Genesis Laboratory Management, LLC
The Laboratory of Choice

STELLUX®* COVID-19 Serological Assays

Qualitative IgM and Quantitative IgG Assessment

Genesis Laboratory is pleased to offer the ALPCO** COVID-19 serological assays which are intended for the qualitative measurement of IgM and quantitative measurement of IgG antibodies against SARS-CoV-2 in serum and plasma. Measuring these antibodies facilitates a better understanding of disease progression and the ability to address broader epidemiological questions about transmission patterns. By leveraging chemiluminescence, the ALPCO serological assays offer superior analytical sensitivity which enables more accurate detection across a broad dynamic range of IgM and/or IgG levels.

Featured Assays

SARS-CoV-2 IgM Chemi ELISA***

Catalog #:	80-SARS2M-CH01
Sample types:	Serum, plasma
Sample size:	10 µL
Range:	Qualitative
Time to results:	2 hours

SARS-CoV-2 IgG Chemi ELISA***

Catalog #:	80-SARS2G-CH01
Sample types:	Serum, plasma
Sample size:	10 µL
Range:	7.5 - 7500 ng/mL
Time to results:	2 hours

STELLUX® chemiluminescence

* STELLUX® is ALPCO's chemiluminescence ELISA platform aimed at detecting key biomarkers in life sciences research.
**ALPCO is a leading provider of immunoassays to advance research and clinical providers https://www.alpco.com/.
*** For In Vitro Diagnostic Use.

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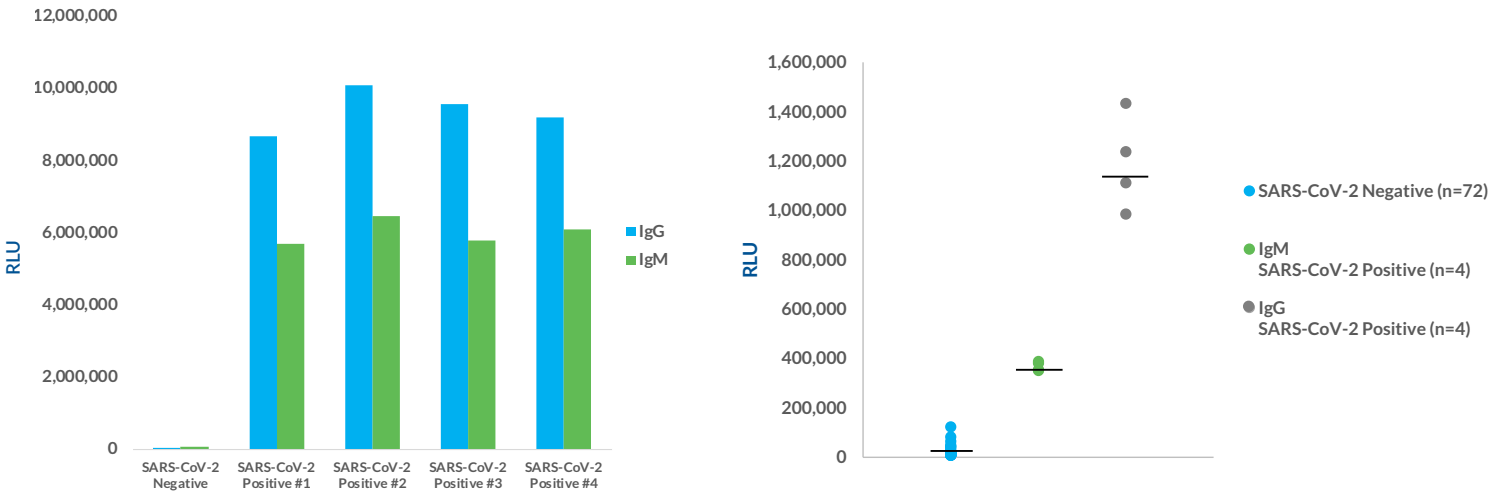
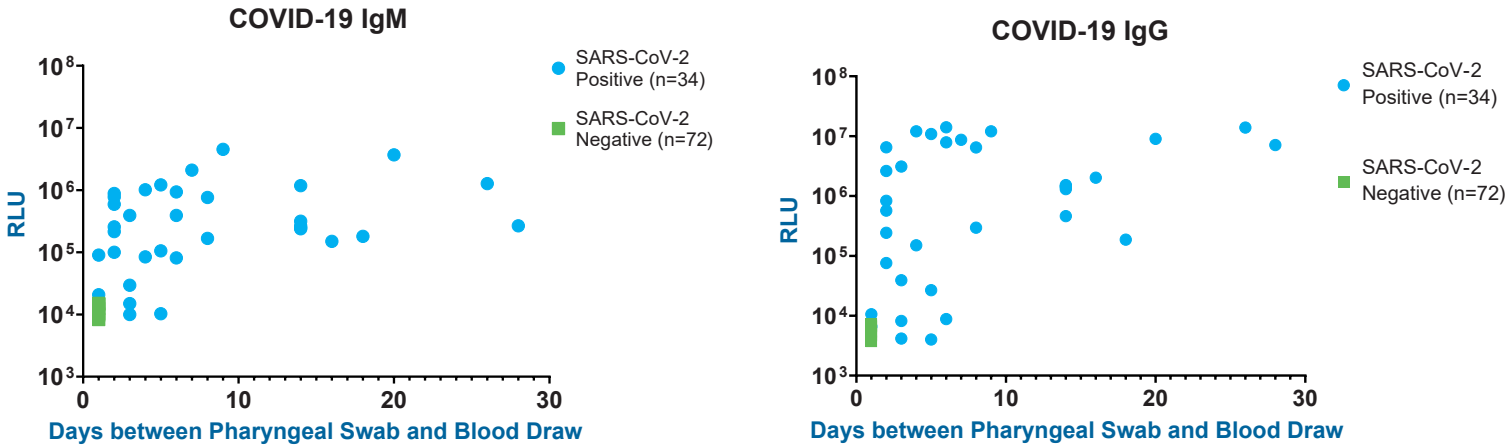
IgM and IgG Detection

