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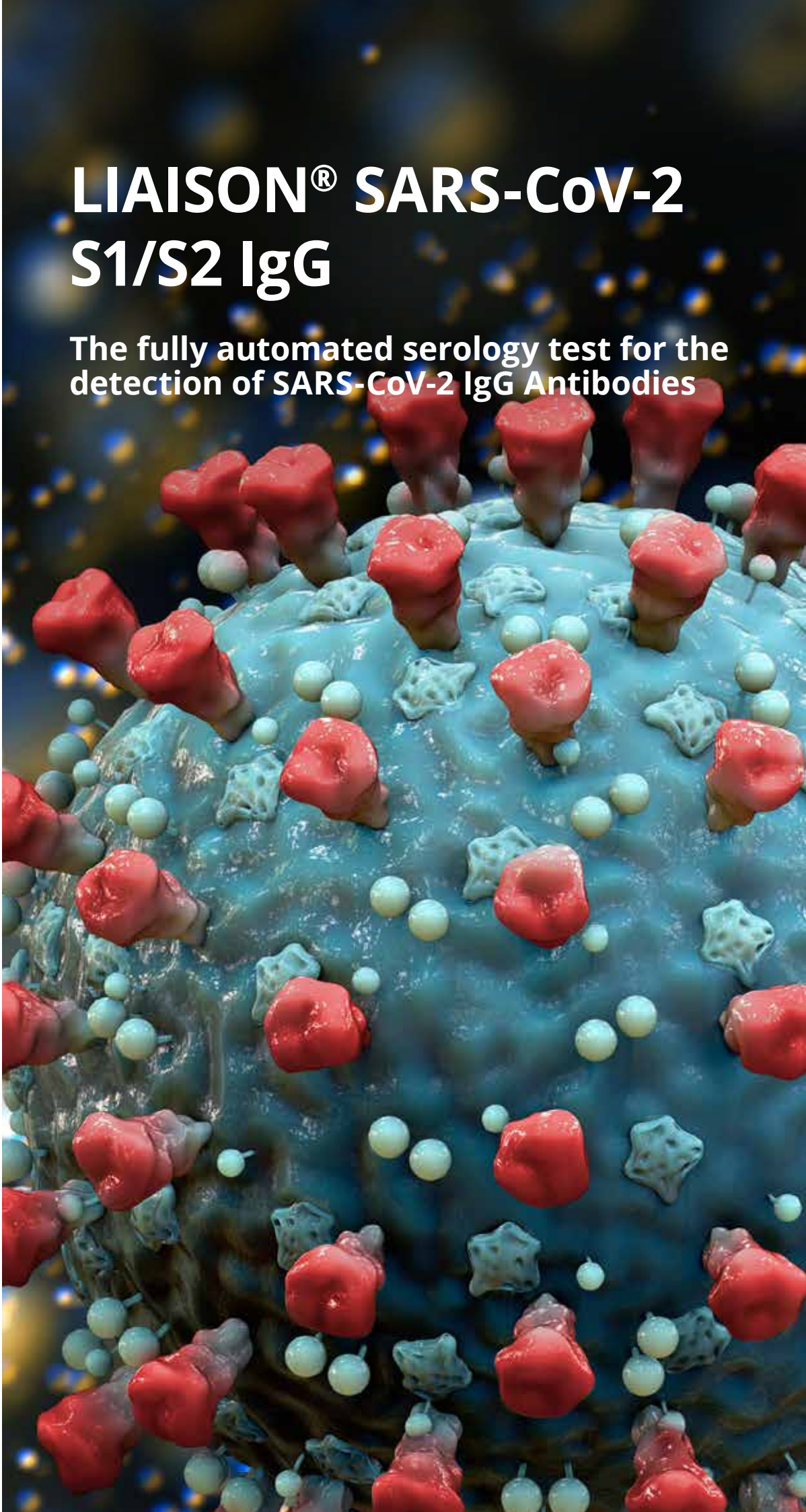
LIAISON® SARS-CoV-2 S1/S2 IgG

The fully automated serology test for the detection of SARS-CoV-2 IgG Antibodies



INFECTIOUS DISEASE

FOR OUTSIDE
THE US
AND CANADA ONLY

DiaSorin

The Diagnostic Specialist

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LIAISON® SARS-CoV-2 S1/S2 IgG

The fully automated serology test to detect IgG antibodies against SARS-CoV-2.

