COVID-SeroKlir
Kantaro SARS-CoV-2 IgG Antibody IVD Kit
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Central Laboratory

COVID-SeroKlir

Precise and reliable measurement of COVID-19 IgG antibodies

- 30,000 COVID-19 patient test data set
- Two phase ELISA protocol
- Minimises false positives and false negatives
- Peer reviewed in *Nature* and *Science*

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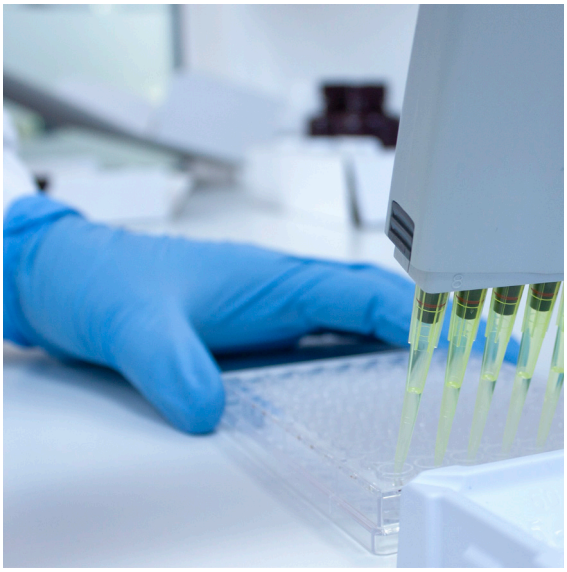
Kantaro COVID-SeroKlir

Kantaro COVID-SeroKlir is a direct ELISA for the quantitative detection of human IgG antibodies to the SARS-CoV-2 virus in serum and plasma (K2-EDTA/ Li-Heparin) samples and is a CE-IVD cleared.

The SeroKlir ELISA kit was developed by clinicians at the Icahn School of Medicine at Mount Sinai Health System, New York[1]. The test has been trialled on a cohort of over 70,000 patients including over 30,000 who were diagnosed with COVID-19[2].

The SeroKlir ELISA kit contains components to test 630 patient samples and uses standard ELISA protocols and equipment.



Kit component	Specification
7 x RBD plates	96 well polystyrene microplate coated with recombinant SARS-CoV-2 spike protein RBD antigen sufficient for 630 screening tests
3 x spike plates	96 well polystyrene microplate coated with full length recombinant SARS-CoV-2 spike protein sufficient for 228 quantitative tests
Controls	RBD Positive Control RBD Negative Control Spike Low Control Spike Mid Control Spike High Control
Calibrators	8 calibrators (range 0-200 AU/mL)
Consumables	RBD conjugate concentrate - IgG ELISA Spike conjugate concentrate - IgG ELISA Conjugate buffer - IgG ELISA Sample buffer - IgG ELISA TMB substrate - IgG ELISA Stop solution - IgG ELISA Wash buffer - IgG ELISA

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Performance data

	Performance specifications
Assay type	Solid phase sandwich ELISA
Format	96 well one-piece plate
Assay length	3.5 hours (RBD ELISA) 3.5 hours (spike ELISA)
Sample types	Serum (20 uL) EDTA plasma (20 uL) Heparin plasma (20 uL)
Assay range	3.2 – 160 AU/mL
Specificity	99.6%
Sensitivity	97.8%

Method

Two phase ELISA interrogating both the full length spike protein and its Receptor Binding Domain (RBD):

- RBD used as first phase to identify antibody negative samples
- Full length spike protein used in second phase to confirm positive samples and return an objective antibody titre result

Analytical sensitivity

The analytical sensitivity - Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) - were established according to the recommendations in CLSI guideline EP17-A2. RBD ELISA and spike ELISA summary data is presented below.

Positive Percent Agreement: For the positive samples confirmed with a known EUA-authorized molecular test, PPA was 97.8%. Two samples that tested negative with the COVID-SeroKlir Kantaro Quantitative SARS-CoV-2 IgG Antibody Kit also tested negative on an existing EUA approved serology test, suggesting that these were true negative samples.

Negative Percent Agreement: For the negative samples the NPA was 99.6%. There were 14 samples that tested positive on the RBD ELISA. Of these samples, 13 subsequently tested negative on the spike ELISA. Therefore the number of negative samples was 281 out of 282.

Clinical utility

An initial qualitative (screening) ELISA is performed against recombinant Receptor Binding Domain (RBD) of SARS-CoV-2. Positive samples from this screen are analysed by a quantitative ELISA against full length SARS-CoV-2 spike protein. The assay aids in establishing the quantitative levels of neutralizing antibodies indicative of an adaptive immune response to SARS-CoV-2 in patients suspected of previous SARS-CoV-2 infection, or for the detection of IgG seroconversion in patients following known recent SARS-CoV-2 infection.

Determination of the number of individuals who are demonstrated to have developed specific antibodies to SARS-CoV-2 aids in the determination of seroprevalence in any geographic region or group of exposed individuals and may be indicative of the potential risk of reinfection. The results of the assay correlate with the neutralization of SARS-CoV-2 virus in vitro. Results are for the detection of SARS-CoV-2 IgG antibodies. IgG antibodies to SARS-CoV-2 generally become detectable at 10-14 days following infection but may occur later. The presence of IgG antibodies, following previously negative testing, defines IgG antibody seroconversion following SARS-CoV-2 infection.

Negative results do not preclude acute SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgG antibodies may not be present for more than two weeks following infection, and patients may remain infectious during acute infection even if IgG antibody is present. Results must be combined with clinical observations, patient history, and epidemiological information. The sensitivity of the COVID-SeroKlir Kantaro Quantitative SARS-CoV-2 IgG Antibody Kit early after infection is unknown.

Bibliography

1) Amanat et al. Nature Medicine 26 2033-1036 (2020)
2) Wajnberg et al. Science 10.1126/science.abd7728 (2020)

Product comparison

	Roche Elecsys Anti SARS-Cov-2	Siemens Atellica / Dimension / ADVIA	Kantaro COVID-SeroKlir
Quantitative	Yes	Yes	Yes
Sample	Plasma and Serum	Plasma and Serum	Plasma and Serum
Specificity	99.98% (n = 5,991)	99.90%	99.6 (n >70,000)
Sensitivity	98.8% (n = 1,423)	99.80%	97.8% (n >70,000)
PPV	Not published	Not published	100.00% (no false positive)
NPV	Not published	Not published	99.60% (minimal false negatives)
Cross reactivity	No	No	No
Instrument	Roche Cobas specific	Atellica / Dimension / ADVIA specific	Any plate reader A450 (correction 540 or 570)
Peer reviewed	No	No	1. Amanat et al. Nature Medicine 26 2033-1036 (2020) 2. Wajnberg et al. Science 10.1126/ science.abd7728 (2020)
FDA / CE	EUA and CE-IVD	EUA and CE-IVD	EUA and CE-IVD