

# COVID-19 ELISA Kit

**Immunoenzymatic assay for the determination of IgG, IgM and IgA antibodies in human serum and plasma**

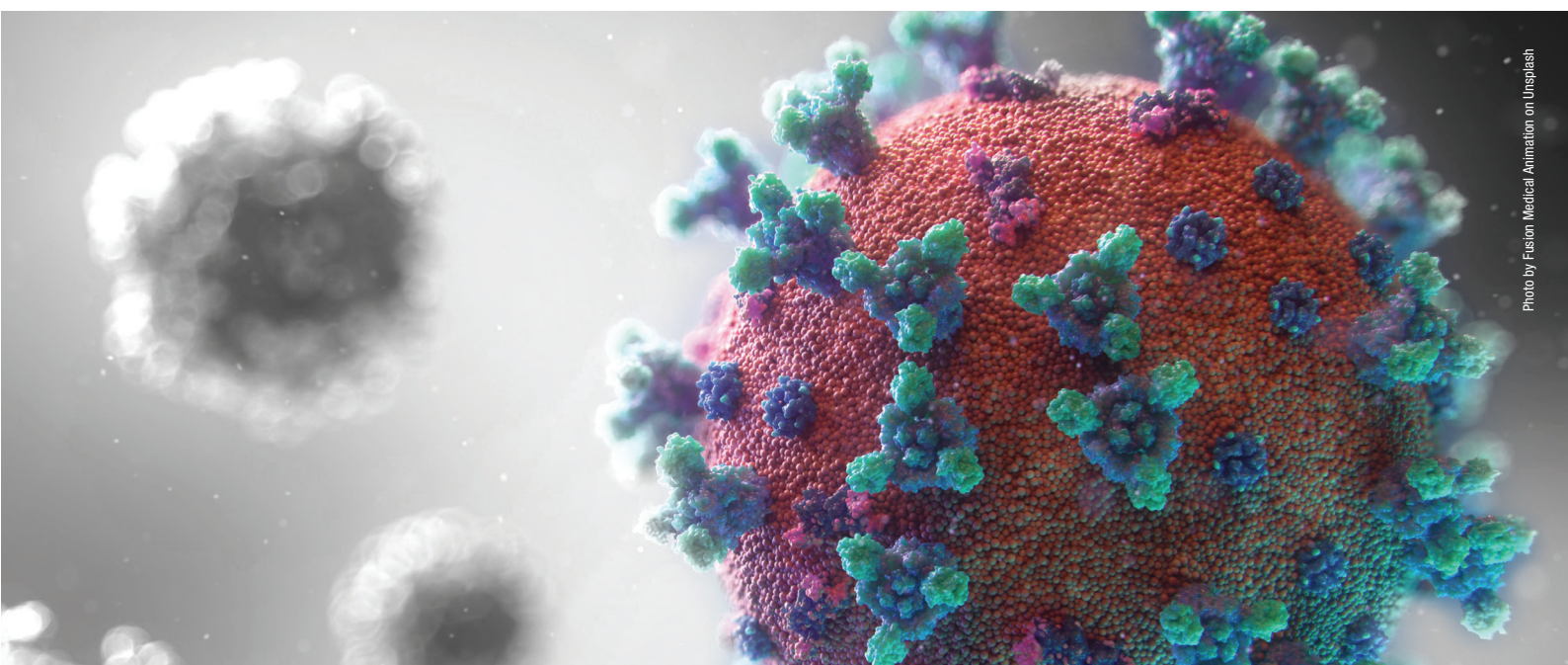


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**Serologic tests are a valid support for the diagnosis of COVID-19.** Side by side with Real-Time qPCR tests for the detection of the viral RNA, serologic tests allow the identification of subjects who have developed an immune response after a SARS-CoV-2 infection. That immune response is a multi-step process that involves many players, such as i) IgM, the immunoglobins primary produced during the first week after the infection, ii) IgG, richly produced during the late phase and responsible for the secondary immune response, and iii) IgA, the immunoglobins involved in the immunity of the mucosae with a pivotal role in the defense from reinfections.

The presence of IgG in serum and plasma indicates a past or asymptomatic infection, whereas the presence of IgM and IgA is useful to confirm or monitor a present one.

## **SARS-CoV-2 IgG**

- Ref. 9290
- Format: 96 tests
- Test type: qualitative ELISA
- Recombinant antigens: Nucleocapsid and Spike
- Sample: plasma or serum
- Test procedure: 45' at RT / 45' at RT / 15' at RT (sample incubation / conjugate / substrate)

## **SARS-CoV-2 IgM**

- Ref. 9291
- Format: 96 tests
- Test type: qualitative ELISA
- Recombinant antigens: Nucleocapsid and Spike
- Sample: plasma or serum
- Test procedure: 45' at RT / 45' at RT / 15' at RT (sample incubation / conjugate / substrate)

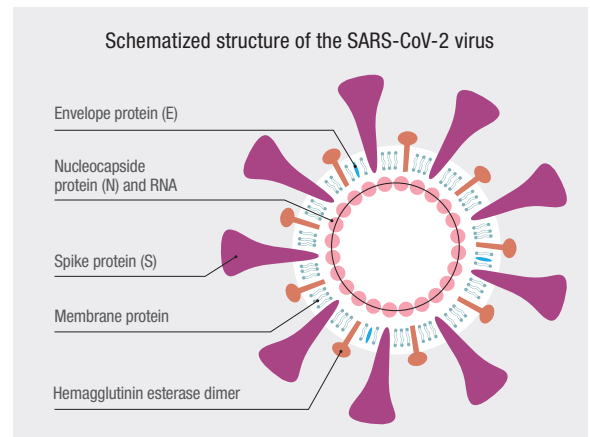
## **SARS-CoV-2 IgA**

- Ref. 9292
- Format: 96 tests
- Test type: qualitative ELISA
- Recombinant antigens: Nucleocapsid and Spike
- Sample: plasma or serum
- Test procedure: 45' at RT / 45' at RT / 15' at RT (sample incubation / conjugate / substrate)

Kits are CE-IVD marked in compliance with 98/79/CE directive. The procedure can be easily applied to automated ELISA test instruments.

