

# COVID-19 Multi-Antigen Serology Panel

Qualitative detection of antibodies to SARS-CoV-2 (EUA Authorized)

## Who We Are

Genalyte is a CAP accredited, CLIA certified lab specializing in large scale serology testing. Our EUA authorized Maverick™ SARS-CoV-2 Multi-Antigen Serology Panel v2 uses a multiplex format to test patient samples for antibodies to five SARS-CoV-2 proteins. The result is unparalleled accuracy across a variety of patient populations.

## Assay Overview and Performance

Maverick™ SARS-CoV-2 Multi-Antigen Serology Panel v2 is designed to test for SARS-CoV-2 antibodies as well as other viruses that have similar symptoms but are not COVID-19. Unlike competitive serology tests that only detect antibodies to a limited number of SARS-CoV-2 antigens, the Maverick™ SARS-CoV-2 Multi-Antigen Serology Panel v2 includes five SARS-CoV-2 antigens. The larger number of antigens tested reduces false positives and negatives. As a result, our multiplex solution can be effectively used in ambulatory and inpatient settings.

### Post Seroconversion: 8-14 days

MAVERICK	PCR Result		
	Pos	Neg	
Pos	80	20	100
Neg	8	842	850
	88	862	

**Sensitivity**                    **91%**  
**Specificity**                   **98%**

### Post Seroconversion: > 14 days

MAVERICK	PCR Result		
	Pos	Neg	
Pos	174	20	194
Neg	7	842	849
	181	862	

**Sensitivity**                    **96%**  
**Specificity**                   **98%**

## Assay Specifications

Antibodies Detected	IgG, IgM
Number of Targets	26
Time to Result	20 minutes
Sample Type	EDTA Whole blood, serum
Detection Method	Photonic Ring Resonance
Min. Sample Volume	10-20µl
Sample Stability	2-8°C (4 day WB; 7 day Serum)

## Panel Antibodies

<b>SARS-CoV-2</b>	Anti-Nucleocapsid IgG and IgM Anti-Spike S1 RBD IgG and IgM Anti-Spike S1S2 IgG and IgM Anti-Spike S2 IgG and IgM Anti-Spike S1 IgG and IgM
<b>Benign CoV</b>	Anti-CoV OC43 IgG and IgM Anti-Cov HKU1 IgG and IgM Anti-Cov nl63 IgG and IgM Anti-Cov 229E IgG and IgM
<b>SARS-CoV</b>	Anti-Nucleocapsid IgG and IgM
<b>MERS</b>	Anti-S1 IgG and IgM
<b>Influenza</b>	Anti-H1 IgG and IgM Anti-H3 IgG and IgM

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## Our Platform

The Maverick™ Diagnostic System (MDS) uses silicon chip based photonic ring resonance technology to perform multiple simultaneous rapid tests on a small volume of whole blood or serum. The system is cloud-connected for assay protocol retrieval and clinical oversight. Results are available in 20 minutes. FDA Cleared in 2019.

## Maverick Immunoanalyzer

- Benchtop solution available for On-Site or Core Laboratory testing
- Can run four patients simultaneously
- Runs multiplex panels with results in 20 minutes
- 250 patients/day
- High sensitivity and specificity
- Cloud-connected with CLIA/CAP pathology oversight
- 11" high X 16" wide X 23" deep



## Reference Lab Testing - Sample Collection and Shipment



- One 4ml EDTA tube is the recommended sample type<sup>(1)</sup>
- Tubes must be barcoded and accessioned onsite using Genalyte's physician portal
- Samples should be shipped for overnight delivery at 2-8°C
- Packaging and transport of specimens should meet IATA and DOT requirements
- Samples should be shipped to the Genalyte Core Lab identified in the LSA

<sup>(1)</sup> An alternative would be serum collected in a 4 ml SST tube