

Press release

LKF focuses on SARS-CoV-2 analysis: Ongoing COVID-19 testing to maintain clinical studies

- **New diagnostic capability for both virus and antibody detection**
- **COVID-19 testing is becoming the standard in clinical trials outside of COVID-19 research**
- **LKF is a global medical laboratory providing all analyses for clinical development**
- **State government declares LKF to be of systemic importance and essential for the protection of the population**

“The corona virus pandemic makes the conduct of clinical studies very complex and leads to standstill in many places. We offer solutions for this,” says Bärbel Wilke, co-founder and CEO of LKF – Laboratorium für Klinische Forschung (Laboratory for Clinical Research). Wilke believes that corona testing could soon be a prerequisite for the inclusion and continued participation of patients in clinical trials. *“By offering both molecular biological tests (PCR) for virus detection and general antibody testing, we are the optimal laboratory partner in the field of clinical trials. The state government has already recognized this and has declared the LKF to be a company of systemic importance,”* said Wilke.

Kiel, 19 May, 2020: LKF - Laboratorium für Klinische Forschung, a member of GBA Group Pharma, has been offering an analytical method for detecting SARS-CoV-2 from nasopharyngeal swabs since this week. This has enabled the company to significantly expand its existing range of COVID-19 testing methods for clinical trials. Based on a Roche LightCycler 480 II, which uses the technique of real-time PCR (polymerase chain reaction), LKF can now perform numerous molecular biological applications (DNA or RNA analyses). The detection of the RNA of the SARS-CoV-2 virus is a prerequisite for the diagnosis of an acute infection with the new corona virus causing the disease COVID-19.

Founded in 1991, the LKF is a specialized medical laboratory for the support of clinical studies of Phases I-IV. Recently, it has established and validated specific analytical methods for the qualitative detection of SARS-CoV-2 in upper respiratory tract samples. The analytical method used is approved in Europe and in the USA as an in vitro diagnostic (IVD) kit and has also been internally validated.

Furthermore, the LKF offers a variety of test methods for the detection of anti-SARS-CoV-2 antibody tests, which can be used to determine whether a patient has already had contact with SARS-CoV-2: IgM and IgA antibodies for the first reaction of the immune system to a SARS-CoV-2 infection and IgG antibodies for the secondary antibody reaction that builds up long-term immune protection. Other tests are expected to follow immediately, such as the latest Elecsys® test from Roche, as soon as it becomes available in Europe.

One-stop shop – also for clinical COVID-19 studies

The company is also involved in the development of COVID-19 drugs and currently supports multiple clinical trials testing new drugs for the treatment of COVID-19. “With our comprehensive test method panel for the quantification of inflammation markers (e.g. cytokines, procalcitonin) on various analytical platforms (e.g. Roche e501, Mesoscale Discoveries Multiplex Assays), we are well equipped for COVID-19 studies,” Wilke said. “All

services are carried out in-house, which guarantees a professional, flexible and rapid approach. This enables the LKF to set up a COVID-19 study within one week from the receipt of the clinical study protocol to the delivery of the laboratory kits to the intensive care units.”

The government of the federal state of Schleswig-Holstein has classified the LKF, which looks back on more than 25 years of experience, as essential for the protection of the population.

“In these difficult Corona times, a great deal of flexibility is required,” said Wilke. “But this is precisely one of our strengths – extreme flexibility. In this way we support our customers in pharmaceutical research in providing optimal care for patients and study participants and in advancing the development of important drugs.”

The following test methods are available at LKF:

- SARS-CoV-2 PCR on a Roche LightCycler 480 II platform
- Antibody tests for the detection of IgA, IgM and IgG from different manufacturers
- Immunological test procedures (ELISA, ECLIA, CLIA, immunoturbidimetry). All test methods have been approved by the FDA and the European authorities and are additionally validated internally at the LKF.

About the LKF

LKF, which is part of GBA Group Pharma, supports Phase I-IV clinical trials. Within its global network of partner laboratories in Europe, North and Latin America, China and Australia, LKF offers worldwide laboratory services for clinical trials. All information is gathered in a central database and is evaluated centrally in Kiel, from where it is sent to the trial centers worldwide. LKF has established a strict quality management system based on the international guidelines GCP (Good Clinical Practice) and ISO 17025. In addition to these quality certificates, LKF has a certificate for sustainable management from EcoVadis, which is regularly renewed.

Scientific consulting, preparation of study-specific laboratory manuals, provision of study-specific laboratory kits, organization of worldwide kit and sample logistics and a comprehensive analytical service (safety panel, biomarkers, PK) are among the core competences of LKF.

About GBA Group Pharma

GBA Group Pharma, headquartered in Hamburg/Germany, is one of the largest and most experienced service providers in the European pharmaceutical and biotechnology sector. As a unique "one stop solution", the company supports the comprehensive process of drug development and marketing, from preclinical to clinical services, including analysis services, provision of clinical trial goods, central laboratory services, QP services and support for release processes and the import and export of approved products.

GBA Group Pharma can meet all BREXIT-related service requirements of pharmaceutical and biotech companies with business activities in the EU.

GBA Group Pharma employs around 500 people in Austria, Germany and the UK and is part of GBA Group, Hamburg.

For further information, please visit www.gba-group.com/pharma and follow us on [LinkedIn](#) and [Twitter](#).

Pictures attached: Picture 1: *Bärbel Wilke, CEO of LKR, ©GBA*; Picture 2: *Visualization of SARS-CoV-2, ©unsplash*

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