For Urgent Care to obtain a sample of my blood for the purpose of SARS-CoV-2 (Covid-19) antibody (serology) testing.

Patient (Guardian) Signature: \_\_\_\_\_ Date \_\_\_\_\_