Anti-SARS-CoV-2 S1 Curve ELISA (IgG)
Instructions for Use

For in vitro diagnostic use. For prescription use only. For use under emergency use authorization only. The results of this semi-quantitative test should not be interpreted as an indication or degree of immunity or protection from infection.

ORDER NO.	ANTIBODIES AGAINST	IG CLASS	SUBSTRATE	FORMAT
EI 2606-9601-20 G	SARS-coronavirus 2 (SARS-CoV-2)	IgG	Ag-coated microplate wells	96 x 01 (96)

CE

Intended Use

The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) is an enzyme-linked immunosorbent assay intended for qualitative and semiquantitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma (tripotassium EDTA, lithium heparin, sodium citrate) run manually or using the EUROLabWorkstation ELISA, Sprinter XL or Dynex DSX® Automated ELISA System. The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) should not be used to diagnose or exclude acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform moderate (automated method) or high (manual and automated method) complexity tests.

Results are for the detection of SARS CoV-2 IgG antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

Samples should only be tested from individuals who are 15 days or more post symptom onset.

The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) is only for use under the Food and Drug Administration's Emergency Use Authorization.

Clinical significance

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, previously called 2019-nCoV) belongs to the family of coronaviruses and, like SARS-CoV, is classified in the genus *Betacoronavirus* [1]. At the end of 2019, SARS-CoV-2 was identified as the causative agent of clustered cases of pneumonia of unclear origin. The virus caused an infection wave which quickly spread worldwide and was declared a pandemic by the WHO at the beginning of 2020 [2-5].

SARS-CoV-2 is predominantly transmitted by droplet infection via coughing or sneezing and through close contact with infected persons [3-4, 6]. Healthcare personnel and family members are especially at risk of infection [6]. The zoonotic reservoir of the virus appears to be bats [3, 4, 6].

The incubation time of SARS-CoV-2 is three to seven, maximally 14 days [2]. The symptoms of SARS-CoV-2 infection are fever, coughing, breathing difficulties and fatigue [2-4, 6]. In most patients the infection manifests with symptoms of a mild febrile illness with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS) [2, 3, 5, 6]. In February 2020, the disease caused by SARS-CoV-2 was named COVID-19 by the WHO.

Suitable methods for the diagnosis of SARS-CoV-2 infections are detection of viral RNA by reverse transcriptase polymerase chain reaction (RT-PCR) or of viral protein by ELISA primarily in sample material from the upper (nasopharyngeal or oropharyngeal swabs) or lower respiratory tract (broncho-alveolar lavage fluid, tracheal secretion, sputum, etc.). The detection of viral antigens is less sensitive than RT-PCR.

The determination of antibodies enables confirmation of recent or prior SARS-CoV-2 infection in patients with typical symptoms and in suspected cases. It also contributes to monitoring and outbreak control [4, 5] . Cross-reactions with antibodies within the genus *Betacoronavirus* have been described [4, 5].

Antigen

The reagent wells of the ELISA were coated with the S1 domain of the spike protein of SARS-CoV-2 expressed recombinantly in the human cell line HEK 293.

Principles of the Test

The test kit contains microplate strips each with 8 break-off reagent wells coated with recombinant S1 domain of the spike protein of SARS-CoV-2. In the first reaction step, diluted samples are incubated in the wells. In the case of positive samples, specific IgG (also IgA and IgM) antibodies will bind to the antigens. To detect the bound antibodies, a second incubation is carried out using an enzyme-labelled anti-human IgG (enzyme conjugate) catalyzing a color reaction.

Contents of the test kit

Component	Color	Format	Symbol
1. Microplate wells coated with antigens 12 microplate strips each containing 8 individual break-off wells in a frame, ready for use	-	12 x 8	STRIPS
2. Calibrator 1 120 RU/ml (IgG, human), ready for use	red colored in decreasing intensity	1 x 2.0 ml	CAL 1
3. Calibrator 2 80 RU/ml (IgG, human), ready for use		1 x 2.0 ml	CAL 2
4. Calibrator 3 40 RU/ml (IgG, human), ready for use		1 x 2.0 ml	CAL 3
5. Calibrator 4 20 RU/ml (IgG, human), ready for use		1 x 2.0 ml	CAL 4
6. Calibrator 5, 10 RU/ml (IgG, human), ready for use		1 x 2.0 ml	CAL 5
7. Calibrator 6, 1 RU/ml (IgG, human), ready for use		1 x 2.0 ml	CAL 6
8. Positive control, (IgG, human), ready for use Human plasma positive for IgG	blue	1 x 2.0 ml	POS CONTROL
9. Negative control, (IgG, human), ready for use normal human plasma in assay buffer	green	1 x 2.0 ml	NEG CONTROL
10. Enzyme conjugate peroxidase-labelled anti-human IgG, ready for use	green	1 x 12 ml	CONJUGATE
11. Sample buffer, ready for use	light blue	1 x 100 ml	SAMPLE BUFFER
12. Wash buffer, 10x concentrate	colorless	1 x 100 ml	WASH BUFFER 10x
13. Chromogen/substrate solution TMB/H_2O_2, ready for use	colorless	1 x 12 ml	SUBSTRATE
14. Stop solution, 0.5 M sulfuric acid, ready for use	colorless	1 x 12 ml	STOP SOLUTION
15. Protective foil	-	3 pieces	FOIL
16. Quality control certificate	-	1 protocol	-
17. Instructions for use	-	1 booklet	-

Additional materials and equipment (not supplied in the test kit)

- Automatic microplate washer: recommended. Washing of the microplates can also be carried out manually.
- Microplate reader: wavelength of 450 nm, reference wavelength range from 620 nm to 650 nm
- Calibrated micropipettes
- Pipette tips
- Stepper pipette: recommended for the pipetting of enzyme conjugate, substrate, and stop solution
- Distilled or deionized water
- Incubator: for incubation of the microplate at +37°C
- Incubator or water bath: recommended to warm the wash buffer
- Stop watch

Storage and Stability

The test kit has to be stored at a temperature between +2°C and +8°C; do not freeze. Unopened, all test kit components are stable until the indicated expiry date.

