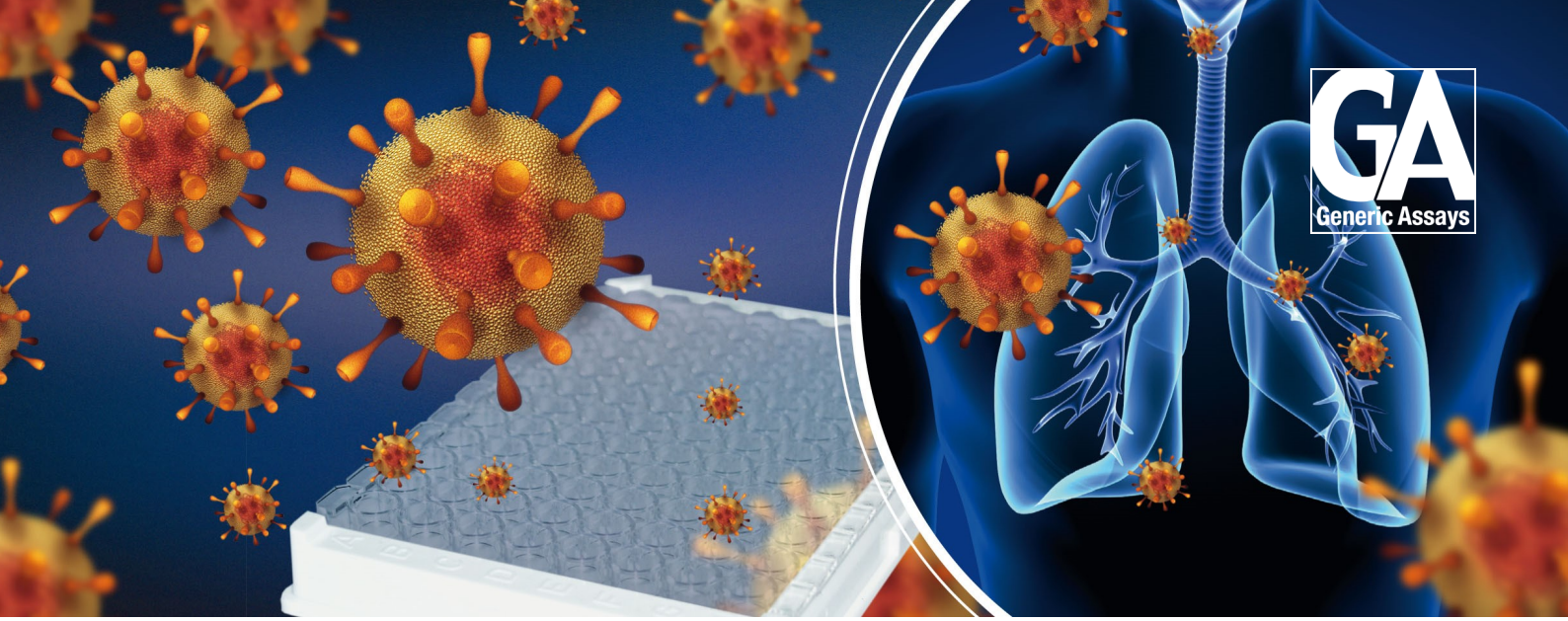
