TECHNICAL INFO: **Anti-SARS-CoV-2 S1 Curve ELISA (IgG) test in serum or plasma**

Method / Test type	**ELISA / Qualitative and Semi-Quantitative (EUROIMMUN under FDA EUA)**
Sample	**Serum or EDTA plasma**
Sample volume	**4 ml**
Min. volume accepted	**2 ml**
Sample collection	**Sample collected through standard phlebotomy venipuncture. Separate the serum or plasma according to your institution guidelines. Ship serum or plasma frozen.**
Shipping	**Ship frozen or refrigerated for next-day delivery**
Stability	**14 days refrigerated** **30 days at -20°C (Frozen)**
Rejection criteria	**Sample that is not serum or EDTA plasma.** **Bacterially contaminated sample** **Sample arriving outside of stability.** **Samples collected from infected individuals less than 15 days post symptom onset.**
Reference range	**<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.** **Numeric results are reported for samples with RU/ml between 11 RU/ml and 120 RU/ml.** **Interpretation based on infected individuals post-14 days onset of symptoms not testing vaccinated individuals, although similarly to infection, 14 days post-2nd vaccination should yield highest IgG result if an IgG response was elicited by vaccine.**
Reporting time	**3 days (from lab receipt)**
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*. 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.** **SARS-CoV-2 is predominantly transmitted by droplet infection via coughing or sneezing and through close contact with infected persons.** **Even with the availability of multiple vaccines against SARS-CoV-2, the SARS-CoV-2 virus is still a major worldwide health problem, due to highly infectious**

	variant (delta) and significant % of populations non-vaccinated.
Test specifics	**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). 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 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 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. When testing infected individuals samples should be collected from individuals greater than 14 days following the onset of symptoms.** **Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.**