ErbaLisa COVID-19 IgM

CE-marked Enzyme Immunoassay (ELISA) kit for the detection of IgM 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 IgM 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 (S) subunit and Nucleocapsid (N) antigens
- Tracer: HRP-Labelled Anti-human IgM
- 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: 2-8°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 validated on microwell plate

Performance Characteristics:

30 serum samples collected from previously RT-PCR confirmed COVID-19 patients were tested. 50 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	30	0
Confirmed Negative	5	45

Validation conducted in the USA:

The diagnostic sensitivity is 100.0%.
The diagnostic specificity is 90.0%.
No interference was observed with Haemoglobin, Bilirubin, Biotin or IgG.

Intra-assay precision CV	8.10%	Inter-assay precision CV	8.22%

Catalogue Number	Product name	Format
IME00137	ErbaLisa COVID-19 IgM	96-well ELISA

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.