In-use stability following the first opening

After initial opening, the reagents are stable until the indicated expiry date if stored at +2°C to +8°C and protected from contamination, unless stated otherwise below.

Warnings and Precautions

- For use Under Emergency Use Authorization Only.
- For *in vitro* diagnostic use only.
- For prescription use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for detecting the presence of IgG antibodies to SARS- CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner
- The product must only be used by trained laboratory personnel in a clinical or research laboratory.
- For in vitro diagnostic use under emergency use authorization only. Use of this product is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.
- If the packed reagents are visibly damaged, do not use the test kit.
- Do not use reagents past the expiration date.
- Before using the product, read the instruction for use carefully. Only the valid version is to be used.
- Do not substitute or mix the EUROIMMUN reagents with reagents from other manufacturers.
- Observe Good Laboratory Practice (GLP) and safety guidelines. Some of the reagents contain preservatives in non-declarable concentrations. Avoid eye and skin contact with samples and reagents. In case of eye or skin contact, rinse thoroughly with water. Remove and wash contaminated clothing. In case of ingestion, obtain medical advice.
- The calibrators and controls of human origin have tested negative for HBsAg, anti-HCV, anti-HIV-1 and anti-HIV-2. Nonetheless, all reagents should be treated as being a potential infection hazard and should be handled with care.

Preparation and Stability of the Samples

- **Samples:** Human serum or tripotassium EDTA, lithium heparin or sodium citrate plasma
- **Sample preparation: Patient samples** are diluted **1:101** in sample buffer.

  For example: dilute 10 µl serum in 1.0 ml sample buffer and mix well by vortexing (sample pipettes are not suitable for mixing).
- **Stability of the samples:**

Samples are stable at room temperature for up to 8 hours. If the assay is performed within 14 days of sample collection, the samples should be kept at +2°C to +8°C; otherwise they should be stored frozen (-20°C or below). If samples are stored frozen, mix thawed samples well before testing. Samples should not be repeatedly frozen and thawed. Frozen samples must be mixed well after thawing and prior to testing.. Do not use bacterially contaminated samples. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine its own specific stability criteria.

Preparation and Stability of the Reagents

Note: All reagents must be brought to room temperature (+18°C to +25°C) approx. 30 minutes before use.

The thermostatically adjustable ELISA incubator must be set to +37°C ± 1°C.

- **Coated wells:** Ready for use. Tear open the resealable protective wrapping of the microplate at the recesses above the grip seam. Do not open until the microplate has reached room temperature to prevent the strips from moistening. Immediately replace the remaining wells of a partly used microplate in the protective wrapping and tightly seal with the integrated grip seam (Do not remove the desiccant bag).
  Once the protective wrapping has been opened for the first time, the wells coated with antigens can be stored in a dry place and at a temperature between +2°C and +8°C for 3 months.
- **Calibrators and controls:** Ready for use. Mix reagents thoroughly before use.
- **Enzyme conjugate:** Ready for use. Mix the reagent thoroughly before use.
- **Sample buffer:** Ready for use.
- **Wash buffer:** The wash buffer is a 10x concentrate. If crystallization occurs in the concentrated buffer, warm it to +37°C and mix well before dilution. Dilute the required volume 1:10 with deionized or distilled water (1 part reagent plus 9 parts water).
  For example: For 1 microplate strip, 5 ml concentrate plus 45 ml water.
  The working-strength wash buffer is stable for 4 weeks if stored at +2°C to +8°C and handled properly.
- **Chromogen/substrate solution:** Ready for use. Close the tube immediately after use, as the contents are sensitive to light. The chromogen/substrate solution must be clear on use. Do not use the solution if it is blue colored.
- **Stop solution:** Ready to use.

Waste Disposal

Samples, calibrators, controls and incubated microplate strips should be handled as infectious waste. Follow local, state and federal regulations regarding handling and disposal of hazardous waste.

Quality Control

The controls and calibrators included in the test kit must be used with each run. Results cannot be validated if the control values deviate from the expected values stated on the quality control certificate. If the values specified for the controls are not achieved, the test results may be inaccurate and the test should be repeated. The positive control and negative control are intended to monitor for substantial reagent failure, but will not ensure precision at the assay cut-off. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations.

Assay procedure

Manual test Method

Sample incubation: (1st step)

Transfer **100 µl** of the **calibrators, positive and negative controls or diluted samples** into the individual microplate wells according to the pipetting protocol. Incubate for **60 minutes at +37°C ± 1°C**.

For manual processing of microplate wells, cover the finished test plate with the protective foil. When using an automated microplate processor for incubation, follow the recommendations of the instrument manufacturer.

Washing:

Manual: Remove the protective foil. Empty the wells and subsequently wash **3 times using 300 µl of working-strength wash buffer** for each wash.
Leave the wash buffer in each well for 30 to 60 seconds per washing cycle, then empty the wells.

