New PCR rapid test method reveals: Danish corona mutation arrived in Bavaria previously unnoticed

- **While Germany is fearful of the SARS-CoV-2 mutations found in the UK and South Africa, the Danish variant thought to have been eradicated, demonstrably spread in Bavaria.**
- **The new PhoenixDx® PCR method developed by Procomcure Biotech in collaboration with the ArminLabs laboratory detected the Danish virus variant in samples from Ansbach and Neu-Ulm.**
- **New and fast PCR mutation analysis provides reliable information on infection and mutation in under two hours, enabling area-wide analyses.**

Augsburg / Salzburg, January 26, 2021: For the first time, the Danish corona virus mutation originally thought to have been eradicated in November 2020, was detected in Bavaria. The Augsburg laboratory ArminLabs detected the Danish virus variant in one patient each from the Neu-Ulm and Ansbach regions using the PhoenixDx® PCR-based mutation screen recently developed by the Austrian manufacturer Procomcure Biotech. A Salzburg partner laboratory detected the N501Y mutation known from the South African and British variants in four samples using the same method.

Only one in a thousand positive samples has been tested for mutations so far

Until now, the identification of different variants of SARS-CoV-2 was only possible by means of extremely complex and expensive genome sequencing. For this reason, only about one in a thousand positive Corona samples has been examined for mutations in Germany to date. The identification of a virus variant takes up to one week and there are only a few laboratories in Germany that are able to carry out such complicated examinations at all. Since the beginning of the pandemic, the Austrian manufacturer Procomcure Biotech, headquartered in Salzburg, has been developing methods and products for corona diagnostics that are used worldwide. For several days now, Procomcure has been able to quickly, reliably and inexpensively analyze large numbers of samples that have tested positive for the virus for multiple mutations simultaneously. The PhoenixDx® Mutant Screen is the first of its kind and can replace the time-consuming and costly sequencing.

The mutation event is fundamental to any national strategy

The "Denmark Mutation" was thought to have been eradicated since November 2020 with the mass killing of 15 million mink in Denmark. Since then, scientists, politicians and the media assumed there was no realistic prospect of further spread. From then on, attention turned to the emerging British and South African mutation. The fear: new variants of the virus could bring new and unfavourable properties such as higher virulence, immune system evasion or increased mortality. The "Denmark variant" mutation now detected by the PhoenixDx® system, for example, allows the virus to bypass the human immune system more easily than the original Wuhan variant. As a result, the Danish mutation discovered here is assumed to weaken already acquired antibodies against it which could compromise the success of a vaccination. According to current knowledge, other mutations are more contagious or more likely to cause severe progression than the wild type. The German government has therefore decided that in future, 5-10% of all positive corona samples should be tested for mutations. To reach this number, inexpensive and

rapid methods are urgently needed. Procomcure Biotech and ArminLabs together have sufficient capacity to test all positive corona samples in Europe for multiple virus mutations in a short time.

New 2-hour test enables area-wide mutation analyses

GA-Diagnostics, an umbrella organization of the analytical laboratories Procomcure Biotech Germany (Winsen), ArminLabs (Augsburg) and Procomcure Biotech Austria (Salzburg), now offers for the first time an innovative solution for the area-wide and cost-saving analysis of all positively tested SARS-CoV-2 samples for clinically relevant mutations. The PhoenixDx® Mutant Screen, a PCR-based multiplex assay system for the detection of multiple mutations in a single test, is the first of its kind worldwide and can replace the time-consuming and cost-intensive sequencing analyses. This approach was developed by the Austrian company Procomcure Biotech, which is the research and production center of the GA-Diagnostic network.

The new test and association comes at the right time as the efficiency of a national testing strategy requires, on the one hand, reliable detection of infected individuals and, at the same time, the rapid implementation of quarantine requirements. This requires the gold standard PCR as a detection method and sufficient IT logistics. The alliance aims to do just this and, with more understanding of the distribution of virological markers, to help identify the right quarantine measures or treatments in Germany and worldwide. After all, improved nationwide screening strategies are an important building block for a way out of the crisis. GA Diagnostics has the capacity to perform 150,000 PCR tests daily.

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