

AESKU.GROUP - A safe future thanks to quantitative **AESKULISA®** SARS-CoV-2 antibody tests

AESKU.GROUP, a leading biotechnology company, based in Wendelsheim, Germany, launched the first quantitative SARS-CoV-2 antibody tests in the 22nd calendar week. **AESKU** is currently the only company in the biotechnology industry, developing quantitative SARS-CoV-2 antibody tests that can certify the acquired immunity of patients or vaccinated individuals.

In the current situation, there is little need to discuss the urgent need for an effective and robust vaccine to treat COVID-19 because not only our society but humanity itself is in a state of emergency. Not only is a vaccine urgently needed, but it must also be possible to verify the success of vaccination through quantitative tests. Quantitative tests that test for neutralizing antibodies, i.e., antibodies that respond to a pathogen and break it down, make it possible to determine the success of an immune reaction and a vaccination in everyday practice.

For the determination of an immune reaction, examining the body's immunoglobulins (Ig), so-called antibodies, has been established for years. Since protein structures on the surface of a pathogen (bacterium, virus) are specific, i.e., unique to particular organisms, and the immune system forms the appropriate, specific antibody, it is possible to examine various antibodies to confirm an infection. In the case of the SARS-CoV-2 viruses, the nucleocapsid protein (N) and the spike protein (S1) and their antibodies are suitable.

AESKU's six different SARS-COV-2 immune assays:

AESKULISA® SARS-CoV-2 NP IgM/ IgA / IgG

The **AESKULISA®** SARS-CoV-2 NP IgA, IgG, and IgM tests are qualitative and quantitative immunoassays for the detection of human IgM, IgA, and IgG antibodies in serum or plasma directed against SARS-CoV-2 in highly conserved nucleocapsid protein (NP).

The nucleocapsid protein is very reactive and stimulates a very strong response to the immune system. This strong immune response provides sensitive detection of antibodies, which allows a clear differentiation between positive and negative samples. They are, therefore, ideal for IgM, IgA, and IgG detection for screening and diagnosis. However, due to the high sensitivity and strong conservation of the nucleocapsid protein in the coronavirus family, the risk of cross-reaction with antibodies against SARS-CoV-1 is increased. Since antibodies against the nucleocapsid protein have no neutralizing effect, they are not suitable for determining the immune status, the so-called antibody titer.

The **AESKULISA®** SARS-CoV-2 NP IgA is recommended for the detection of acute infections.

The **AESKULISA®** SARS-CoV-2 NP IgG allows the confirmation of pathogen contact and the determination of the immune status.

The **AESKULISA®** SARS-CoV-2 NP IgM allows to determine the first specific reaction of the immune system.

AESKU uses immunogenic nucleocapsid proteins of SARS-CoV-2 expressed in insect cells for the sensitive detection of IgM, IgA, and IgG antibodies.

AESKULISA® SARS-CoV-2 S1 IgM/ IgA / IgG

AESKULISA® SARS-CoV-2 S1 IgA, IgG, and IgM tests are qualitative and quantitative immunoassays for the detection of human IgM, IgA, and IgG antibodies of the highly specific spike protein (S1) in serum or plasma directed against SARS-CoV-2.

The spike protein has the advantage over the nucleocapsid protein that is highly specific for the SARS-CoV-2 virus. This results in a much lower risk of cross-reactions with antibodies against other members of the coronavirus family. IgG antibodies react against the receptor-binding domain (RBD) on the spike proteins and are therefore considered neutralizing. Therefore, and are suitable for monitoring the antibody titer of patients. In this respect, **AESKU**'s tests are one step ahead of clinical research, as there is no scientific proof yet at which antibody level immunity is reached. **AESKU** is currently the only company in the biotechnology industry that has developed quantitative SARS-COV-2 antibody tests.

The **AESKULISA**® SARS-CoV-2 S1 IgA is recommended for the detection of acute infections.

The **AESKULISA**® SARS-CoV-2 S1 IgG allows the confirmation of pathogen contact and the determination of the immune status. It can be used to detect and monitor the antibody titer of a patient.

The **AESKULISA**® SARS-CoV-2 S1 IgM allows to determine the first specific reaction of the immune system.

AESKUs test capacities

At its headquarters in Wendelsheim, **AESKU** currently produces 300,000 tests daily and has tested more patients than, for example, Euroimmun or Roche. To set up the production, **AESKU** initially used different patient samples of positive PCR tests from hospitals in Germany and abroad. Such PCR tests are currently the gold standard in clinical diagnostics, i.e., determining whether someone is carrying the virus or not. ELISA antibody tests against the various antibody classes, on the other hand, allow a precise differentiation between active but symptom-free disease and antibodies that indicate a past infection.

The marketing of the tests is to start in the 22nd calendar week. Pre-series tests have already been conducted in Italy and South America, where entire towns and cities are being tested. With the SARS-CoV-2 **AESKULISA**®s it is also possible to determine whether the coronaviruses (e.g., SARS, MERS, cold viruses ...), which have been known for a long time, brought along a SARS-CoV-2 immunity.

AESKUs **AESKULISAS**® can be used everywhere and in an uncomplicated way by using common reagents. **AESKULISAS**® are easy and fast to use due to the possibility of automating them. –

AESKU's motto "We for Rhineland-Palatinate"

CEO and founder of **AESKU**, Dr. Torsten Matthias, not only wants to provide researchers with an excellent tool to detect the infestation of the population, he has submitted a proposal to the government of Rhineland-Palatinate on how it would be possible to determine the number of undetected cases in the population and to determine the immune status of each citizen. Under the motto "We for Rhineland-Palatinate," Dr. Matthias wants to make his contribution with **AESKU** to improve the social and economic situation of the people and the economy and to enable a steady return to normal everyday life.

Samples are to be collected decentrally in donation centers, previously recommended by the state government, and then processed centrally in specially equipped specialized laboratories at the **AESKU** headquarters in Wendelsheim by experienced laboratory personnel. In this way, 300,000 samples per month could be evaluated.

Each of these donation centers will be equipped free of charge with **AESKU's** own **HERA** software, an intelligent gateway software between the laboratory information system and the analytical instruments, which has an integrated database application with decentralized, rights-controlled access. **HERA** is also suitable to better prepare the country for the future, especially for epidemics like the current one, and to optimize the networking of the health authorities for better communication and interaction.

At a glance:

Advantages of the **AESKULISA** SARS-CoV-2 immune assays at a glance:

First quantitative test in the market

Room Temperature incubation

Easy to automate, optimized for use in Triturus® / DSX

- Common reagents
- Optimized incubation (30 min, 30 min, 30 min)
- Assay Protocol Files available
- Nucleocapsid Protein IgA / IgG/ IgM
or
- Spike-Protein S1 IgA / IgG/ IgM