After washing, thoroughly dispose of all liquid from the microplate by tapping it on absorbent paper with the openings facing downwards to remove all residual wash buffer.

Automatic: Remove the protective foil. Free positions on the microplate strip should be filled with blank wells of the same plate format as the parameter to be investigated. Wash the wells **3 times with 450 µl of working-strength wash buffer** (program setting: e.g. TECAN Columbus Washer "Overflow Mode").

After washing, strongly tap the microplate on absorbent paper with the openings facing downwards in order to completely remove wash buffer residues.

Conjugate incubation: (2nd step)

Pipette **100 µl of enzyme conjugate** (peroxidase-labelled anti-human IgG) into each of the microplate wells.
Incubate for **30 minutes at +37°C ± 1°C**.

For manual test performance cover the reagent wells with the protective foil.

Washing:

Remove the protective foil. Empty the wells. Wash as described above.

Substrate incubation: (3rd step)

Pipette **100 µl of chromogen/substrate solution** into each of the micro-plate wells.
Incubate for **30 minutes at room temperature** (+18°C to +25°C), protected from direct sunlight.

Stopping:

Pipette **100 µl of stop solution** into each of the microplate wells in the same order and at the same speed as the chromogen/substrate solution was introduced.

Measurement:

Photometric evaluation of the color intensity should be made at a **wavelenth of 450 nm** and a reference wavelength between 620 nm and 650 nm **within 30 minutes of adding the stop solution**. Prior to measuring, slightly shake the microplate to ensure a homogeneous distribution of the solution.

Assay Procedure: Automated Test Methods: Sample dilution and test performance are carried out fully automatically using an analysis device. The incubation conditions programmed in the respective software validated by EUROIMMUN may deviate slightly from the specifications given in the ELISA test instruction, but have been validated in respect of the combination of the EUROIMMUN EUROLabWorkstation ELISA, the EUROIMMUN Sprinter XL and the DYNEX DSX and this EUROIMMUN ELISA. Validation documents are available on enquiry.

Instrument settings

EUROLabWorkstation ELISA (EUROIMMUN):

Minimum Sample Volume	100-200 ul (higher volume required depending on the tube type used)
Sample/Plate Capacity:	>700 samples/15 plates
Temperature conditions:	Room temperature (+18 °C to +25 °C)
Pre-incubation steps:	Liquid levels of the system liquid, system waste liquid containers, wash buffer containers and washer waste liquid containers should be checked; Self test to be performed prior to starting a worklist
Min./Max. pipetting volume:	5 to 1100 ul
Reagents/Consumables:	EUROIMMUN reagents and consumables
Run-time:	Standard (~2.5 hours to complete run)
Wavelength Settings:	Microplate reader should be set at wavelength of 450 nm, reference wavelength range from 620 nm to 650 nm
Software Version:	EUROLABWorkstation ELISA Software 2.3.6

Sprinter XL (EUROIMMUN):

Minimum Sample Volume	150 ul (higher volume required depending on the tube type used)
Sample/Plate Capacity:	160/240 configuration: up to 160/240 samples/6 plates
Temperature conditions:	Room temperature (+18 °C to +25 °C)
Pre-incubation steps:	Liquid levels of the system liquid, system waste liquid containers, wash buffer containers and washer waste liquid containers should be checked; Self test to be performed prior to starting a worklist
Min./Max. pipetting volume:	5 to 1000 ul
Reagents/Consumables:	EUROIMMUN reagents and consumables
Run-time:	Standard (~2.5 hours to complete run)
Wavelength Settings:	Microplate reader should be set at wavelength of 450 nm, reference wavelength range from 620 nm to 650 nm
Software Version:	Sprinter XL Software 4.0.0.0

DSX® Automated ELISA System (DYNEX):

Minimum Sample Volume	150 ul (higher volume required depending on the tube type used)
Sample/Plate Capacity:	96 samples/4 plates
Temperature conditions:	Room temperature (+18 °C to +25 °C)
Pre-incubation steps:	Liquid levels of the system waste liquid containers, wash buffer containers and washer waste liquid containers should be checked; Self test to be performed prior to starting a worklist
Min./Max. pipetting volume:	25 to 1000 ul
Reagents/Consumables:	EUROIMMUN reagents; Dynex DSX® consumables
Run-time:	Standard (~2.5 hours to complete run)
Wavelength Settings:	Microplate reader should be set at wavelength of 450 nm, reference wavelength range from 620 nm to 650 nm
Software Version:	DSX® Revelation 6.28 and above

NOTE: Respective user manuals should be referred for additional details. The instruments are only to be operated by trained professionals

Pipetting Protocol

	1	2	3	4	5	6	7	8	9	10	11	12
A	C 1	P 1	P 9	P 17								
B	C 2	P 2	P 10	P 18								
C	C 3	P 3	P 11	P 19								
D	C 4	P 4	P 12	P 20								
E	C 5	P 5	P 13	P 21								
F	C 6	P 6	P 14	P 22								
G	pos.	P 7	P 15	P 23								
H	neg.	P 8	P 16	P 24								

The pipetting protocol for microplate strips 1 to 4 is an example for the **6-point calibrated analysis** of 24 patient samples (P 1 toP 24).