The new LIAISON® SARS-CoV-2 S1/S2 IgG test provides diagnostic laboratories with:

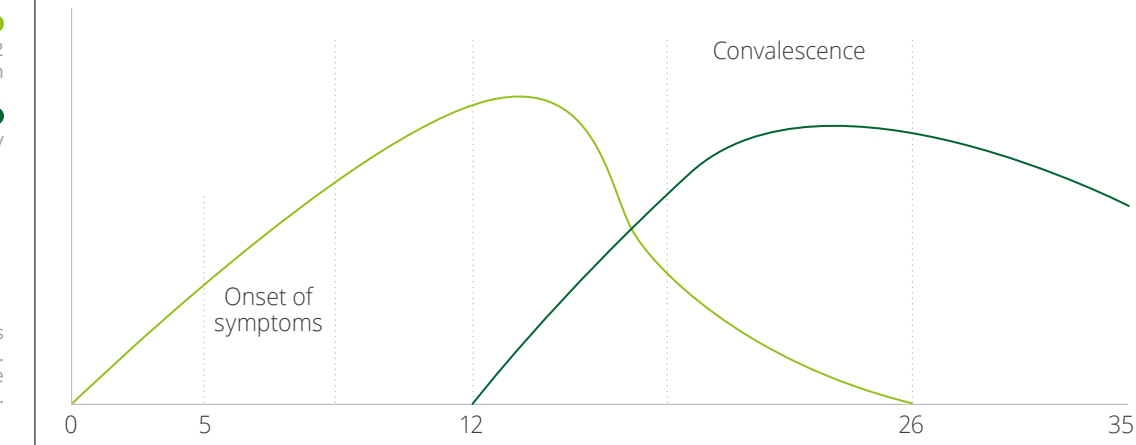
- A fully automated quantitative solution for the detection of IgG antibodies against S1/S2 antigens of SARS-CoV-2
- Up to 170 results/hour on LIAISON® XL
- Detection of Neutralizing antibodies: 94.4% positive agreement to Plaque Reduction Neutralization Test (PRNT)
- High sensitivity and specificity to assure accurate results

COVID-19 and SARS-CoV-2

Coronavirus disease (COVID-19) is a respiratory infectious disease caused by the newly discovered coronavirus SARS-CoV-2. The first cases were reported by Chinese authorities in December 2019, in Wuhan City, Hubei province. The initial outbreak in Wuhan spread rapidly, affecting first other regions of China and then an increasing number of countries world- wide. The Director General of the World Health Organization declared COVID-19 a global pandemic on 11 March 2020. [1]

Timing of seroconversion

Timing of seroconversion is a key factor in establishing the appropriate time window to use serology tests. Recent publications indicate that the median for IgG seroconversion is between 9 and 14 days after disease onset. [2,3]
Furthermore, since viral RNA can be detected in patients after 20 or more days [4] a positive IgG result should not be interpreted as a sign that a patient has stopped being infective.



RNA and IgG trends in COVID-19 infection. This figure is for illustrative purpose only.

Spike antigens for better diagnostic results

The S1 and S2 proteins are derived from the SARS-CoV-2 spike protein: they are responsible for the binding and fusion of the virus to the host cell. As the protein on the viral surface that is responsible for entry into the host cell, the spike protein and its antigens are the main antigen target of neutralising antibodies. [5]

The LIAISON® SARS-CoV-2 tests uses magnetic beads coated with S1 & S2 Antigens.

