

Press release

July 30th, 2021

Measuring Corona Immune Status - Swiss GENIUS Pharmaceutical AG launches distribution of the neutralising antibody test GEN*monitor*TM as a rapid test in Germany, Austria, and Switzerland

- Measuring immunity is the crucial tool to assess the success of the vaccination campaign in Europe and to respond with appropriate measures to the coming fourth wave. The key to this measurement is neutralising antibody testing.
- The Swiss pharmaceutical company - GENIUS Pharmaceutical AG (GENIUS Pharma) - today officially announced the launch of its CE - marked rapid test for the qualitative detection of neutralising IgG antibodies against the SARS-CoV-2 spike protein.
- The product is available immediately in Europe for healthcare professionals from pharmaceutical wholesalers and distribution partners.

After intensive market research together with the quality management and the developer, Prima Lab from Switzerland, GENIUS Pharma today released the novel in-vitro diagnostic product GEN*monitor*TM for distribution.

GEN*monitor*TM COVID-19 NEUTRALISING Ab RAPID TEST is an excellent IVD product for the qualitative detection of neutralising IgG antibodies to the SARS CoV-2 Spike1 protein. Used by healthcare professionals, this CE-marked diagnostic assay detects neutralising antibodies in human plasma, serum or whole blood samples in as little as 10 minutes, providing information about a test subject's immunity.

GENIUS Pharma is thus building on the previous success of the rapid tests in the DACH region and wants to continue the established testing procedure. With the GEN*monitor*TM, the determination of neutralising antibodies is to be specifically checked and monitored by trained specialists after vaccination. Likewise, the neutralising antibodies of convalescents should also be able to be checked and monitored by such testing.

This "**monitoring**" is carried out after sample collection already 10 minutes after testing and shows whether neutralising antibodies are present and thus whether immunity against certain variants of SARS-CoV-2 can be assumed according to the current standard of knowledge. In this way, the test can support medical professionals in making recommendations on further vaccination policies.

According to GENIUS Pharma, this is urgently necessary so that the approx. 3.2 million recovered and approx. 49.0 million fully vaccinated people (2 vaccinations) in Germany alone can now have their vaccination protection checked directly by their doctor in just 10 minutes, in addition to the usual laboratory analyses.

"Developments such as in Australia or Singapore, where the number of cases is rising again despite a good vaccination rate, could be recognised in order to allow for re-immunisation through refresher vaccinations if the antibody titre is insufficient," is the opinion of Markus Neumann, MD, medical-scientific advisor and responsible for the quality analysis of partner products at GENIUS Pharma.

GENIUS Pharma attaches particular importance to the fact that the rapid test - GEN*monitor*[™] can achieve high reliability in determining seroconversion after full vaccination. This has been evaluated with the western vaccines Pfizer, Moderna and AstraZeneca on the basis of studies*. For example, with the Pfizer/Biontech vaccine, neutralising antibodies can be detected in the blood by GEN*monitor*[™], with a detection reliability of 98.3% in the period of 14-21 days after full vaccination.

With the launch of GEN*monitor*[™] in the DACH region, GENIUS Pharma has succeeded in reaching an important milestone in its market establishment.

"It is very important to have an initial indicator of whether or not immunity to the SARS-CoV-2 virus is still present after vaccination or recovery," notes Markus Neumann, MD. "Particularly in times when politics and science are still at disagreement as to which quantitative threshold values are necessary to demonstrate sustainable vaccination protection, close-meshed and transparent monitoring of the qualitative immune response is a relevant step for patients and physicians to meaningfully control the vaccination regime," continues Dr. Neumann.

From today's perspective, most vaccine manufacturers recommend a booster vaccination about 12 months after completing the first full vaccination cycle. According to GENIUS Pharma, an initial qualitative analysis for neutralising antibodies with the GEN*monitor*[™] could already be relevant for those vaccinated in the first quarter of 2021.

As a next step, GENIUS plans to launch a handy analysis device for quantitative test evaluation of neutralising antibodies at the "point of care".

For more information on the GEN*monitor*[™], please visit <http://www.geniuspharma.ch>.

* Alle hier angeführten Originalstudien wurden an den genannten Instituten durchgeführt und können bei Bedarf verfügbar gemacht werden. Es wird in dieser Pressemitteilung auf die folgenden Studien Bezug genommen:

Q8R318 Study Report - Italian National Cancer Institute (Milan, Italy), Interuniversity Center for Research on Influenza and other Transmissible infections (Genova, Italy), Pharmacological Research Institute Mario Negri (Bergamo, Italy) and PRIMA Lab SA (Balerna, Switzerland); May 2021. Q8R334 und Q8R335 Study Report. PRIMA Lab SA (Balerna, Switzerland); June 2021

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Über GENIUS Pharma

GENIUS Pharmaceutical AG (GENIUS Pharma) produces and distributes high-quality pharmaceutical in vitro diagnostics (IVD) for applications that are commercially viable for GENIUS Pharmaceutical AG's customers while adding value for the investors behind GENIUS Pharmaceutical AG, all in a supportive and rewarding work environment for GENIUS Pharmaceutical AG employees. The goal of GENIUS Pharmaceutical AG is to improve healthcare through unconventional thinking. With its daily work, GENIUS Pharmaceutical AG wants to make a contribution to humanity. For this reason, GENIUS Pharmaceutical AG has been striving for 13 years to provide first-class healthcare solutions in a world afflicted by inefficiencies and widespread discontent. This goal drives the management and employees of GENIUS Pharmaceutical AG to perform for in vitro diagnostics every day.

GENIUS Pharmaceutical AG explores innovative ways to use data and systems, leveraging the skills and expertise of the entire team to improve the management of clinical service delivery and ultimately the achievement of measurable and better health outcomes. GENIUS Pharmaceutical AG is committed to implementing health transformation by fully focusing on efficient management, cost and quality of clinical service delivery.

End of press release

This press release is for distribution in Germany, Austria and Switzerland only.

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