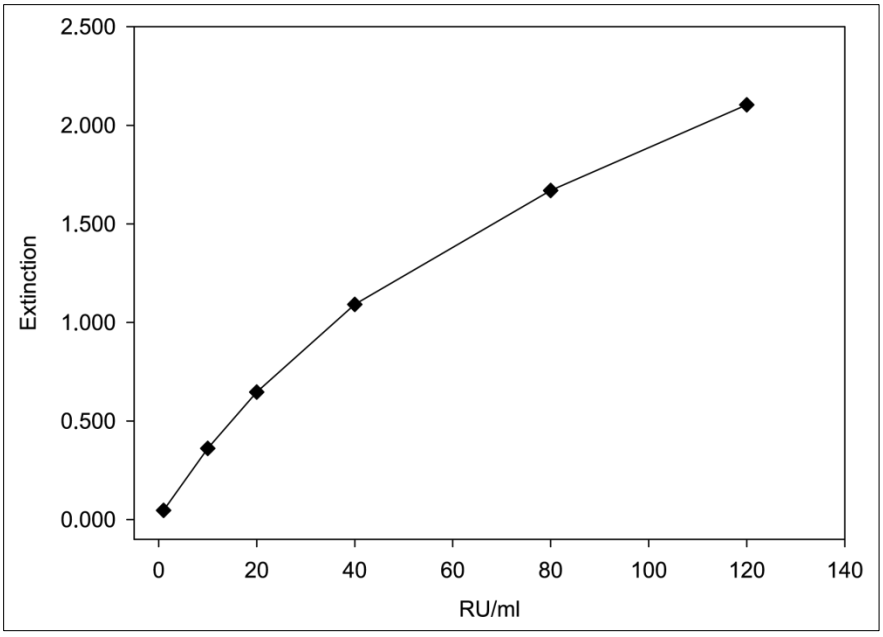
In this example the calibrators (C 1 to C 6), the positive (pos.) and negative (neg.) controls as well as the samples have been incubated in one well each.

The wells can be broken off individually from the strips. This makes it possible to adjust the number of test substrates used to the number of samples to be examined and minimizes reagent wastage.

Calculation and Interpretation of Results

For automated test methods, the results will be provided directly to the end user.

For manual test methods,the standard curve from which the concentration of antibodies in the samples can be determined is obtained by point-to-point plotting of the OD readings measured for the 6 calibration sera against the corresponding units (linear/linear). Use “point-to-point” plotting for calculation of the standard curve by computer. The following plot is an example of a typical calibration curve. Please do not use this curve for the determination of antibody concentrations in samples.



If the OD for a sample lies above the OD of calibrator 1 (corresponding to 120 RU/ml), the result should be reported as “>120 RU/ml”.

Result interpretation:

<8 RU/ml:	**negative**	**IgG Antibodies for SARS-CoV-2 are not detected**
≥8 to <11 RU/ml:	**borderline**	**IgG antibodies determination is indeterminate/equivocal with this sample. Test another sample later after one to two weeks.**
≥11 RU/ml:	**positive**	**IgG antibodies for SARS-CoV-2 are detected.**

In case of a borderline result, a secure evaluation is not possible. It is recommended the patient may be re-drawn one to two weeks later and re tested with the EUROIMMUN Anti-SARS-CoV2 S1 Curve ELISA (IgG) assay.

Numeric results are reported for samples with RU/ml between 11 RU/ml and 120 RU/ml. Numeric results below 11 RU/ml should not be reported outside of the laboratory. Results above 120 RU/ml are reported as >120 RU/ml.

X Limitations of the Procedure

- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of the test early after infection is unknown. False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made.
- A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.
- False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an immune response.
- Not for the screening of donated blood.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to infection.
- Correct performance of sample collection and storage is crucial for the test results.
- The binding activity of the antibodies and the activity of the enzyme used are temperature-dependent. It is therefore recommended using a thermostatically adjusted ELISA incubator in all incubation steps. The higher the room temperature during the incubation steps, the greater will the OD be. The same variations also apply to the incubation times. However, the calibrators are subject to the same influences, with the result that such variations will be largely compensated in the calculation of the result.
- Insufficient washing (e.g. less than 3 wash cycles, too small wash buffer volumes, or too short residence times) can lead to false OD readings.
- Residual liquid (>10 µl) in the reagent wells after washing can interfere with the substrate and lead to false low OD readings.
- The partial or complete adjustment of the test system to the use of instruments for automated sample processing or other liquid handling devices may result in differences between the results obtained with automated processing and those obtained with manual procedure. It is the responsibility of the user to validate the instruments used so that they yield test results within the valid range.
- Use of Anti-SARS-CoV-2 S1 Curve ELISA (IgG) is limited to laboratory personnel who have been trained. Not for home use.

- This assay has not been evaluated with fingerstick specimens. This test is not authorized for use with fingerstick whole blood.
- The performance of this test has not been established in individuals who have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The samples for the positive percentage agreement were collected from the Mid West region of United States in August 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of this device has not been established in samples collected from individuals less than 15 days following the onset of symptoms. Samples should be collected from individuals greater than 14 days following the onset of symptoms. Samples should not be tested if collected from individuals less than 15 days post symptom onset.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.
- Performance characteristics have not been established for the assay used in conjunction with other manufacturers' assays for specific SARS-CoV-2 serological markers. Laboratories are responsible for establishing their own performance characteristics.
- The performance of the assay has not been established with cord blood, neonatal specimens, cadaver specimens, or body fluids other than serum or plasma.
- Results obtained with the assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Performance has only been established with the specimen types listed in the *Intended Use*. Other specimen types have not been evaluated and should not be used with this assay.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
- The immune response may be depressed in elderly, immunocompromised, or immunosuppressed patients. Immunocompromised patients who have COVID-19 may have a delayed antibody response and produce levels of antibody which may not be detected as reactive by the assay.
- This test should not be used for donor screening to prevent SARS-CoV-2 transmission during blood, tissue, or organ donations.
- The presence of 0.25 g/dL and higher levels of hemoglobin may result in a decrease or increase of the observed value (RU/mL) of up to 18%. The presence of 20 mg/dL and higher levels of bilirubin may result in an increase of the observed value of up to 28%. The presence of 500 mg/dL cholesterol may result in an increase of the observed value of up to 16%. The presence of 4.0 g/dL and higher levels of albumin may result in an decrease of the observed value of up to 28%. Do not test hemolyzed or icteric samples.