- The antigens used in the tests are expressed in human cells to achieve proper folding, oligomer formation, and glycosylation, providing material similar to the native spikes. This strategy ensures that the antigen-antibody complex forms with the required specificity.
- The S1 and S2 proteins are both targets to neutralizing antibodies. By using these antigens, the likelihood of concordance to a neutralization assay is increased significantly

Diagnostic Sensitivity

	LIAISON® SARS-CoV-2 S1/S2 IgG			Total	Sensitivity (Wilson 95% CI)
	< 12 AU/mL	12 -15 AU/mL	≥ 15 AU/mL		
≤ 5 days	31	2	11	44	25.0% (14.6% - 39.4%)
5-15 days	4	1	47	52	90.4% (79.4% - 95.8%)
> 15 days	1	0	38	39	97.4% (86.8% - 99.5%)

Diagnostic Specificity

	LIAISON® SARS-CoV-2 S1/S2 IgG			Total	Specificity (Wilson 95% CI)
	< 12 AU/mL	12 -15 AU/mL	≥ 15 AU/mL		
Laboratory routine	89	0	1	90	98.9% (94.0% - 99.8%)
Blood donors	985	8	7	1000	98.5% (97.5% - 99.2%)

Concordance with Plaque Reduction Neutralization Test

The comparison to PRNT was evaluated by testing 304 samples collected during the outbreak from subjects whose PRNT result was available.

LIAISON® SARS-CoV-2 S1/S2 IgG	PRNT titers		Total
	negative	*positive*	
Negative (< 12.0 AU/mL)	176	1	177
Equivocal (12.0 – 15.0 AU/mL)	1	6	7
Positive (> 15.0 AU/mL)	3	117	120
Total	180	124	304

	Proportion	Wilson 95% CI
Negative agreement	97.8% (176/180)	94.4% - 99.1%
Positive agreement	94.4% (117/124)	88.8% - 97.2%

The presence of NAbs is commonly considered as a possible sign of protection against a pathogen. It should be noted that lack of scientific data at this time does not allow yet to determine if neutralizing IgG antibodies against SARS-CoV-2 provide long term immunity to the virus or if they protect patients against re-infection.

1. European Centre for Disease Prevention and Control (ECDC). Novel Coronavirus. Available from: https://www.ecdc.europa.eu/en/novel-coronavirus-china (last page update March 24 2020)
2. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. Zhao J. et al. Clin Infect Dis. 2020 Mar 28
3. Severe Acute Respiratory Syndrome Coronavirus 2–Specific Antibody Responses in Coronavirus Disease 2019 Patients. Okba et al. Emerg Infect Dis. 2020 Apr 8;26(7)
4. Temporal profiles of viral load in posterior oropharyngeal saliva samples and serum antibody responses during infection by SARS-CoV-2: an observational cohort study. To K. et al Lancet Inf Dis, Published Online March 23, 2020 https://doi.org/10.1016/S1473-3099(20)30196-1
5. Developing antibody tests for SARS-CoV-2. Petherick, A. www.thelancet.com Vol 395 April 4, 2020

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Ordering information & Specs

LIAISON® SARS-CoV-2 S1/S2 IgG	311450
KIT FORMAT	110 test/integral
TIME TO FIRST RESULT	35 min
THROUGHPUT	Up to 170 test/hour
OPEN/ON BOARD KIT STABILITY	Up to 2 weeks
CALIBRATION STABILITY	Up to 2 weeks
No potential cross-reactivity with other coronaviruses observed	Samples tested: 3 Anti-Human CoV OC43; 1 Anti-Human CoV HKU1, 4 Anti-Human CoV unknown strain.
No Biotin potential inference observed	Up to 3500 ng/mL

Controls

LIAISON® SARS-CoV-2 S1/S2 IgG	311451
KIT FORMAT	2 levels x 2 vials (up to 40 runs)
Open/on board controls stability	Up to 4 weeks

Please visit: **www.diasorin.com/covid19CE**
for more information and updates

Available only on LIAISON®

Product availability subject to required regulatory approval

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