

## Tests for the Detection of Antibodies to SARS-CoV-2: Importance of the Critical Professional Interpretation

In the current COVID-19 pandemic, it is necessary to count on early diagnosis of the infection and its distribution in the population, in order to take appropriate clinical and epidemiological decisions. It is fundamental to have useful laboratory tests for each context.

From a clinical point of view, direct tests are adequate for these requirements, because they can reveal the presence of the agent, the SARS-CoV-2. The gold standard is the reverse-transcription polymerase chain reaction in respiratory samples. This test gives positive results since early infection states, even before the beginning of the symptoms or in absence of them.<sup>[1]</sup> Nevertheless, it requires specialized human resources and high-complexity equipment, with high costs and needlessly time-consuming conditions, which make their use difficult in low-complexity laboratories.

Indirect tests for the detection of specific antibodies have advantages: They require low blood samples, lower cost, minor equipment requirements, and some immunological tests, which give results in minutes. In the acute phase of the infection, Immunoglobulin M (IgM)-specific detection has lower usefulness than PCR, because the positive results appear after 7–10 postinfection days.

For epidemiological purposes, the use of Immunoglobulin G (IgG) detection tests in population was proposed. These antibodies appear around 14–20 days postinfection and remain present for a long time.<sup>[2]</sup> Nevertheless, serological tests have some limitations: there are no immunoassays with 100% of sensitivity and specificity, so the results must be interpreted in terms of probability. The sensitivity of available immunoassays is around 90% and the specificity near 97%.<sup>[3]</sup> Positive predictive value (PPV) and negative predictive value must also be taken in account, and they depend also on the prevalence of the infection in the population. With 90% sensibility and 97% specificity, in a population with 30% of prevalence, the PPV is 92.8%. The same test, in a population with 0.3% of prevalence, would only show 8.3% PPV. So, in 92 of 100 positive tests, inappropriate action would be taken with these results.

In conclusion, knowledge about the advantages and limitations of each test will help to select the most appropriate one to each clinical and epidemiological situation, and to an adequate interpretation of the results. The professional criterion is the key element to take clinical and sanitary decisions. Immunoassays are a good promise and could have a great importance in the future, to know who has had asymptomatic infection, not for diagnosis of current infection.

Finally, it is necessary to consider the bioethical aspects, their principles, and their values, in the context of human rights in this particular and difficult moment for humanity.

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### Conflicts of interest

There are no conflicts of interest.

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