Conditions of Authorization for the Laboratory

The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) Letter of Authorization, along with the Authorized Fact Sheet for Healthcare Providers, the Authorized Fact Sheet for Recipients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

Authorized laboratories using the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of this product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and EUROIMMUN US, Inc. (support@euroimmun.us) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. EUROIMMUN US. Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

*The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate (automated method) or high (manual and automated method) complexity tests" as "authorized laboratories."

Analytical performance

Detection Capability:

The Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) were determined in accordance with the guidelines in CLSI EP17-A2.

The LoB corresponds to the highest measurement result that is likely to be observed for analyte-free samples with a probability of 95%. Each sample was run 15 times (3 runs with 5 replicates each, each run performed on a different day with 2 different lots) to reach a total of 150 measurements. The LoB was estimated as the 95th percentile value from 75 measurements of analyte-free samples over several independent series. The LoB was determined to be 0.54 RU/mL.

The LoD is the lowest concentration of IgG antibodies to SARS-CoV-2 in a sample that can be detected with a probability of 95%. Each sample was run 15 times (3 runs with 5 replicates each, each run performed on a different day with 2 different lots) to reach a total of 150 measurements. LoD was calculated on the LoB and 75 measurements of low analyte samples. The LoD for EUROIMMUN SARS-CoV-2 S1 Curve ELISA (IgG) was determined to be 0.78 RU/mL.

The LoQ is defined as the lowest amount of analyte in a sample at which the within laboratory CV is < 20%. The LoQ for EUROIMMUN SARS-CoV-2 S1 Curve ELISA (IgG) was determined to be 1.12 RU/mL, based on 150 measurements of low analyte samples.

Single-Site Precision: Single-Site precision of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) was investigated using samples at different concentration levels (negative, borderline, moderate positive, high positive) using native/spiked samples, assayed in 80 determinations per sample performed in 40 different runs on 20 different days (with 2 runs per day and 2 replicates per run). The results are presented in the table below.

Sample No.	Mean **RU/ml**	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) **RU/ml**									
		Repeatability		Between Run		Within-Day		Between-Day		Within-Device/ Within Lab	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	2.53	0.23	9.0%	0.35	13.9%	0.42	16.5%	0.31	12.3%	0.52	20.6%
2	7.63	0.27	3.5%	0.58	7.6%	0.64	8.3%	0.00	0.0%	0.64	8.3%
3	10.23	0.27	2.6%	0.98	9.6%	1.02	10.0%	0.00	0.0%	1.02	10.0%
4	30.03	0.71	2.4%	2.53	8.4%	2.63	8.8%	0.00	0.0%	2.63	8.8%
5	91.93	4.22	4.6%	5.31	5.8%	6.78	7.4%	2.14	2.3%	7.11	7.7%

n = 80	**RU/ml**				
	Sample 1	Sample 2*	Sample 3*	Sample 4	Sample 5
Mean value (x):	2.53	7.63	10.23	30.03	91.93
Range of values	1.35 - 3.75	5.96 - 8.88	8.13 - 12.64	21.94 - 34.62	69.27 - 106.09
Expected result	negative	borderline	borderline	positive	positive
% positive	0.0%	0.0%	21.3%	100.0%	100.0%
% borderline	0.0%	22.5%	78.8%	0.0%	0.0%
% negative	100.0%	77.5%	0.0%	0.0%	0.0%

** Samples near Cut-off*

Reproducibility (Between-Lot): Reproducibility of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) was investigated using samples at different concentration levels (negative, borderline, moderate positive, high positive) using native/spiked samples, assayed in 90 determinations per sample performed in 2 different runs on 5 different days (with 2 runs per lot and 3 replicates per run). The results are presented in the table below.

Sample No.	Mean (**RU/ml**)	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) **RU/ml**											
		Repeatability		Between-run		Between-Day		Within-Lot		Between-Lot		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	2.78	0.19	6.7%	0.27	9.7%	0.00	0.0%	0.33	11.8%	0.28	10.1%	0.43	15.5%
2	8.02	0.27	3.3%	0.28	3.5%	0.08	1.0%	0.40	4.9%	0.10	1.3%	0.41	5.1%
3	11.05	0.59	5.3%	0.44	4.0%	0.00	0.0%	0.74	6.7%	0.11	1.0%	0.75	6.7%
4	10.42	0.38	3.7%	0.34	3.3%	0.32	3.0%	0.60	5.8%	0.00	0.0%	0.60	5.8%
5	31.08	0.92	2.9%	1.12	3.6%	0.64	2.1%	1.58	5.1%	0.65	2.1%	1.71	5.5%
6	93.33	5.65	6.1%	3.23	3.5%	0.00	0.0%	6.51	7.0%	1.24	1.3%	6.63	7.1%

n = 90	**RU/ml**					
	Sample 1	Sample 2*	Sample 3*	Sample 4*	Sample 5	Sample 6
Mean value (x):	2.78	8.02	11.05	10.42	31.08	93.33
Range of values	1.73 - 3.75	7.23 - 9.30	9.66 - 13.78	9.34 - 12.23	27.44 - 35.41	79.83 - 110.58
Expected result	negative	borderline	borderline	borderline	positive	positive
% positive	0.0%	0.0%	48.9%	16.7%	100.0%	100.0%
% borderline	0.0%	48.9%	51.1%	83.3%	0.0%	0.0%
% negative	100.0%	51.1%	0.0%	0.0%	0.0%	0.0%