A total of 4 SARS-CoV-2 positive and 1 SARS-CoV-2 negative samples were tested for IgM and IgG levels. The ALPCO COVID-19 serological assays were able to effectively discriminate signal between the two cohorts.



IgM and IgG Profiling

A total of 34 SARS-CoV-2 positive and 72 SARS-CoV-2 negative samples were tested for IgM and IgG levels from zero to 30 days post diagnosis. The trends in both plots are indicative of classical immune response.



All SARS-CoV-2 positive samples tested for the presence of SARS-CoV-2 IgM displayed a positive antibody result. All SARS-CoV-2 negative samples tested for the presence of SARS-CoV-2 IgM displayed a negative antibody result.

		Comparator method/Clinical truth (PCR)	
		Positive	Negative
ALPCO IgG Assay	Positive	30	0
	Negative	0	80

Positive Percent Agreement (PPA): 30/(30+0) x 100% = 100%

Negative Percent Agreement (NPA): 80/(80+0) x 100% = 100%

Sensitivity for SARS-CoV-2 IgG: 100%

Specificity for SARS-CoV-2 IgG: 100%

Matrix Equivalency

Both serum and plasma were evaluated as part of this clinical study and are claimed as suitable for use in the assay. Please note that assay cutoff and sample dilution are uncharged regardless of whether serum or plasma are used.

Conditions of authorization for the laboratory

The SARS-CoV-2 IgM Chemiluminescence ELISA Letter Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/emergency-situations-medicaldevices/emergency-use-authorization#covid19ivd.

Regulatory Statement

- This test has been submitted to the FDA for review under EUA for the declared public health emergency for COVID.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARSCoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

FDA EUA Guidelines

The ALPCO SARS-CoV-2 Chemiluminescence IgG and IgM assays meet the following FDA EUA guidelines for specificity:

If a large number of known negative samples (e.g., ≥75 samples collected in the US prior to December 2019) are tested from a population with a high prevalence of vaccination against, and/or infection with, the following viruses, and specificity >98% is observed, cross-reactivity testing for the following viruses would not be expected at this time: anti-influenza A (IgG and IgM), anti-influenza B (IgG and IgM), anti-HCV (IgG and IgM), anti-HBV (IgG and IgM), anti-Haemophilus influenzae (IgG and IgM), anti-229E (alpha coronavirus), anti-NL63 (alpha coronavirus), anti-OC43 (beta coronavirus), anti-HKU1 (beta coronavirus), ANA, anti-respiratory syncytial virus (IgG and IgM) and anti-HIV.

The ALPCO SARS-CoV-2 Chemiluminescence IgG and IgM assays utilized 30 sero-positive (via PCR testing) SARS-CoV-2 samples and 80 sero-negative samples (serum/plasma from 2012 or earlier) in this study. Results showed 100% specificity and 100% sensitivity in both assays.