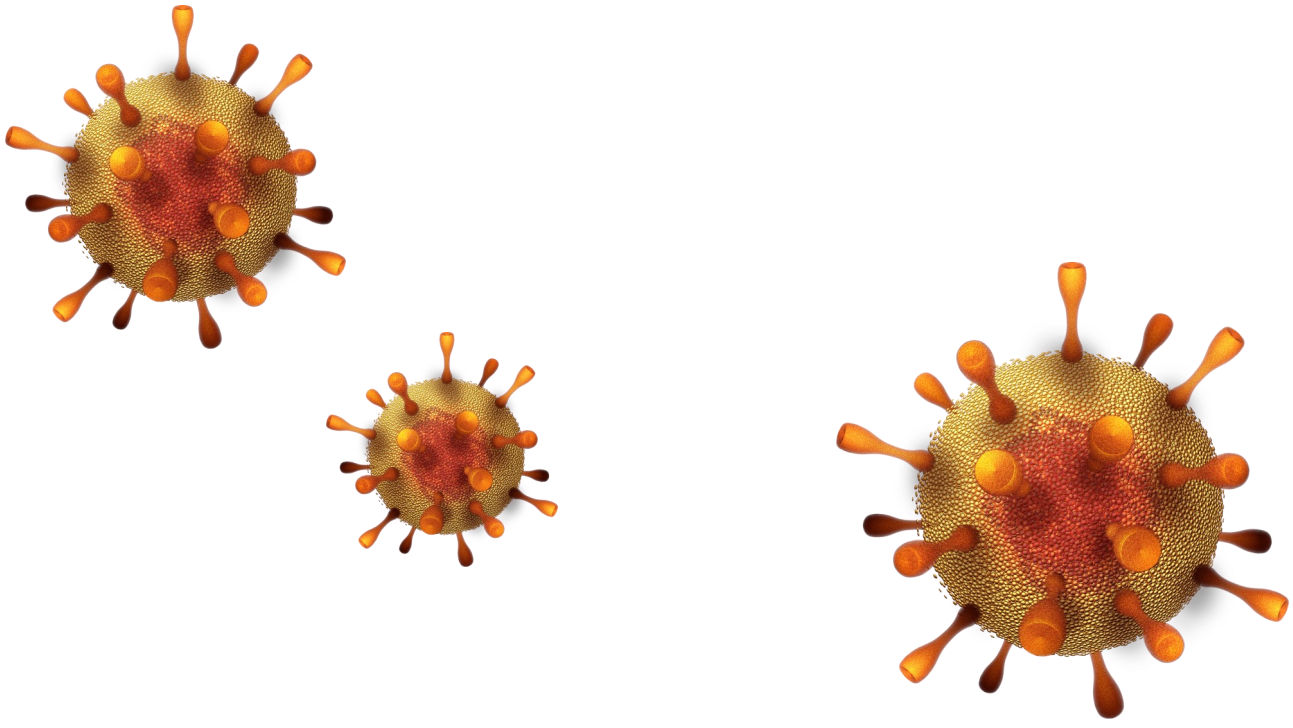


