

## Press Release

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### medac Diagnostics Portfolio

## **With immediate effect: medac's proven methods for SARS-CoV-2 testing for the German-speaking world**

- **3 million proven serological tests already being shipped, further 17 million tests available**
- **Separate measurement of IgG and IgM, use of S and N antigens**
- **Rapid test processing – results available after 35 minutes**
- **Fast and easy pathogen detection using multiplex PCR test**
- **Guaranteed long-term reliability for delivery of both tests**

*Wedel (8 May 2020).* Support in the fight against coronavirus: with immediate effect, medac GmbH is offering a proven antibody test for SARS-CoV-2 within Germany, Austria and Switzerland as well as a rapid and particularly easy-to-use PCR test for direct virus detection in Germany and Austria. Doctors, laboratories and hospitals can rely on the Wedel-based pharmaceutical company as a single source for proven, fast and comprehensive diagnostics.

### **Rapid processing and proven serological tests**

The fully automated Maglumi 800 and Maglumi 4000 Plus systems can process up to 100 other laboratory markers alongside the SARS-CoV-2 antibody tests. These include inflammation markers such as CRP, PCT and interleukin 6 or cardiological markers which play a role in SARS-CoV-2 diagnostics, with up to 280 results per hour being processed on the Maglumi systems. Initial results are available after only 35 minutes.

medac uses the innovative non-enzyme-coupled chemiluminescence immunoassays (CLIA) method, which separately detects specific IgG and IgM antibodies in the blood of infected patients. The use of highly specific recombinant antigens and proven  $\mu$ -capture technology in

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the IgM test ensures stable, rapid and sensitive serological detection of an acute or recovered SARS-CoV-2 infection. The test offered by medac uses both antigens — the spike glycoprotein (S antigen) and the nucleocapsid phosphoprotein (N antigen) — to ensure optimal sensitivity. No cross-reactivity to harmless coronaviruses has been observed as yet.

The technical benefits of CLIA technology were already evident in the BioClia® 6500 system, introduced in May 2019 for the diagnosis of autoimmune disorders. In addition to the faster processing of tests, other significant advantages are a larger linear measurement range for quantification and the higher sensitivity and specificity of the CLIA method.

medac is cooperating with established global firm Snibe-Diagnostic. The company specialises in clinical laboratory instruments and in vitro diagnostic reagents, and has been developing highly sensitive chemiluminescence immunoassays for more than 25 years. To ensure security and optimal management of the current pandemic, full and comprehensive availability of supply has been guaranteed. A total of 20 million serological tests are currently available.

Serological testing for antibody detection is an ideal complement to direct detection of the virus by PCR and is crucial when seeking to answer epidemiological questions. 26 Maglumi systems have already been installed in Germany – with further systems and 3 million tests in the process of being delivered.

### **Reliability and testing in the daily routine**

The antibody test offered by medac was awarded its European CE IVD marking on 19 February 2020, the first test to be so certified worldwide. Since then, it has been tested in independent studies, including in the epicentre of Italy and in renowned German laboratories, and has proven its reliability. The test is already being used routinely in Spain and Italy and is now also available for Germany, Austria and Switzerland.

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### **Multiplex PCR tests: easier and faster for more efficient laboratory work**

The CE-IVD-certified GeneProof SARS-CoV-2 PCR test is based on multiplex real-time RT-PCR technology and effectively detects specific sequences of the viral genes RdRp (RNA-dependent RNA polymerase), E (envelope) and N (nucleocapsid) in a single run.

The crucial advantage of medac's multiplex PCR test is its simplified workflow. Firstly, it allows for omission of the otherwise usual step of preparing the sample (RNA extraction). Secondly, the ready-to-use mastermix reduces to a minimum the number of pipetting steps required to perform PCR. The sample can be added directly to the mastermix. 'What we need at the moment is rapid and reliable testing for SARS-CoV-2 infections. Our multiplex RT-PCR test now makes this possible,' says Ralf Tönnies, Head of medac Diagnostics.

The GeneProof SARS-CoV-2 PCR test is validated for the most common thermocyclers on the market and is, with its universal PCR program and universal control, compatible with all other PCR tests offered by GeneProof. The SARS-CoV-2 PCR represents a consistent expansion of medac's PCR portfolio in general and with respect to detection of respiratory infections in particular.

PCR quality is monitored by GeneProof's own participation in the leading German inter-laboratory survey conducted by Instand e.V. Based on material measured against standards from the Global European Virus Archive (EVAg) and with synthetic positive controls, the GeneProof SARS-CoV-2 test achieves sensitivity of up to 1.77 cp/µl. In line with WHO recommendations (Corman et al, 2020) for SARS-CoV-2 PCR tests, the PCR test offered by medac has a specificity of 100 percent.

So as to meet the needs of the market and of existing enquiries, unlimited quantities of GeneProof SARS-CoV-2 PCR tests are available with immediate effect. Short delivery times for additional tests are guaranteed via established European manufacturer GeneProof.

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**Figure 1:** The fully automated Maglumi 4000 Plus  
**Figure 2:** SARS-CoV-2 test kit



**Figure 3:** GeneProof SARS-CoV-2 PCR test

### **medac: over 50 years of therapies and diagnostics from a single source**

medac has specialised in the new and further development of therapeutic and diagnostic agents under one roof for more than 50 years. The mission of this medium-sized German pharmaceutical company is to ensure the reliable provision of safe, innovative drugs and medical devices. Patient quality of life and user-friendliness are at the heart of its everyday commitment.

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### medac Gesellschaft für klinische Spezialpräparate mbH

medac is a privately owned German pharmaceutical company with facilities in Wedel and Tornesch, Germany. medac's treatments support doctors and patients throughout the world in overcoming acute and chronic diseases in the fields of oncology, haematology, urology and autoimmune conditions. In addition, medac develops and distributes specialised diagnostic test systems. medac has been committed to combining therapeutics and diagnostics under one roof since 1970. Further information on the company and its products is available online at [www.medac.de](http://www.medac.de).