



## COVID-19 Antibody Test Consent

I understand that this test looks for antibodies developed in response to SARS-CoV-2 (COVID-19), NOT the virus itself. I am electing to have this antibody test to assess whether I may have been exposed to the novel coronavirus in the past.

I hereby attest that I have been advised to take this test only as a completely asymptomatic individual and that I have been symptom-free for at least seven days. I understand that if I choose to have this test fewer than seven days after the resolution of symptoms, the results may be less reliable.

I understand that the test has potential risks associated with it, such as possible discomfort or other complications that may occur during sample collection and possible incorrect test results.

I understand that my test results are only a preliminary measure of IgG or IgG/IgM antibodies (qualitative measure) and that the values of antibodies (quantitative measures) may vary. I further understand that this test does not guarantee immunity to COVID-19 or any other virus.

I understand that, some antibody tests have been internally validated by the manufacturer and/or laboratory developer and it is permitted for use under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), originally issued by the FDA on March 16, 2020, it has not been reviewed or approved by the FDA.

I understand that some antibody tests have been authorized by FDA under an EUA for use by authorized laboratories during this public health emergency for the detection of nucleic acid (genetic material) from the SARS-CoV-2 via PCR analysis, (virus that causes COVID-19), however, it has been not cleared or approved by the FDA.

I also understand that certain limitations apply to COVID-19 antibody tests, such as the following: that negative results do not rule out a SARS-CoV-2 infection, particularly in individuals who have knowingly been in contact with the virus and that follow-up molecular testing may be necessary to rule out infection in those individuals; that positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E; and that results from antibody testing should not be used as the sole basis to or either diagnose or exclude SARS-CoV-2 infection or to inform infection status.

I HEREBY CERTIFY THAT I HAVE READ THE ABOVE ACKNOWLEDGEMENT AND HAVE HAD AN OPPORTUNITY TO ASK QUESTIONS ABOUT ITS CONTENTS. BY SIGNING BELOW, I CONSENT TO UNDERGO THE COLLECTION AND LABORATORY TESTING FOR COVID-19 ANTIBODY TESTS AS SET FORTH HEREIN.

Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_

\_\_\_\_\_  
Client Signature (or Legal Guardian)

\_\_\_\_\_  
Printed Name

\_\_\_\_\_  
Relationship if signing on behalf of the client