

COVID-19 SPIKE

Quantitative Monotest
with high correlation to
neutralizing antibodies

COVID-19 SPIKE QUANTITATIVE VIRCLIA® 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® MONOTEST - 24 tests



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 1,129 samples against a commercial ELISA kit.

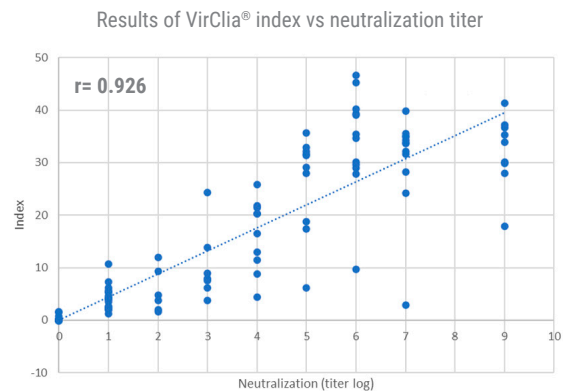
No. of Samples	Sensitivity	Specificity
1,129	95%	100%

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.



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Related products and ordering information

Reference	Description	Pack size
VCM100	COVID-19 SPIKE QUANTITATIVE VIRCLIA® IgG MONOTEST	24 tests
VCM097	COVID-19 VIRCLIA® IgG MONOTEST	24 tests
VCM098	COVID-19 VIRCLIA® IgM+IgA MONOTEST	24 tests