ErbaLisa COVID-19 IgG

CE-marked Enzyme Immunoassay (ELISA) kit for the detection of IgG antibodies to SARS-CoV-2 in human serum

Erba Mannheim and Calbiotech have developed a reliable and automation-friendly COVID-19 ELISA, allowing for comprehensive and accurate IgG antibody assessment.

Our solid phase assay uses proven technology, and total incubation time is 50 min at room temperature with a simple one step serum dilution. ErbaLisa COVID-19 assays are built for superior performance and reliable interpretation of results.

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 µL
- Sample Size: 100 µL (1:21 Dilution)
- Reading wavelength: 450nm
- Storage: 2-8ºC

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.

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.

www.erbamannheim.com

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Developed and manufactured in the U.S.A.