Clinical Data

GA CoV-2 IgG

GA CoV-2 IgM

GA CoV-2 IgG +

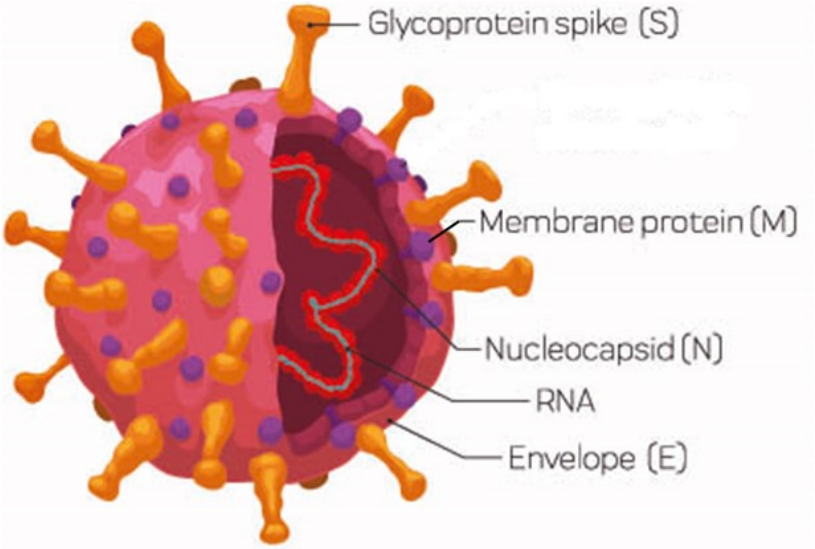


GA CoV-2 IgG / IgM / IgG +

Anti SARS-CoV-2 ELISA Kits in Clinical Evaluation

Introduction

The Severe Acute Repiratory Coronavirus 2 (SARS-CoV-2) belongs to the betacoronavirus group, a group that also comprises SARS-CoV (2003) and MERS-CoV (2012). First identified in a respiratory disease outbreak in Wuhan City, Hubei Province, China, SARS-CoV-2 is responsible for the current global pandemic. Like all coronaviruses, the genome of SARS-CoV-2 encodes the spike protein (S) with the immunogenic domains S1 and S2, the envelope protein, the membrane protein (M) and the nucleocapsid protein (N).

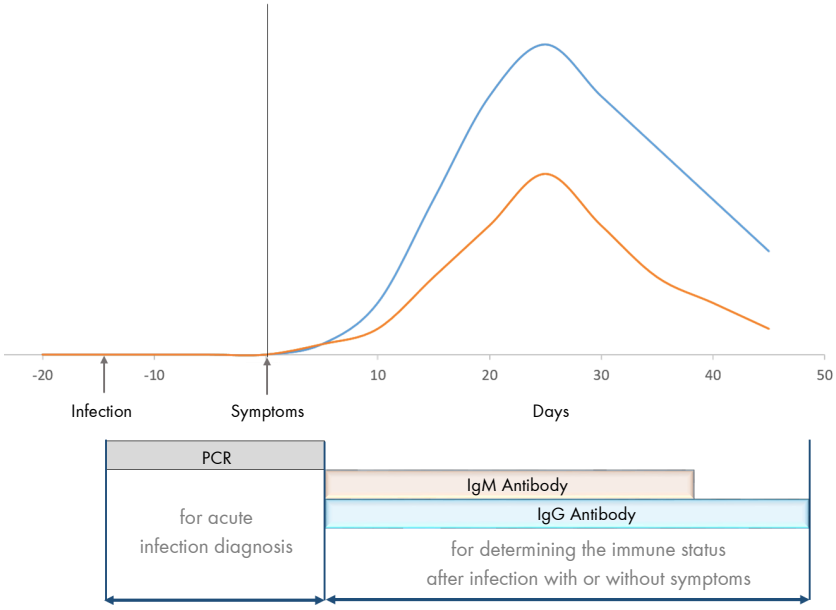


Coronavirus disease 2019 (COVID-19) is typically characterized by respiratory symptoms occurring mainly after droplet transmission. However, patients infected with the SARS-CoV-2 can show a wide range of symptoms. In the mild form of COVID-19, symptoms are similar to those of a cold/flu, while in severe cases a developing pneumonia of both lungs can lead to the death of the patient. By ACE2 (angiotensin converting enzyme 2), which is abundantly present in the lungs, the virus gains access to the host cells.

The current understanding of the incubation period of SARS-CoV-2 infections is still limited. Different studies show ranges from 2 to 14 days. These estimates are in line with known incubation periods of other human coronaviruses, including SARS (range: 2 to 14 days, mean: 5 days), MERS (range: 2 to 14 days), mean: 5 to 7 days) and non-SARS human coronavirus (range: 2 to 5 days, mean: 3 days).

GA CoV-2 IgG / IgM / IgG +

Illustrative course of SARS-CoV-2 antibodies



Commonly performed PCR SARS-CoV-2 tests examine the genetic material of the virus in oral swabs and give a positive result only if the virus is still present. Therefore, these tests do not identify individuals who have survived an infection, recovered and removed the virus from their bodies.

Reliable determination of a SARS-CoV-2 infection by patient screening is an essential component to assess the individual immune status, to control the existing pandemic and to reduce the spread of SARS-CoV-2 by targeted measures.

GA CoV-2 IgG / IgM

Clinical Specificity

A total no. of 1000 samples (blood donors; samples from diagnostic routine; 500 collected until December 2019 and 500 collected during the outbreak) were tested for anti-SARS-CoV-2 IgG and IgM antibodies with the GA SARS-CoV-2 IgG and IgM assays.

