

SARS-CoV-2 (COVID-19) Serology/Antibody Test Options

In response to the global COVID-19 pandemic, Clinical Labs of Hawaii (CLH) now offers two serological (antibody) assays to support clinical evaluation of patients who may have been previously infected or exposed to SARS-CoV-2. Both are authorized by the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA).

The SARS-CoV-2 viral genome encodes four structural proteins (Spike (S), Nucleocapsid (N), envelope, and membrane proteins). The S protein is present on the viral surface with importance for entry into human cells, and the N protein interacts with viral RNA. The S and N proteins are two major antigenic targets that elicit the generation of antibodies by the immune system. Antibodies to both proteins typically develop post infection while antibodies to the S antibody only typically develop after a Spike-protein based mRNA vaccine. Most patients seroconvert within 2-3 weeks of illness.

Detection of antibodies indicates exposure to SARS-CoV-2. It is important to note that antibody tests, alone, cannot establish the immediate diagnosis of COVID-19 and cannot detect or rule out the presence of the virus. It is also unknown, at this time, how long antibodies persist following exposure and if antibodies serve as an indication of the presence or absence of protective or sustained immunity. Individuals recovering from COVID-19 may still be infectious for some time after seroconversion occurs and antibodies become detectable. For this reason, a positive antibody result should not alter quarantine, isolation, social distancing, or PPE practices.

Note: FDA, CDC, Infectious Disease Society of America (IDSA) and other expert groups recommend a narrow role for COVID-19 antibody testing. Those may include:

- Supporting diagnosis in patients who present too late for or have negative PCR (particularly pediatric patients for whom multisystem inflammatory syndrome may be a consideration)
- Determining susceptibility or resistance if a patient is exposed to COVID-19 depending upon immune status
- Identifying those with a suitable antibody response to provide plasma donation
- Assessing seroprevalence, public immune status and COVID-19 epidemiology

Insurance coverage is based on determination of medical necessity. Healthcare providers and patients are advised to contact their insurance company directly for coverage eligibility for antibody testing.

Test Information:

SARS-CoV-2 IgG Antibody	Test Code	CPT	Specimen	Reported TAT	Test Site	Method	Negative Percent Agreement (NPA)	Positive Percent Agreement (PPA)	
								Days Post Onset	PPA
N-protein (Nucleocapsid)	COVIGG (4223)	86769	Serum	24-48 hours	CLH Heights	CMIA (chemiluminescence)	99.63%	<3	0.00%
								3 – 7	50.00%
								8 – 13	91.18%
								>=14	100.00%
S-protein (Spike)	COVTAB (4230)	86769	Serum	24-48 hours	CLH Heights	ECLIA (electrochemiluminescence)	99.98%	0 – 7	90.6%
								8 – 14	87.0%
								>=15	96.6%

IMPORTANT: ASYMPTOMATIC patients can go to any CLH location for this blood test with an order from their provider. Due to social distancing guidelines, we recommend booking an appointment at www.clinicallabs.com/appointments/

References:

- <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/serologyantibody-tests-faqs-testing-sars-cov-2>
- <https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/serology/idsa-covid-19-ql-serology-v1.0.pdf>
- <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>
- <https://www.fda.gov/media/144035/download>
- <https://www.fda.gov/media/137381/download>

If you have any questions, please contact our Client Services Department at 808-677-7998 on Oahu or 1-866-281-6816 toll free.

Thank you for choosing Clinical Labs of Hawaii.