** Samples near Cut-off*

Reproducibility (Between-Site): Reproducibility of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)) was investigated using samples at different concentration levels (negative, borderline, moderate positive, high positive) using native/spiked samples, assayed in 90 determinations per sample performed at 3 different sites on 5 different days (with 2 runs per day and 3 replicates per run). The results are presented in the table below.

Sample No.	Mean (**RU/ml**)	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) **RU/ml**											
		Repeatability		Between-run		Between-Day		Within-Site		Between-Site		Reproducibility	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	3.19	0.14	4.4%	0.08	2.4%	0.12	3.9%	0.20	6.4%	0.87	27.3%	0.89	28.0%
2	9.02	0.26	2.8%	0.30	3.4%	0.10	1.1%	0.41	4.5%	0.65	7.2%	0.77	8.5%
3	11.43	0.41	3.6%	0.06	0.5%	0.36	3.1%	0.55	4.8%	0.94	8.2%	1.09	9.5%
4	12.73	0.63	4.9%	0.40	3.1%	0.25	2.0%	0.78	6.2%	0.65	5.1%	1.02	8.0%
5	17.48	0.50	2.9%	0.79	4.5%	0.56	3.2%	1.09	6.2%	0.78	4.4%	1.33	7.6%
6	64.40	2.36	3.7%	2.53	3.9%	1.26	2.0%	3.68	5.7%	2.73	4.2%	4.58	7.1%
7	98.27	4.16	4.2%	4.93	5.0%	0.00	0.0%	6.45	6.6%	6.68	6.8%	9.29	9.5%

n = 90	**RU/ml**						
	Sample 1	Sample 2*	Sample 3*	Sample 4	Sample 5	Sample 6	Sample 7
Mean value (x):	3.19	9.02	11.43	12.73	17.48	64.40	98.27
Range of values	2.06 - 4.54	7.56 - 10.42	9.34 - 12.94	10.71 - 17.63	12.63 - 119.83	55.61 - 75.58	84.89 - 115.27
Expected result	negative	borderline	borderline	positive	positive	positive	positive
% positive	0.0%	0.0%	65.6%	97.8%	100.0%	100.0%	100.0%
% borderline	0.0%	95.6%	34.4%	2.2%	0.0%	0.0%	0.0%
% negative	100.0%	4.4%	0.0%	0.0%	0.0%	0.0%	0.0%

** Samples near Cut-off*

Instrument specific precision: Instrument specific precision for the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) was investigated using pre-characterized native samples (positive and negative) performed on the EUROIMMUN EUROLabworkstation ELISA, EUROIMMUN Sprinter XL and Dynex DSX® Automated ELISA System. Repeatability SD's and %CV's were calculated based on 88 determinations per sample performed at 1 site with 1 run per day and 88 replicates per run according to the package insert. The following results were obtained:

Instrument	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)					
	Sample 1			Sample 2		
	Mean (RU/ml)	SD	%CV	Mean (RU/ml)	SD	%CV
EUROLabWorkstation ELISA	30.87	1.78	5.8%	2.03	0.33	16.0%
Sprinter XL	32.19	3.79	11.8%	2.42	0.33	13.5%
DSX®	38.28	2.19	5.7%	2.78	0.56	20.1%

n = 88	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)					
	EUROLabworkstation ELISA		Sprinter XL		DSX®	
	Sample 1	Sample 2	Sample 1	Sample 2	Sample 1	Sample 2
Mean value (x):	30.87	2.03	32.19	2.42	38.28	2.78
Range of values	26.77 – 35.12	1.25 – 3.23	16.99 – 37.82	1.67 – 3.4	34.09 – 45.62	1.37 – 3.62
Expected result	positive	negative	positive	negative	positive	negative
% positive	100.0%	0.0%	100.0%	0.0%	100.0%	0.0%
% borderline	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% negative	0.0%	100.0%	0.0%	100.0%	0.0%	100.0%

Linearity: To investigate the linearity of the assay, dilution sets of two clinical serum samples in addition to the high concentration calibrator were used to prepare a dilution series comprised of 11 levels by mixing negative and high positive samples. Each level was tested with 4 replicates per sample preparation on 1 lot of EUROIMMUN SARS-CoV-2 S1 Curve ELISA (IgG). The mean of the 4 replicates for each sample was calculated. Linearity was demonstrated for the interval of 1.12 to 120 RU/ml with deviations from linearity within 15%. Taking into consideration the estimates of LoB, LoD, LoQ, precision, and linearity, the analytical measuring interval is 1.12 to 120 RU/mL.

Cross-reactivity (analytical specificity): Due to low homologies of the S1 protein within the coronavirus family, cross-reactions to most of the human pathogenic representatives of this virus family are virtually excluded. However, due to the close relationship of SARS-CoV(-1) and SARS-CoV-2, cross-reactions between these two viruses are likely. Cross-reactions were not observed.