The GA CoV-2 IgM assay showed a specificity of >98%, while the data for the GA CoV-2 IgG kits resulted in a slightly lower specificity (>95%). The false positive IgG antibodies were mainly reactive with the nucleocapsid. These antibodies were probably generated during previous infections by other coronaviruses.

GA CoV-2 IgG / IgM / IgG +

Clinical Sensitivity

A clinical study performed in a European emergency center encompassing 104 samples with PCR data ascertained IgG and IgM against SARS-CoV-2 (65 patients with PCR positivity and 39 with negative samples).

Less than/equal to 7 days post onset of symptoms (CI confidence interval)

	PCR+	PCR-	total
GA CoV-2 IgG +	8	0	8
GA CoV-2 IgG -	7	13	20
total	15	13	28

IgG <= 7d	%	95% CI
clinical sensitivity	53.3	30.1 - 75.2
clinical specificity	100	77.2 - 100

	PCR+	PCR-	total
GA CoV-2 IgM +	4	0	4
GA CoV-2 IgM -	11	13	24
total	15	13	28

IgM <= 7d	%	95% CI
clinical sensitivity	26.7	10.9 - 51.0
clinical specificity	100	77.2 - 100

Between 8 to 10 days post onset of symptoms

	PCR+	PCR-	total
GA CoV-2 IgG +	10	0	10
GA CoV-2 IgG -	4	13	17
total	14	13	27

IgG 8-10d	%	95% CI
clinical sensitivity	71.4	45.4 - 88.3
clinical specificity	100	77.2 - 100

GA CoV-2 IgG / IgM / IgG +

Between 8 to 10 days post onset of symptoms

	PCR+	PCR-	total
GA CoV-2 IgM +	7	0	4
GA CoV-2 IgM -	7	13	20
total	14	13	27

IgM 8-10d	%	95% CI
clinical sensitivity	50.0	26.8 - 73.2
clinical specificity	100	77.2 - 100

More than 10 days post onset of symptoms

	PCR+	PCR-	total
GA CoV-2 IgG +	35	0	35
GA CoV-2 IgG -	1	13	14
total	36	13	49

IgG >10d	%	95% CI
clinical sensitivity	97.2	85.8 - 99.5
clinical specificity	100	77.2 - 100

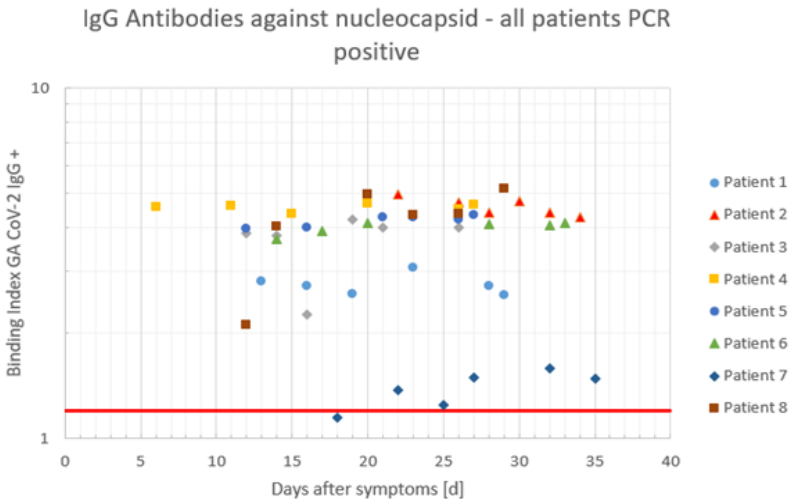
	PCR+	PCR-	total
GA CoV-2 IgM +	34	0	34
GA CoV-2 IgM -	2	13	15
total	36	13	49

IgM >10d	%	95% CI
clinical sensitivity	94.4	81.9 - 98.5
clinical specificity	100	77.2 - 100

All assays (GA CoV-2 IgG / IgM / IgG +) showed sensitivities of ≥98 % after 14 days of PCR confirmation.

