

# COVID-19 SPIKE

Quantitative Monotest  
with high correlation to  
neutralizing antibodies

## COVID-19 SPIKE QUANTITATIVE VIRCLIA<sup>®</sup> IgG MONOTEST

Indirect chemiluminescent immunoassay (CLIA)  
to detect and quantify IgG antibodies against  
SARS-CoV-2 Spike in human serum or plasma.

- SARS-CoV-2 Spike protein antigen.
- Quantitative assay in IU/ml for detection of IgG antibodies according to First WHO International Standard for anti-SARS-CoV-2 immunoglobulin, NIBSC code: 20/136.
- 5-PL master curve with single-point calibrator.
- Wide quantification range: 8.36-1,000 IU/ml.
- Excellent clinical sensitivity and specificity.
- Strong correlation with neutralization assay.
- Compatible with the broadest infectious disease CLIA monotest panel in the market, with over 90 parameters available.



VirClia<sup>®</sup> MONOTEST - 24 tests

VirClia<sup>®</sup> Lotus



## Fundamentals

Antibodies reacting with epitopes on the spike protein of the virus contribute the majority of the neutralizing activity of the immune response. Correlation between anti-spike antibody levels and neutralization titers have been found both in infected patients and in vaccinated individuals.

**COVID-19 SPIKE QUANTITATIVE VIRCLIA® IgG MONOTEST** shows almost perfect agreement with neutralization assay.

## The True Monotest

- On-demand testing: **One monotest= one reportable test**. Nothing else is required.
- **Individual Quality Control per monotest**, no need for extra controls or calibrations.
- **Random Access automated protocol** with results in 1h.
- **Same day results**, no batching, no sample cumulation.



## Technical Specifications

**Clinical sensitivity and specificity** was determined by testing 100 samples against a commercial ELISA kit.

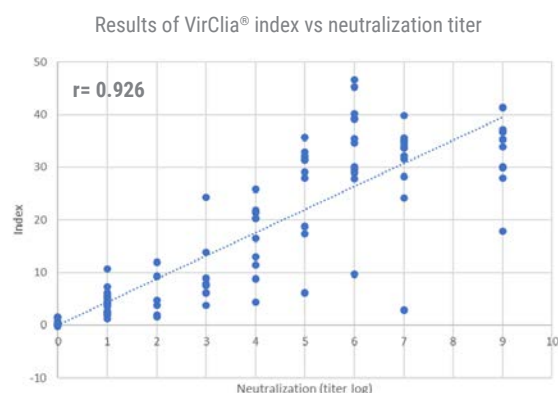
No. of Samples	Sensitivity	Specificity
<b>100</b>	<b>100%</b>	<b>100%</b>

**Measuring range** was established as LoQ + highest internal calibrator. The results were as follows:

VirClia® instrument: 1,007.16 IU/ml

VirClia® Lotus instrument: 1,008.36 IU/ml

**Comparison to neutralization assay** was evaluated by testing 135 samples corresponding to 45 vaccinees (3 samples per each). Agreement was measured through Cohen's kappa coefficient with a value of 0.951, indicating almost perfect agreement. The Spearman's coefficient of rank correlation ( $r$ ) was 0.926 ( $P=0.000$ ), indicating a high correlation between both methodologies.



## Related products and ordering information

Reference	Description	Pack size
24B12088	COVID-19 SPIKE QUANTITATIVE VIRCLIA® IgG MONOTEST <span style="background-color: green; color: white; padding: 2px;">NEW</span>	24 tests
24B12085	COVID-19 VIRCLIA® IgG MONOTEST	24 tests
24B12086	COVID-19 VIRCLIA® IgM+IgA MONOTEST	24 tests