Enzywell SARS-CoV-2
IgA, IgG e IgM

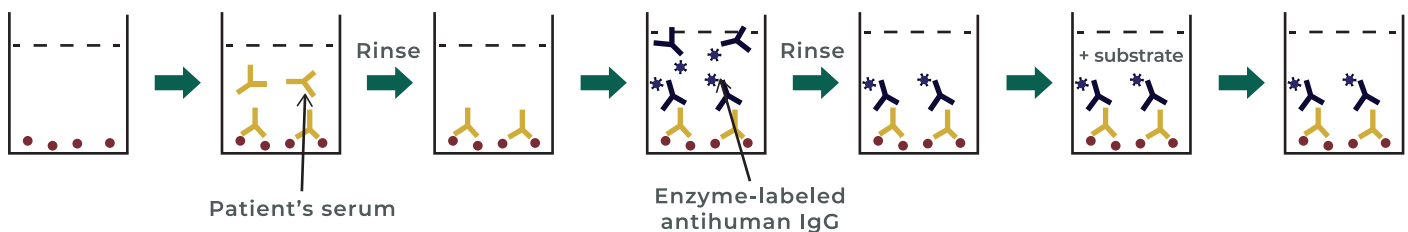ELISA kits for the serological diagnosis
of Covid-19 infection

The new ELISA serological test kits for diagnosing the SARS-CoV-2 infection were developed in collaboration with the National Institute for Infectious Disease Lazzaro Spallanzani in Rome, where the virus circulating in Italy was first isolated.

The antigen used in the solid phase of the kit is prepared, according to a patented protocol, in our BSL3 high biological containment laboratories. The native virus is first deactivated, to ensure complete safety.

Our kits detect the various serum antibody isotypes: IgA, IgG and IgM produced in the immune response to the virus. In general, the detection of IgM - antibodies produced in the early post-infection phases - is a marker of the acute phase, while IgG are produced in a later phase. If a patient has been in contact with other Coronaviruses in the past, however, the IgG titre may rise more quickly than that of the IgM and IgA.

Detecting IgA is particularly important in SARS-CoV-2 infections, as these antibodies are produced in the respiratory mucosa. The purpose of these antibodies is to bind to the virus and prevent its entry into the body, and are therefore an effective marker of the acute phase.
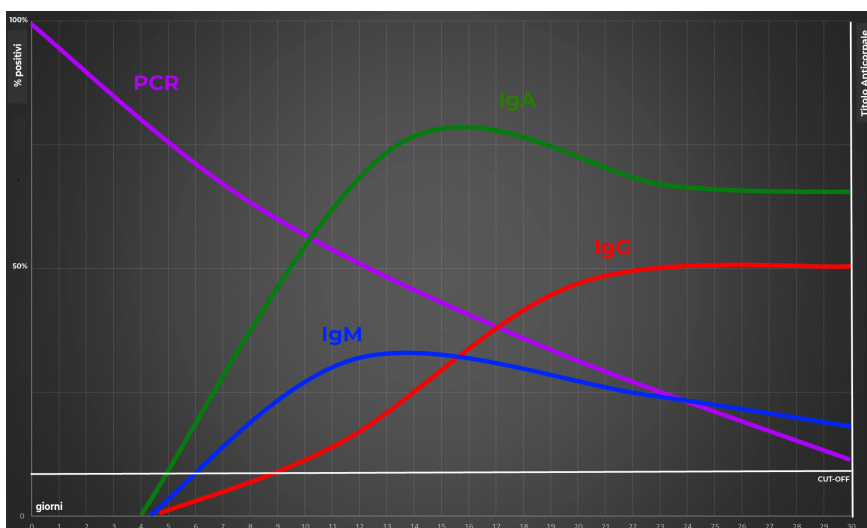
Indirect ELISA

Patient's serum   Rinse   Rinse   **Enzyme-labeled antihuman IgG**   + substrate

SARS-CoV - 2 is a "new" virus, the use of the "whole" virion allows us to determine antibodies directed against all viral proteins, even in their conformational state.

Molecular tests are most sensitive in the early stages of SARS-CoV-2 infection. The positivity rate, higher than 90% in the first three days of the onset of symptoms, declines quickly; less than 80% on the sixth day and well under 50% after 14 days.

The sensitivity of molecular tests is higher than serological tests if performed within 5.5 days of onset of symptoms, while the determination of IgM and IgA is more sensitive in later stages. In asymptomatic patients, the molecular test has a sensitivity of 52%, if performed alone but determining IgM and IgA simultaneously sensitivity levels rise to more than 96%

Performing serological tests and molecular tests contemporarily is particularly useful in the case of asymptomatic patients, allowing the immune response against the virus to be highlighted, and thus estimation of the real incidence rate of the infection in the population.

Graphic elaboration of the evolution of antibody titers in relation to positivity to molecular tests (see bibliography).

Advantages of Enzywell SARS-CoV-2 kits

Kits are based on the robust, well-known and accessible to all analysis laboratories ELISA methodology.
Based on the native antigen obtained from the actual virus circulating in the population.

Common analytical protocol for all three kits:

- Same incubation time and temperature
- Incubation at room temperature (no thermostat required)
- Same dilution of the sample
- Liquid and ready-to-use reagents
- Common reagents interchangeable between kits

The kits in question allow the detection of the various antibody classes produced as a result of the immune response to the SARS-CoV-2 infection:

IgA especially important in respiratory viruses, because they are produced in respiratory mucosa, the entrance door of the virus;

IgG produced in the later stages of infection, a good marker of prior infection;

IgM, acute phase marker, the first antibody produced by the immune system in response to an infection.

Available kits:

Enzywell SARS-CoV-2 IgA   **91402**   **96 test**
Kit for determining anti-SARS-CoV-2 IgA in human serum
Sensitivity: 93.7% CI95%: 84.7 – 97.5
Specificity: 96.3% CI95%: 93.9 – 97.7

Enzywell SARS-CoV-2 IgG   **91400**   **96 test**
Kit for determining anti-SARS-CoV-2 IgG in human serum
Sensitivity: 92.5% CI95%: 83.6 – 96.8
Specificity: 95.8% CI95%: 93.4 – 97.3

Enzywell SARS-CoV-2 IgM   **91401**   **96 test**
Kit for determining anti-SARS-CoV-2 IgM in human serum
Sensitivity: 87.7% CI95%: 77.5 – 93.6
Specificity: 97.0% CI95%: 94.5 – 98.3

Bibliography:
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