Other potential interferences with various autoantibodies such as anti-mitochondrial antibodies (AMA), rheumatoid factors (Rhf), and antibodies against non-related structures like *Haemophilus influenzae* type B (HIB), hepatitis B (HBV), hepatitis C (HCV), respiratory syncytial virus (RSV), parainfluenza, Epstein-Barr virus (EBV), vaccination against influenza viruses and tick-borne encephalitis (TBE) were not observed. In patient samples with high antibody titers against adenovirus and enterovirus, very high antibody titers against different autoantigens and with severe bacterial pneumonia, cross reactivity was observed in a few individual cases.

No.	Panel	n	**EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)**			
			positive	borderline	negative	% Cross-Reactivity
1	SARS-CoV(-1) Infection (2005)	2	0	0	2	0.0%
2	SARS-CoV(-1) Infection (2020)	1	0	0	1	0.0%
3	HCoV-229E Infection	11	0	0	11	0.0%
4	HCoV-OC43 Infection	6	0	0	6	0.0%
5	Fresh vaccination against influenza and follow-ups (2007)	40*	0	0	40	0.0%
6	Acute, severe bacterial pneumonia with high concentrations of procalcitonin	58	1	0	57	1.7%
7	Acute EBV infections with heterophile antibodies	22	0	0	22	0.0%
8	ANA and other autoantibodies	40	1	0	39	2.5%
9	Rheumatoid factors (Rhf)	40	0	0	40	0.0%
10	Anti-mitochondrial antibody (AMA)	19	0	0	19	0.0%
11	Vaccinations against tick borne encephalitis	25	0	0	25	0.0%
12	Haemophilus influenzae (IgG)	5	0	0	5	0.0%
13	Hepatitis B Infection (PCR Positive)	6	0	0	6	0.0%
14	Hepatitis C Infection (IgG)	6	0	0	6	0.0%
15	Respiratory Syncytial Virus (RSV)	35	0	0	35	0.0%
16	Adenovirus Infection (IgG)	30	1	0	29	3.3%
17	Human parainfluenza Infection (IgG)	30	0	0	30	0.0%
18	Enterovirus Infection (IgG)	30	1	0	29	3.3%

*Samples were from 6 different donors

Interference: Potential interference from high levels of hemoglobin, triglycerides and bilirubin was evaluated. Samples at different anti-SARS-CoV-2 IgG antibody concentrations across the assay measuring range were spiked with potential interfering substances and incubated with the test system according to the package insert. Lipemic and icteric samples showed no influence on the result up to concentrations of 20 mg/ml triglycerides and 0.1 mg/ml bilirubin, respectively. Cholesterol in concentrations up to 500 mg/dL and albumin at 4 g/dL showed no influence on the result in this ELISA. Negative bias of up to 17.5% was observed in the presence of 0.25 g/dL and 1 g/dL hemoglobin, while a 17.5% negative or 16.8% positive bias was observed in the presence of 0.5 g/dL hemoglobin, increasing the risk of falseerroneous results. Positive bias of up to 27.5% was observed in the presence of 20 mg/dL and higher levels of or 40 mg/dL bilirubin. Hemolytic, lipemic and icteric samples showed no influence on the result up to concentrations of 10 mg/ml hemoglobin, 20 mg/ml triglycerides and 0.4 mg/ml bilirubin in this ELISA. Positive bias of up to 15.7% was observed in the presence of 500 mg/dL cholesterol; negative bias of up to 27.8% was observed in the presence of 4 g/dL and higher levels of 6 g/dL albumin. Following possible interfering substances also showed no influence on the result in this ELISA up to concentrations of 60 g/l albumin and 13 mmol/l cholesterol.

Class specificity was evaluated with samples that cover the range of reactivity from negative to high positive. These samples were spiked with monoclonal anti-S1 IgM antibodies, and then both spiked and un-spiked samples were tested according to the package insert. The mean recovery in relation to the un-spiked sample ranged from 80.6% - 119.5%.

Matrix comparison: The usability of plasma was investigated using 15 sample pairs of serum and corresponding plasma (EDTA, heparin, citrate). Passing-Bablok regression was performed for the comparison of plasma to serum and showed the following results:

	EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)		
	Heparin plasma	**EDTA plasma**	**Citrate plasma**
n	15	15	15
Assay RU/ml range (serum)	3.28 - 58.01	3.28 - 58.01	3.28 - 58.01
Assay RU/ml range (plasma)	3.83 - 62.88	2.99 - 60.4	3.42 - 57.75
Regression equation (y = plasma, x = serum)	-0.4722 + 1.026 x	0.09411 + 0.9767x	0.09107 + 0.9424 x
95% C.I. of intercept	-1.984 - 1.031	-0.8234 - 1.509	-0.9665 - 2.157
95% C.I. of slope	0.8671 - 1.148	0.8742 - 1.081	0.8642 - 1.007
Coefficient of determination R^2	0.9734	0.9774	0.9900

Comparison between manual and automated modes of operation: A comparison study was performed by using previously determined anti-SARS-CoV-2 antibody positive or negative samples tested manually and on three different instruments, EUROLabWorkstation ELISA (n = 63), Sprinter XL (n = 103) and DSX® Automated ELISA System (n = 118), by 1 operator using 1 kit lot. The results of the regression analyses using Passing-Bablok regression are summarized in the tables below:

System	n	Slope	Intercept	% Agreement		
				Positive	Borderline	Negative
EUROLabWorkstation ELISA	63	0.989	-0.355	96.8% (30/31)	100% (8/8)	100% (24/24)
Sprinter XL	103	0.984	-0.189	97% (64/66)	91.6% (11/12)	100% (25/25)
DSX® Automated ELISA System	118	1.048	0.156	98.6% (73/74)	88.9% (8/9)	100% (35/35)

Clinical performance

Positive Agreement to PCR: The positive percent agreement was determined by investigating 30 serum samples from 30 different patients, using the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG). The RT-PCR used to characterize these samples are all commercially available and authorized by the FDA for use under EUA. The tables show the results with respect to SARS-CoV-2 specific IgG antibodies . The determined positive agreements are shown in groups, i.e. the early (0-7 days post PCR confirmation), medium (8-14 days post PCR confirmation) and later phase (≥15 days post PCR confirmation).

