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medac Diagnostics: a complete package for COVID-19 testing

With immediate effect: 3 million proven antibody tests for SARS-CoV-2 and mastermix ready-to-use PCR tests. 17 million more antibody tests available

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 safe, fast and comprehensive diagnostics.

Multiplex PCR: the faster, more reliable test for acute COVID-19 infection

Real-time PCR (polymerase chain reaction) detects the nucleic acid of the SARS-CoV-2 virus and is considered the international gold standard for detection of acute infection with this pathogen. PCR tests can be used from the immediate onset of the disease and show whether a person has COVID-19 at the time of testing. Testing ideally involves the taking of a nasopharyngeal swab, since – according to current knowledge – virus concentrations are highest in the throat at the start of the infection.

The PCR test is used to examine the sample taken. medac's multiplex PCR test simplifies the workflow for laboratories, giving them a crucial advantage. Firstly, it allows for omission of the otherwise usual step of preparing the sample (RNA extraction). Secondly, it reduces the number of pipetting steps required to perform PCR. This simplification is possible because medac's PCR test is a ready-to-use reagent mix, the components of which have been adapted to enable direct use of the patient sample. This unique combination, together with very good sensitivity and specificity, enables laboratories to work easier, faster and therefore more efficiently.

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Antibody test gives vital information on previously undetected cases as well as epidemiology and immunity

Based on a blood sample, the serological test for antibody detection is the ideal downstream supplement to direct detection of the virus by PCR. This test is crucial for answering epidemiological questions, as Prof. Lothar H. Wieler, President of the Robert Koch Institute, has emphasised.¹ The results of antibody studies, for example, are significant in achieving more accurate assessment of the progression and severity of the pandemic.

The antibody test uses a blood sample to detect specific antibodies that have been produced in response to SARS-CoV-2 by the immune system. These antibodies are measured in the form of immunoglobulin levels. A positive result for immunoglobulin M (IgM) indicates an early-phase infection (from about 3 days) and a positive result for immunoglobulin G (IgG) indicates a later phase of the infection (from about 5 to 7 days). In contrast to other serological test procedures, the CLIA test procedure now offered by medac measures IgM and IgG levels separately.

By using medac's antibody test, it is therefore possible to do more than just determine whether someone has been infected with the virus and is therefore immune. medac's test uses IgM measurement to provide additional valuable information as to whether a person is infected at the time of testing. Subsequent PCR testing to confirm the acute infection thereby allows for detection of patients without typical symptoms who would not otherwise have been diagnosed as COVID-19 cases. This is of great importance in the fight against the SARS-CoV-2 pandemic, helping to prevent the unchecked spread of undetected cases.

The existence of immunity to SARS-CoV-2 depends on neutralising antibodies, which can render the virus harmless. Neutralising antibodies bind to two specific structures of the

¹ See Prof. Lothar H. Wieler, President Robert Koch-Institut; URL:<https://www.ovb-online.de/weltspiegel/bayern/coronavirus-studie-antikoerper-robert-koch-institut-ausbreitung-pandemie-13647282.html> (17.04.2020).

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SARS-CoV-2 virus. These structural proteins are called antigens (S and N antigens). Neutralising antibodies – against the N antigen in particular – have already been detected. Both antigens are used in the test offered by medac.

Rapid processing: initial results available after only 35 minutes

The antibody testing is fully automated. medac provides high-performance systems for testing, enabling the analysis of large sample quantities in a very short period. In addition to the SARS-CoV-2 antibody tests, these laboratory workstations can process up to 100 other laboratory markers in parallel. These include inflammation markers such as CRP, PCT, 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. medac uses state-of-the-art technology that enables stable, rapid and sensitive detection of SARS-CoV-2 infection using chemiluminescence analyses (CLIA).

In its work, medac is cooperating with established global firm Snibe Diagnostic, which has been specialising in clinical laboratory instruments and in-vitro diagnostic reagents for many decades.

Reliability and testing in the daily routine

The antibody test offered by medac was awarded its European IVD CE 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 prominent 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.

Guaranteed long-term reliability for delivery of both tests from a single source

medac is the exclusive distribution partner for the antibody tests in Germany, Austria and Switzerland and is already partnering with over 20 laboratories. Other countries are in the

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pipeline. The multiplex PCR tests are being offered by medac exclusively in Germany and Austria.

In order to ensure security in planning and optimal management of the current pandemic, full and comprehensive availability in the supply of both antibody and PCR tests is guaranteed. 17 million more antibody tests are available. The availability of the multiplex-PCR tests is unlimited. Ralf Tönnies, head of medac Diagnostics, knows how important this is in the current situation: ‘We are pleased to be able to provide urgently needed PCR and antibody tests in such large volumes. It is particularly important that we can ensure long-term availability and thus relieve laboratories and clinics of any worries about the availability of tests. That’s why we are now launching these products on the market.’

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 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.