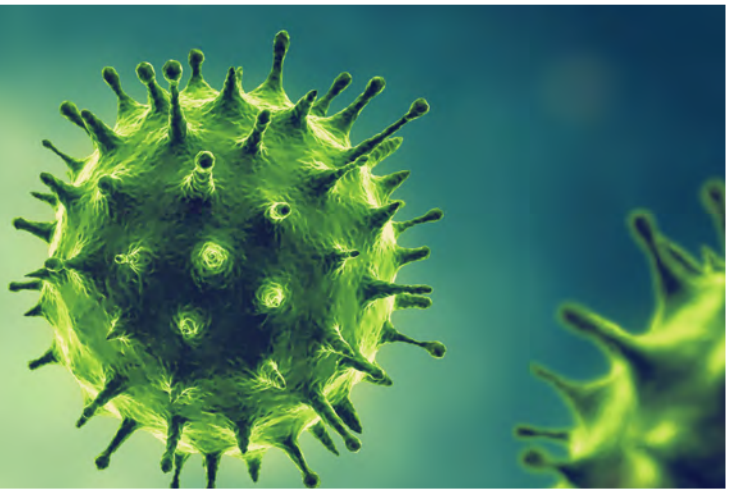
VibrantAmerica

VIBRANT COVID-19 IMMUNECHECK

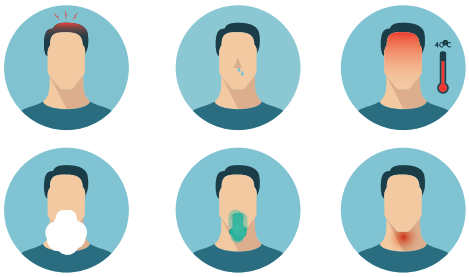
The first FDA-EUA authorized test on Dried Blood Spot. Test for exposure to COVID-19.



Which Patients Need the Vibrant COVID-19 Test?

The CDC reports that the following symptoms may appear 2-28 days after exposure:

- Coughing
- Fever
- Shortness of breath
- Sore throat
- Fatigue
- Body aches
- Headaches
- Gastrointestinal distress
  - *Diarrhea*
  - *Abdominal cramping*



Vibrant COVID-19 Testing

- Vibrant has developed a novel test for COVID-19. This test is a highly sensitive and accurate serum assay for COVID-19 viral antibodies.
- Our test was internally developed and validated according to FDA EUA requirements. The independent review of this validation by the FDA is pending. This test does not require confirmation by CDC prior to reporting results

Please Note:

A patient cannot order their own tests

A doctor's requisition or lab script is required for all testing

Clinical Connections and Testing for COVID-19

- Vibrant has developed a novel test for COVID-19. Vibrant's COVID-19 panel is a highly sensitive and accurate assay collected via either dried blood spot or serum for viral antibodies.
- The Vibrant COVID-19 Ab assay is a chemiluminescence immunoassay (CLIA) intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum or Dried Blood Spot (DBS) using fingerstick blood specimen collected by the health care provider.
- The Vibrant COVID-19 Ab assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.
- Our test was internally developed and validated according to FDA EUA requirements. This test does not require confirmation by CDC prior to reporting results

1(866) 364-0963
support@vibrant-america.com
www.vibrant-america.com
1021 Howard Ave. Ste. B
San Carlos, CA 94070

What Does the Vibrant COVID-19 Test Include?

IgM and IgG Antibodies to:

SARS-CoV-2 Nucleoprotein	*SARS-CoV-2 Spike Glycoprotein (S2)*
SARS-CoV-2 Spike Glycoprotein (S1)	*SARS-CoV-2 Receptor Binding Domain*

Quick Validation Data*

Table 1: *Overall Performance (IgM and IgG) of Vibrant COVID-19 Ab Assay*

Vibrant COVID-19 Ab Assay		Clinical Diagnosis-NP Swab (RT-PCR) or Prior to Outbreak		Total	Analysis (95% Confidence)
		Positive	Negative		
Combined IgG/IgM	Positive	52	7	59	Positive Percent Agreement (PPA) = 98.11% *(90.06% - 99.67%)*
	Negative	1	494	495	Negative Percent Agreement (NPA) = 98.60% *(97.14% - 99.32%)*
Total		53	501	554	

**Please refer to Vibrant America's full validation report for expanded detail on the validation process and quality controls for the COVID-19 panel*

Table 2: *The antibody results for the SARS-CoV-2 PCR positive specimens stratified based on the time in days between NP swab RT-PCR test results and the time serum was collected for the antibodies to SARS-CoV-2 antigens*

Days after NP swab RT-PCR test	# of Samples	Overall IgM + IgG	IgG PPA	IgM PPA
< 7 days	7	85.71%	71.43%	85.71%
7 - 14 days	20	100%	100%	100%
> 14 days	26	100%	100%	88.46%
Total	53	98.11%	96.23%	92.45%

Regulatory Statement

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the presence of antibodies against SARS-CoV-2, not for any other viruses or pathogens;
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.