



Customers of EUROIMMUN AG

- Immunfluoreszenz
- Enzymimmuntechniken
- Radioimmuntests
- Histologie und Zytologie
- Molekularbiologie
- Autoimmunkrankheiten
- Infektionskrankheiten
- Allergologie
- Antigen-Nachweise
- Erbmerkmale

Lübeck, 6. May 2020

Dear EUROIMMUN customer,

Yesterday, our [Anti-SARS-CoV-2 ELISA \(IgG\) was approved by the US-American Food and Drug Administration \(FDA\) by an emergency use authorization \(EUA\)](#). The results of a new independent validation effort by the U.S. Government provided the scientific evidence used to support the authorization. We are delighted that the excellent performance and reliability of our test system was therewith also officially acknowledged in the US.

According to the latest study results obtained using a broad data base, the test shows a specificity of 99.6% and a sensitivity of 93.8% from day 21 after onset of symptoms (please find further information [here](#)). These data are continuously updated with new results from numerous studies from all over Germany.

For instance, the following independent research institutes apply the Anti-SARS-CoV-2 ELISA (IgG) in their investigation:

- University Clinic Charité, Berlin
- Robert Koch Institute, Berlin
- University of Marburg
- University of Munich
- University of Bonn (“Heinsberg study”)

Moreover, Prof. Dr. Lohse, Director of the I Medical Clinic and Polyclinic of the University Clinic Hamburg-Eppendorf (UKE) presented the results from a UKE study using the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) and underlined its high specificity of 99.7% during a [press conference](#) (in German) on 22nd April 2020.

However, further studies have yet to show whether the detection of antibodies against the different viral antigens (spike protein/S1 domain or nucleocapsid protein) are associated with immunity against SARS-CoV-2. This also includes investigations within the framework of different vaccine development projects. Since these are virtually all based on the spike protein or its S1 domain, respectively, our ELISA is ideally suited for this purpose.

Generally, it is to expect that mainly antibodies of class IgG, which are detected by our test, play a role in the development of immunity. This is indicated as well by the recently published results of the [“Heinsberg study”](#) by the University of Bonn, in which the high quality of the EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) was proven and which showed a very good correlation of the ELISA with a neutralisation assay. The latter is an important indicator for acquired immunity.

In addition to the existing tests, EUROIMMUN provides a new ELISA which received the CE mark this week. The assay detects antibodies against the nucleocapsid protein (N protein) of SARS-CoV-2. As the high degree of homology between the N proteins of different members of the coronavirus family may lead to false positive reactions, our researchers modified this protein: Conserved areas were eliminated and a designer antigen (NCP) was produced



which only contains those epitopes that are relevant for specific detection of antibodies against SARS-CoV-2. Consequently, the EUROIMMUN Anti-SARS-CoV-2-NCP ELISA presents an exceptionally high specificity.

New scientific studies indicate that the immune response to the N protein is initiated earlier than that to the S1 domain. As a consequence, antibodies against NCP indicate an infection already after 10 days with high sensitivity. Those directed against the S1 domain indicate infection after 21 days. With these ELISAs, EUROIMMUN now offers two CE-marked test systems which can lead to an even higher reliability of positive antibody findings when they are applied in combination. Please find further information [here](#).

In order to meet the worldwide demand for our test systems, we have increased our production capacities by tenfold over the last six weeks and are still expanding them substantially. Like this, we are confident that we will be able to meet the challenges ahead.

We hope you master this difficult time with lots of confidence and stay healthy.

Sincerely,

Dr. Wolfgang Schlumberger
CEO EUROIMMUN AG