GA CoV-2 IgG / IgM / IgG +

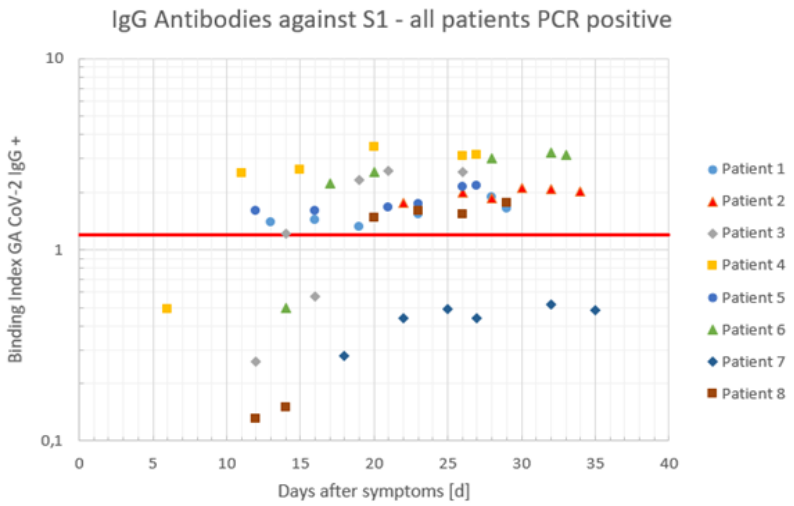
Red line represents the cut-off value

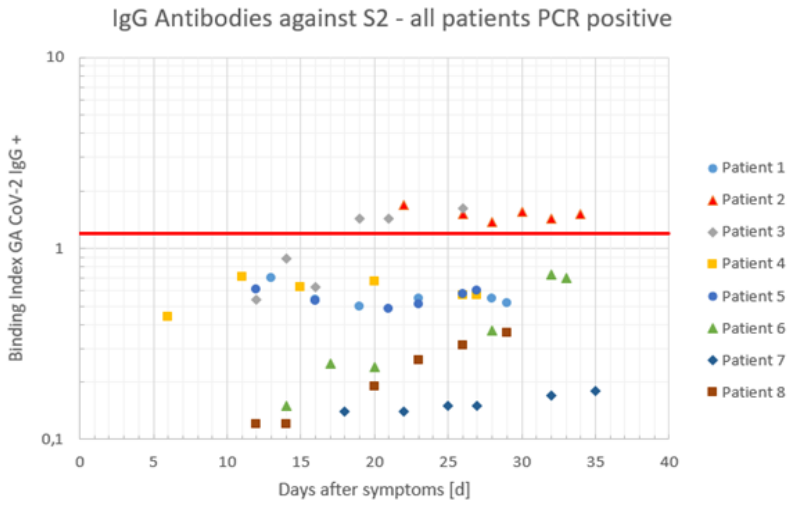


The GA CoV-2 IgG + ELISA COVID-19 confirmation kit detects three different IgG antibodies reactive to:

nucleocapsid, spike protein domain 1 (S1) and spike protein domain 2 (S2).

Seroconversion was assessed in eight COVID-19 patients with confirmed SARS-CoV-2 by PCR. Of these eight patients, all demonstrated the generation of IgG against the nucleocapsid within the observation period. One patient did not show positive IgG to S1 until the 35th day after onset of symptoms whereas 6 patients did not develop detectable IgG to S2.