## SARS-CoV-2: structure and mechanism of virulence

SARS-CoV-2 virus belongs to the Coronaviridae family and has a single-stranded RNA genome of approximately 30,000 base pairs. The genome contains a series of genes coding for structural and accessory proteins, the most important of which are the spike protein (S), the nucleocapsid (N), the envelope protein (E) and the RNA-dependent RNA polymerase (RdRp). The main mechanism underlying the virulence of SARS-CoV-2 has recently been identified in the binding of protein S to the enzyme ACE2 (angiotensin-converting enzyme 2), which mediates the entry of the virus into the host cell. ACE2 is a ubiquitous receptor, present on the surface of human cells, particularly in the upper and lower respiratory tract, the gastrointestinal tract, heart, kidneys and testes.

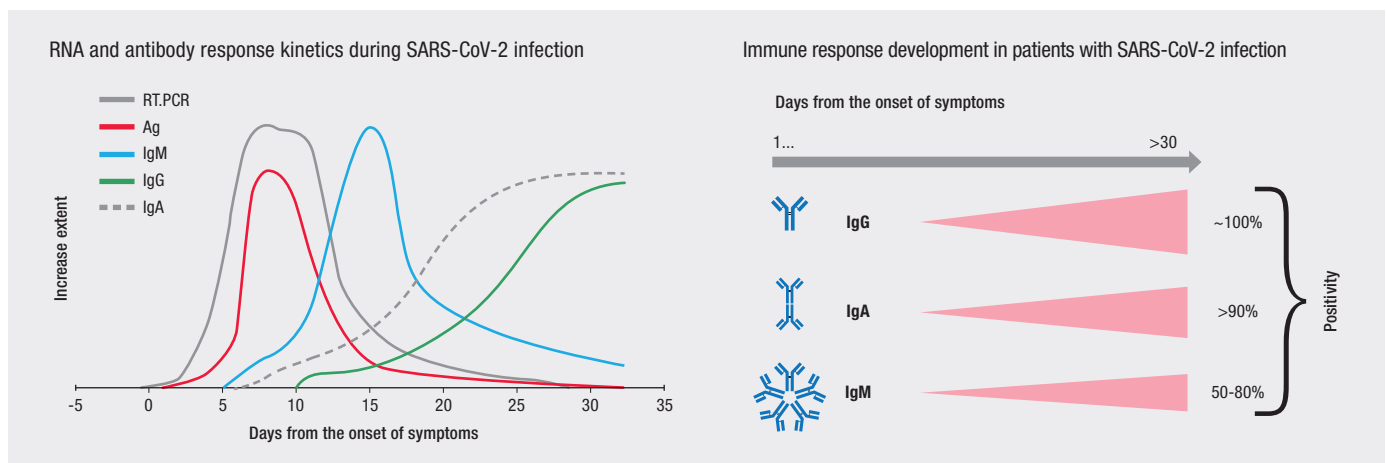


## SARS-CoV-2: antibody response

Viral proteins S and N induce an immune response resulting in a peculiar behavior and kinetics compared to others viral infections, with a titre of IgG and IgA immunoglobulins higher than those of the IgM class. It was indeed extensively demonstrated that the immune response to the SARS-CoV-2 virus is characterized by the constant production of IgG, generally detectable by the 10<sup>th</sup> to 18<sup>th</sup> day from the onset of symptoms and present in almost all patients up to 3-4 weeks after infection. The appearance of the IgA generally occurs from the 7<sup>th</sup> to the 15<sup>th</sup> day from the onset of symptoms and their presence persists for 3-4 weeks after infection in over 90-95% of patients.

The onset of IgM, on the other hand, appears to be more inconstant, albeit early, with an onset generally from the 5<sup>th</sup> to the 12<sup>th</sup> day after the appearance of symptoms and in a very variable percentage of patients, from 50% to 90%. IgM are also the least stable immunoglobulins over time as they tend to disappear after 4-6 weeks.

The possibility of performing a serological diagnosis on all three types of immunoglobulins therefore offers the opportunity to have a complete picture, which may reflect the stage of infection, the acquisition of long-term immunity and the protection state of the mucous membranes of the respiratory tract.



## References

- Wang H, Li X, Li T, et al. The genetic sequence, origin, and diagnosis of SARS-CoV-2. *Eur J Clin Microbiol Infect Dis* 2020 doi: 10.1007/s10096-020-03899-4.
- Sungnak W, Huang N, Bécavin C, et al. SARS-CoV-2 entry factors are highly expressed in nasal epithelial cells together with innate immune genes. *Nat Med* 2020 doi:10.1038/s41591-020-0868-6.
- Padoan A, Sciacovelli L, Basso D, et al. IgA-Ab response to spike glycoprotein of SARS-CoV-2 in patients with COVID-19: A longitudinal study. *Clin Chim Acta* 2020;507:164-6.
- Sun B, Feng Y, Mo X, et al. Kinetics of SARS-CoV-2 specific IgM and IgG responses in COVID-19 patients. *Emerg Microbes Infect* 2020 doi:10.1080/22221751.2020.1762515.
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