Statement by nal von minden GmbH, specialist for *in-vitro* diagnostics, on the depiction of antibody tests for COVID-19 in the media

Antibody tests for SARS-CoV-2 are currently the subject of controversial discussion suggesting that they are not validated or approved and are insufficient for acute diagnostics.

We agree only conditionally with the assertion that an initial diagnosis with antibody tests is not possible. If used correctly and repeated in due course, antibody tests are a reliable diagnostic tool that should be used in addition to RT-PCR.

We do not deny that RT-PCR is still the gold standard in testing for the novel SARS-CoV-2 virus. Unfortunately, however, it is likely to reach its limits in terms of both laboratory capacity and availability of test components. Secondly, a PCR does not detect infectious virus particles, but their genetic material. This RNA is detected regardless of whether it comes from an intact, infectious virus or simply viral remnants (intermediates) that are still present. The accuracy of RT-PCR results is also limited when the virus has long since migrated deeper into the lungs and is no longer detectable by a relatively simple nasal or throat swab.

An antibody test for COVID-19 IgG and IgM, on the other hand, reveals whether the body has dealt with the virus as part of an adaptive immune response. After the onset of symptoms, the body usually needs between three and seven days to produce these specific antibodies to fight the virus. If the rapid test for these antibodies is positive, this means that the body's adaptive immune system has mounted a response to the virus and the treating physician can take appropriate action. If the result is negative, appropriate precautions must be taken and further testing or re-testing must be carried out. This is because a primary infection is characterised by the presence of detectable IgM antibodies on average three to seven days after the onset of symptoms, while the subsequent presence of IgG antibodies can continue to indicate a previous infection with SARS-CoV-2 for months – even if the virus can no longer be detected in PCR tests. These IgG antibodies can indicate immunity. However, in some cases antibodies can only be detected in sufficient quantities weeks after infection, and in case of a sufficient innate or cellular immune response to contain the virus, the absence of detectable specific antibodies is also conceivable.

Thus, COVID-19 antibody tests used at the right time can close diagnostic gaps and take the pressure off overburdened laboratories. Antibody rapid tests pursue a different goal than RT-PCR diagnostics.

Yes, there are bad apples among antibody rapid test suppliers, but you can trust nal von minden GmbH's well-evaluated tests. Our NADAL® COVID-19 IgG/IgM rapid tests have a diagnostic sensitivity of more than 90% and a diagnostic specificity of 99% for IgM detection. The tests have been evaluated with clinical samples from symptomatic patients in comparison to the PCR method. Further studies are currently being carried out by hospitals in Paris, the Bremen hospital group, the Karolinska Institute in Sweden, the University of Regensburg and laboratories commissioned by the Israeli government. It is becoming increasingly clear that our tests are doing very well. It is therefore advisable to carry out further tests starting the second to third week after initial suspicion. In this way, even asymptomatic individuals from risk areas can be evaluated to determine, with high probability, whether they are infected with SARS-CoV-2.

In addition, more potentially affected individuals can be efficiently examined, making faster and more targeted action possible and reducing the burden on laboratories. In the medium term, the antibody

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could also be used to determine so-called herd immunity. The more data available on this and thus on the rate of infection, the more soundly measures to contain the pandemic can be evaluated and validated.

We at nal von minden GmbH are manufacturers of a comprehensive selection of medical products for *in-vitro* diagnostics. We develop and produce some of our products in Germany. Others are manufactured abroad by our long-standing partner companies, e.g. in China. Joint development and evaluation of the tests is of utmost importance to us – above all, so that we can meet the specific needs of our customers. As a matter of principle, technical documentation is meticulously compiled and reviewed, and joint evaluations and studies are carried out in addition to internal ones.

With regard to its tests, nal von minden GmbH welcomes external review. We are open to justified criticism at any time, provided there is a fair exchange of arguments and no blanket prejudgement. We always act according to our motto: We help you care! Let us tackle this together. It is more important than ever.
You can find more information about our test on our website.

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