



ErbaLisa COVID-19 IgG

ELISA kits for detection of IgG
antibodies to SARS-COV-2

Making Automation Affordable
for Labs Everywhere

CE

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Enzyme immunoassay (ELISA) kit for the accurate detection of IgG antibodies to SARS-CoV-2

Coronaviruses are composed of several proteins including the spike (S), envelope (E), membrane (M), and nucleocapsid (N). IgG levels become elevated after 10 to 14 days and are the most abundantly produced antibody class in response to a viral antigen. IgG remains in the body long after the infection is over, maintaining a long-term response. Serology testing for IgG can be combined with IgM and/or nasopharyngeal PCR tests for accurate and efficient diagnosis of COVID-19 at multiple stages of infection.

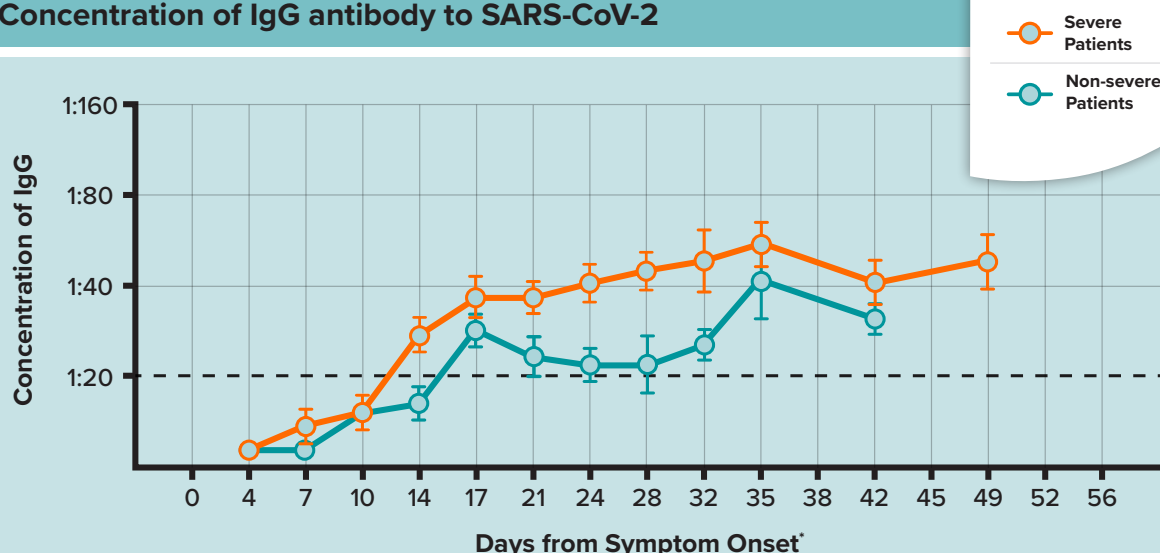
ErbaLisa COVID-19 IgG kits are designed to be easy to carry out, with ready to use reagents and automation-friendly features. Total incubation time is 50 minutes at room temperature with a simple one step serum dilution. In contrast to lateral flow rapid tests, ErbaLisa kits offer high sensitivity and specificity, semi-quantitative detection and high-throughput testing when used with automated analyzers.



Current examples of the clinical utility of IgG antibody testing:

- Providing an accurate epidemiological picture of how many people have been infected
- Monitoring treatment and recovery stages of the infection as well as identifying people who have successfully developed IgG antibodies to SARS-CoV-2
- Identifying patients with high antibody levels who can donate their antibody-rich, convalescent plasma, to potentially save other patients with severe Covid-19

Concentration of IgG antibody to SARS-CoV-2



* In the first 14 days of the onset of infection with SARS-CoV-2 patient results may be negative for IgG antibodies.

Main Features

Number of tests: 96

Principle: Indirect ELISA using recombinant Spike subunit antigen

Tracer: HRP-Labelled Anti-human IgG

Assay format: Semi-quantitative

Total incubation time: 50 minutes

Sample type: Serum

Sample volume: 10 μ L

Sample Size: 100 μ L (1:21 Dilution)

Reading wavelength: 450nm

Storage: 2-8°C

Built for convenience

- Ready to use reagents
- Removable strips
- Break-apart wells
- All incubation steps at room temperature
- Interchangeable reagents
- Calibrator and Controls included
- Ready for automation
- 1:21 sample dilution can be performed directly on microwell plate

Performance Characteristics

58 serum samples collected from previously RT-PCR confirmed COVID-19 patients were tested. 107 Normal healthy patients with samples collected before COVID-19 outbreak (prior to December 2019) were tested. The results are as follows:

	Test Positive	Test Negative
Confirmed Positive	57	1
Confirmed Negative	2	105
Intra-assay precision CV	5.29%	
Inter-assay precision CV		6.37%

Validation conducted in the USA and Italy:

The diagnostic sensitivity is 98.3%.
The diagnostic specificity is 98.1%.
No interference was observed with Haemoglobin, Bilirubin, Biotin or IgM.

Ordering information

Catalogue Number	Product name	Format
IME00136	ErbaLisa COVID-19 IgG	96-well ELISA

This kit has been granted Notification Status by the FDA, under product code QKO. Our submission number is D386770. In the first 14 days of the onset of infection with SARS-CoV-2 patient results may be negative for IgG antibodies. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.





Bringing immunoassay solutions to growing labs everywhere

Erba Mannheim is a fully integrated global in vitro diagnostics company, offering a comprehensive suite of clinical testing products to the growing number of smaller hospitals, reference labs, and physician clinics in the developed and emerging markets with reliable, affordable and innovative health care products.

In 2017, Calbiotech Inc. joined the Erba Mannheim group, bringing over 20 years of expertise in developing immunoassay kits that have been manufactured and distributed to over 80 countries across the globe.

Experience true versatility in ELISA automation with the new ELAN 30s.



Combine up to 6 different tests in every run, independent of assay protocol and incubation times.



Ideal for running a full panel of clinical parameters in parallel.



Complete walk-away automation, up to 240 tests per run.



For more details, please contact your local Erba Mannheim associate.