Days post PCR confirmation	n	Anti-SARS-CoV-2 S1 Curve ELISA (IgG)			
		pos	bord	neg	Positive Agreement to PCR (95% C.I.) Borderline counted as negative
0-7 days	0	0	0	0	N/A
8-14 days	0	0	0	0	N/A
≥15 days	30	28	1	1	93.3% (78.7% - 98.2%)
Total Subjects	30	N/A	N/A	N/A	N/A

Negative Agreement: To evaluate the negative percent agreement of the Anti-SARS-CoV-2 S1 Curve ELISA (IgG) presumed SARS-CoV-2 negative samples from apparently healthy blood donors from the US, Europe and China prior to November, 2019 (prior to the COVID-19 pandemic) were used. A second panel with samples taken from healthy blood donors during the COVID-19 outbreak was also used.

The agreement of the Anti-SARS-CoV-2 S1 Curve ELISA (IgG) results with the expected negative results combined from both panels corresponds to 99.2% (95% C.I. 98.4% - 99.6%; borderlines counted as positive).

Panels before COVID-19 pandemic	n	Anti-SARS-CoV-2 S1 Curve ELISA (IgG)			
		pos	bord.	neg	Negative % Agreement borderline counted as positive
US Blood donors (2017)	400	1	0	399	99.8%
European Blood donors (2017)	250	0	0	250	100.0%
Chinese Blood donors (2013)	49	0	1	48	98.0%
Chinese Pregnant women (2013)	99	1	0	98	99.0%
European Children (0 - 3 years, Oct. 2019)	100	4	1	95	95.0%
Overall	898	6	2	890	99.1%

Panels during COVID-19 pandemic	n	Anti-SARS-CoV-2 S1 Curve ELISA (IgG)			
		pos	bord	neg	Negative % Agreement borderline counted as positive
European Children (2020)	70	0	0	70	100.0%
Overall	70	0	0	70	100.0%

Overall	968	6	2	960	99.2%

Independent Clinical Agreement Validation Study: The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) was tested on 2021-07-09 and 2021-08-13 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI).
The test was validated against a panel of previously frozen samples consisting of 56 SARS-CoV-2 antibody-positive serum samples and 107 antibody-negative serum and plasma samples. Each of the 56 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 56 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG). The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods.
Antibody-positive samples were selected at different antibody titers. All antibody-negative samples were collected prior to 2020 and include i) Seventy (97) samples selected without regard to clinical status, “Negatives” and ii) Ten (10) samples selected from banked serum from HIV+ patients, “HIV+”. Testing was performed by one operator using one lot of the EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG). Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008). For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody-negative samples with HIV was statistically higher than the false positive rate among antibody-negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman). The results and data analysis are shown in the tables below.

The EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG) displayed a positive agreement of 91.1% (95% C.I. 80.7% - 96.1%), counting borderlines as negative,and a negative agreement of 100.0% (95% C.I. 96.5% - 100.0%).

EUROIMMUN Anti-SARS-CoV-2 S1 Curve ELISA (IgG)	Comparator Method			Total
	Positive (IgM/IgG)+	Negative (IgM/IgG)-	Negative HIV+	
Positive IgG+	51			51
Negative IgG-	2	97	10	109
Borderline	3			3
Total	56	97	10	163

Measure	Estimate	Confidence Interval
IgG Sensitivity (PPA)	91.1% (51/56)	(80.7%; 96.1%)
IgG Specificity (NPA)	100% (107/107)	(96.5%; 100%)
PPV for prevalence = 5%	100%	(55.1%; 100%)
NPV for prevalence = 5%	99.5%	(99.0%; 99.8%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Limitations of the study:

1. Samples were not randomly selected, and sensitivity and specificity estimates may not be indicative of the real-world performance of the device.
2. These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including fingerstick blood.
3. The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

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Technical Support

In case of technical problems you can obtain assistance via the EUROIMMUN website (https://www.euroimmun.de/en/contact/).

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Meaning of the symbols

Symbol	Meaning	Symbol	Meaning
STRIPS	Microplate strips	STOP SOLUTION	Stop solution
CAL 1-6	Calibrators 1 to 6	FOIL	Protective foil
CAL 1	Calibrator 1	RUO	For research use only
CAL 2	Calibrator 2	LOT	Lot description
CAL 3	Calibrator 3		Protect from sunlight
CAL 4	Calibrator 4		Storage temperature
CAL 5	Calibrator 5		Unopened usable until (YYYY-MM-DD)
CAL 6	Calibrator 6	CE	CE-labelled
POS CONTROL	Positive control		Manufacturing date (YYYY-MM-DD)
NEG CONTROL	Negative control		Manufacturer
CONJUGATE	Conjugate		Observe instructions for use
SAMPLE BUFFER	Sample buffer	REF	Order number
WASH BUFFER 10x	Wash buffer, 10x concentrate		Contents suffice for <n> analyses
SUBSTRATE	Substrate		Biological risks