GA CoV-2 IgG / IgM / IgG +

GA CoV-2 IgG / IgM

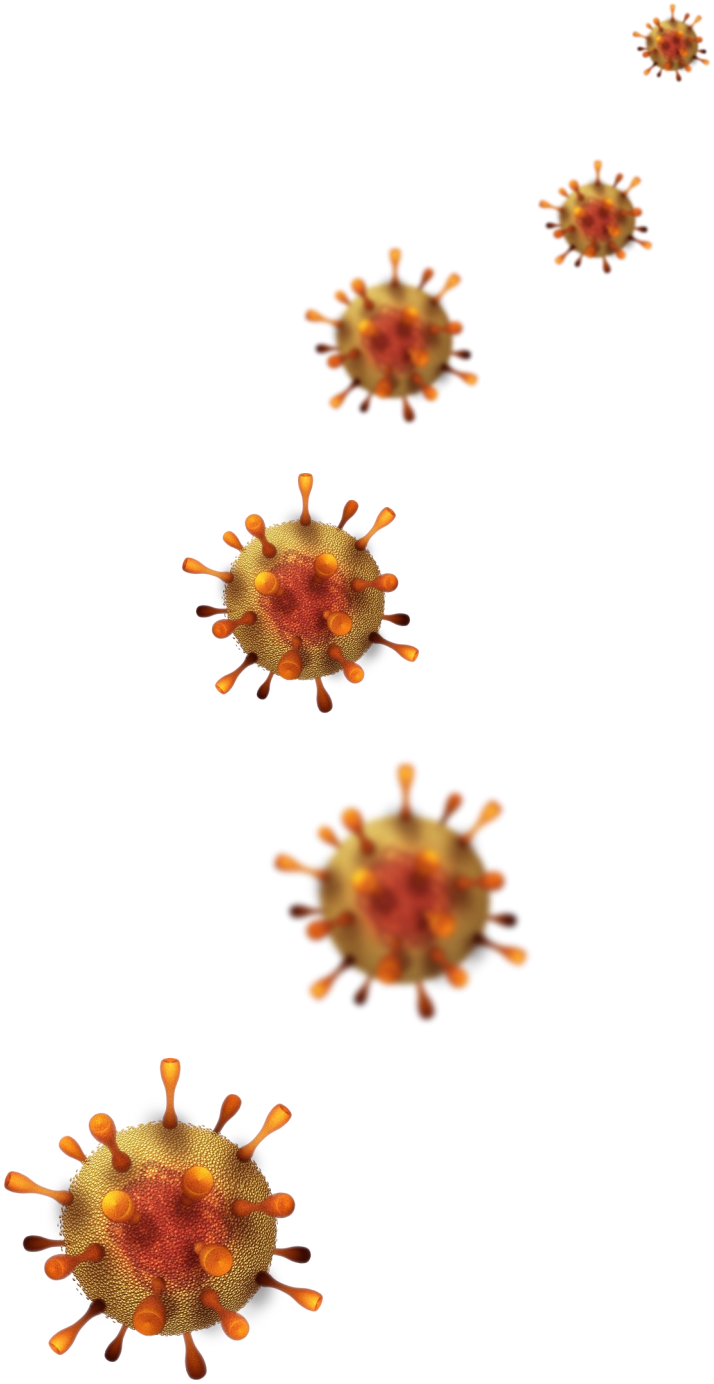
- ELISA screening for the determination of IgG or IgM SARS-CoV-2 antibodies in serum and plasma
- 96 determinations per test kit including positive and negative controls
- 105 min total assay time
- 15 months shelf life
- Fully automatable
- CE marked

GA CoV-2 IgG +

- IgG confirmatory test specific for SARS-CoV-2 N-, S1- and S2-proteins
- 24x4 determinations per test kit including positive and negative controls
- 105 min total assay time
- 15 months shelf life
- Fully automatable
- CE marked

Order information

Pathogen	Product Name	Method	Description	Article Number
SARS-CoV-2	GA CoV-2 IgG	ELISA	96x1 Determinations	3920
SARS-CoV-2	GA CoV-2 IgM	ELISA	96x1 Determinations	3930
SARS-CoV-2	GA CoV-2 IgG +	ELISA	24x4 Determinations	3940



GA Generic Assays GmbH
Ludwig-Erhard-Ring 3
15827 Dahlewitz/Berlin

Phone:+49 33708 9286-0
info@genericassays.com
www.genericassays.com

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