

Beutner Labs COVID-19 antibody testing accurately measures immune response to infection and vaccine

Commercial antibody tests targeting various components of the virus causing COVID-19 are now widely available. Most tests detect antibodies to the spike (S), membrane (M), envelope (E), and nucleocapsid proteins. In general, these tests are a measure of antibody response in a person who has recent or has had a past infection with the SARS-CoV-2 virus.

However, some of these tests may not be suitable for detection of antibody response to the vaccines. This is because the current FDA-EUS approved vaccines developed by Moderna, and BioNTech-Pfizer are mRNA vaccines directed against specific components of the spike protein.

Antibody tests targeting proteins other than the RBD of the S1 unit are unlikely to detect COVID-19 vaccine-induced antibody response and produce false negative antibody results. Therefore, it is very important to select a test optimally designed to measure and track vaccine induced antibody response.

Humoral immune responses are typically characterized by primary immunoglobulin (IgM) antibody responses followed by secondary antibody responses associated with immune memory composed of IgG and IgA antibody isotypes. SARS-CoV-2 elicits robust humoral immune response, including production of virus-specific antibodies of the IgM, IgG, and IgA isotypes. Patients

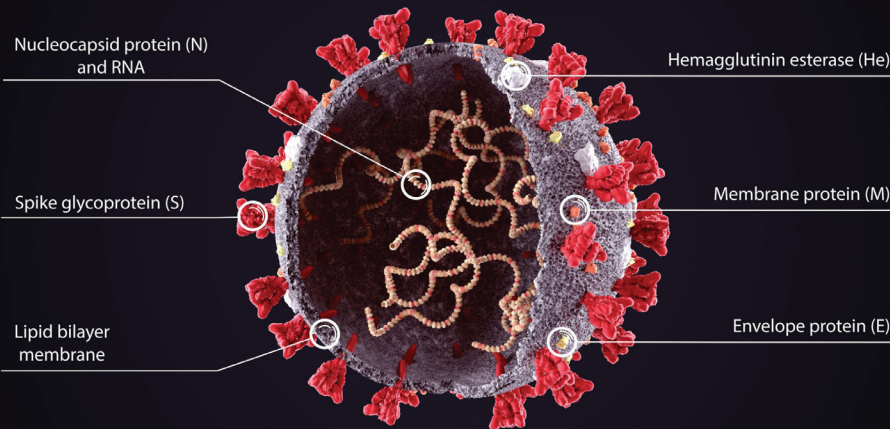


FIGURE 1:

Anatomy of the COVID-19 virus showing the spike (S), membrane (M) and envelope (E) proteins embedded on the virion shell, and the nucleocapsid (N) protein located in the interior core.

have been shown to begin producing antibodies, a process called seroconversion, within 20 days of symptom onset, although the timing for IgM and IgG production are variable. Data also shows that IgA might be detected earlier than IgG and produce robust mucosal immunity.

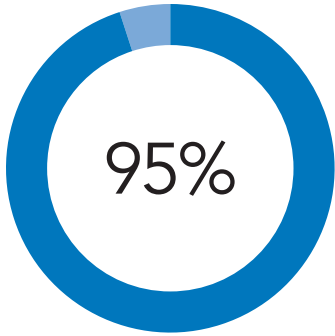
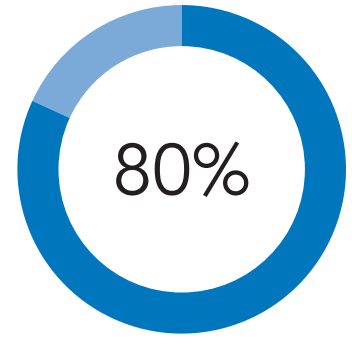
The Beutner Labs COVID-19 antibody test specifically measures the components of spike protein—namely the receptor binding domain (RBD) of the S1 unit.

Beutner Labs, a NYS/CLIA/CAP and ISO-certified laboratory offers SARS-CoV-2 IgM, IgG and IgA antibodies. It is one of the few tests that can measure all three immunoglobulin types semi-quantitatively and is NYSDOH approved. The test detects antibodies against the SARS-CoV-2 spike protein/structural protein (S1 RBS RBD). It is effective in detecting vaccine-induced antibody responses and SARS-CoV-2 infection. The following data from our partner laboratory, KSL diagnostics highlights the usefulness of this test.

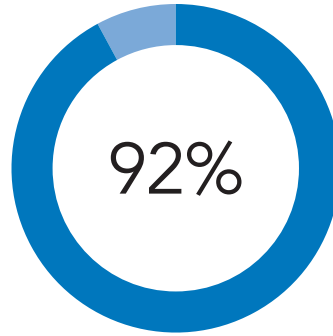
Longitudinal Antibody Response Study

KSL Diagnostics, in collaboration with its local partners, has launched a longitudinal study to measure the antibody responses in vaccinated individuals. Blood is collected (a) before SARS-CoV-2 vaccination, (b) 15 days post first dose vaccination, (c) 15 days post second dose vaccination, (d) six months post first dose, and (e) one year post first dose. Individuals in the study were given either Moderna or Pfizer vaccines. At the time of this writing, only the 15 days post first vaccination antibody response data was available and is summarized in these charts.

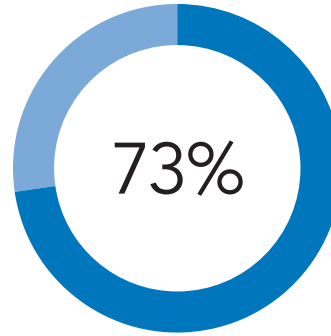
80.2% of all **pre-vaccine negative test subjects** showed antibodies 15 days after the first vaccination.



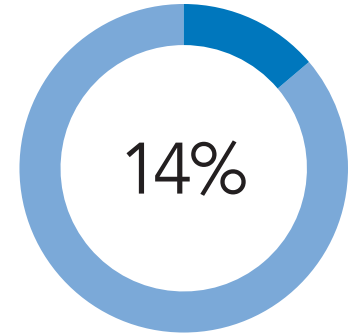
Test subjects **55 years or younger** show antibodies.



Test subjects **56-65 years old** show antibodies.



Test subjects **66-79 years old** show antibodies.



Test subjects **80 years or older** show antibodies.

Sensitivity — 59 PCR confirmed patient sera samples were tested on the Beutner Labs SARS-CoV-2 Antibody Tests. Results of the 59 PCR positive patients along with the percent positivity for different sample draw days are shown below.

Stage of Disease	Days Since 1 st Symptoms	# Patients	IgA Antibody		IgG Antibody		IgM Antibody	
			# Pos	% Pos	# Pos	% Pos	# Pos	% Pos
Acute phase (early)	≤ 7 days	10	7	70.0%	7	70.0%	6	60.0%
Recovery period (mid)	8-14 days	19	17	89.5%	18	94.7%	16	84.2%
Cure/ discharge period (late)	≥ 15 days	30	30	100.0%	30	100.0%	29	96.7%

Specificity — Sensitivity was determined by testing 865 SARS-CoV-2 PCR negative patient samples and 252 SARS-CoV-2 PCR positive patient samples for a total of 1,117 patient samples tested.

	IgA Antibody		IgG Antibody		IgM Antibody	
Sensitivity	91.5%	95% CI 80.6%-96.8%	93.2%	95% CI 82.7%-97.8%	86.4%	95% CI 74.5%-93.6%
Specificity	98.8%	95% CI 99.1%-100.0%	99.2%	95% CI 98.31%-99.7%	99.4%	95% CI 98.5%-99.8%

**Questions?
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