

MVZ Labor Dr. Limbach & Kollegen GbR | Im Breitspiel 16 | 69126 Heidelberg

To whom it may concern

My name is [REDACTED] and I am the [REDACTED] of the MVZ Laboratory Dr. Limbach & Colleagues in Heidelberg Germany. Together with [REDACTED] we founded the Limbach Laboratory in 1979 in Heidelberg Germany as a small laboratory practice (www.labor-limbach.de). During the last 40 years our laboratory has developed very quickly to one of the major private diagnostic laboratories in Germany and the major laboratory within the meanwhile founded Holding the Limbach Group SE (www.limbachgruppe.com).

My additional responsibilities had been and still are and include General Lab Quality Management related to accreditation, Consultant and Monitor of Clinical Trials and coordination of test development and immunochemistry testing of associated laboratories. Within the past 30 years, I have been a member of different advisory panel boards for diagnostic companies including Roche, Bayer, Siemens, Dia-Sorin, Bio-Merieux and BRAHMS.

Geschäftsleitung

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Fachärztin für Hygiene

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Fachärztin für Transfusions-
medizin

MVZ Labor Dr. Limbach – Key Characteristics

THE ORIGIN: COMPETENCE AND QUALITY FOR MORE THAN 40 YEARS



- > Founded in 1979 H J Limbach, H J Roth
- > Until 1986 focus only and primarily on specialties, radioimmunoassay testing – nephrology & dialysis
- > Today's competencies: nephrology & dialysis, hygiene, infectiology, gynaecology, autoimmune diagnostics
- > Co-operations with other labs in Germany and Central and Eastern Europe
- > 30 specialists in laboratory medicine, microbiology, transfusion medicine, hygiene, human genetics
- > 29 scientists
- > More than 600 employees

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HEIDELBERG

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DIN EN ISO/IEC 17025 und DIN EN ISO 15189
(Reg.Nr. D-PL-13176-01-00 und D-ML-13176-01-00)

LIMBACH  GRUPPE

Service Offerings – Whole Portfolio

Competence and quality for more than 40 years

Diagnostics and analytics				Consulting & Training	Other services
 Allergy diagnostics - Diagnosis for evaluation of Type I reactions - Determination of antibodies	 Autoimmune diagnostics Comprehensive range of analysis methods for autoantibodies	 Drug analysis and toxicology - Analysis of saliva and blood - Detection of new abuse-relevant drugs	 Haematological diagnostics Evaluation of transfusion and bleeding tendency	 Hygiene consulting - Hygiene audit - Hygiene management - Outbreak analysis - Consulting for building projects	 Transport service and sample logistics - Network of courier services and an additional evening network for samples delivery - Possibility of frozen sample transportation - Transportation of dangerous goods and class 2 biological substances
 Endocrinological diagnostics Gynaecological, pediatric and internal endocrinology	 Lipometabolism diagnostics Comprehensive analysis spectrum for diagnosis of dyslipoproteinemia	 Hematological diagnostics - Automated and manual differential blood count - Diagnosis of anaemia	 Infectiological diagnostics - Microbiological diagnosis - Diagnosis of multi-resistant pathogens	 Infectiological consulting - Local antibiotic guidelines - Appointments with experts for antibiotics management - ABX team assistance - Review of antibiotic resistance pathogens and resistances	 IT Services - In House laboratory information systems - Electronic transmission of laboratory orders to enhance efficiency of practice procedures
 Therapeutic drug monitoring Antipsychotics, antiepileptics, antiarrhythmics, antidepressants and antibiotics	 Carbohydrate metabolism diagnostics Portfolio of analyses of blood sugar regulation disorders				

MVZ Labor Dr. Limbach
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We do perform more than 3000 different tests with focus on specialties in various diagnostic areas. More than 4.5 million patient orders were performed on an annual basis, resulting in approximately 25 million tests per year.

Limbach Group – Key Characteristics

LARGEST GERMAN LABORATORY SERVICES GROUP



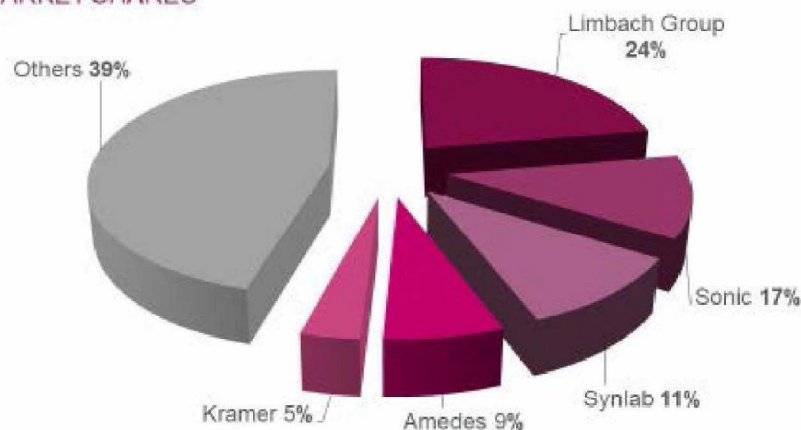
- > Merger of 33 regional labs creates the Limbach Group as holding company in 2014
- > Extensive range of laboratory diagnostic services for physicians, hospitals, patients and other medical facilities
- > Special competencies: nephrology & dialysis, hygiene, infectiology, endocrinology, gynaecology, autoimmune diagnostics
- > Co-operations with other labs in Germany and Central and Eastern Europe
- > 300 specialist: Medical Doctors in laboratory medicine, microbiology, transfusion medicine, pathology, hygiene, human genetics
- > More than 6.000 employees in Germany

MVZ Labor Dr. Limbach
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The Limbach Group is the largest diagnostic laboratory service provider in Germany and will be, due to other co-operating laboratories in Bulgaria, Finland, Georgia, the Netherlands, the Middle East, Spain, Switzerland and Poland, the largest Group in Europe.

Laboratory Market in Germany

MARKET SHARES



For further development of our diagnostic portfolio and equipment, we started cooperation with companies like SNIBE Diagnostics, China, some months ago, as well as Shenzhen YHLO Biotech Co, China, via our German distributor. Initial Idea was to implement technologies, equipment and immunological tests provided by Chinese manufacturer.

Due to the actual SARS-CoV-2 pandemic evolution, we changed our testing protocols to focus on evaluation of antibody-tests provided by Snibe on Maglumi 800 and YHLO on iFLASH 1800 within the last 2 to 3 weeks.

We did compare performance of four SARS-CoV-2 antibody tests from Snibe, YHLO, Euroimmun and Immundiagnostik.

Based on the evaluation data, the combined testing of 2019-nCoV IgM and IgG on iFlash 1800 has demonstrated excellent performance and led to the introduction of this test as routine method in the Limbach Group, not only as a supplemental to RT-PCR, but also to perform population screening.

Brief summary of evaluation results, evaluation ongoing:

- Up to now, we evaluated 160 serum samples from various selected patient groups.
- One hundred forty-four samples: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Seven samples: IgM-Ab positive, IgG-Ab positive
- Two samples IgM-Ab ~ 7 AU/ml, IgG positive
- Nine samples IgM-Ab negative, IgG-Ab positive
- Thirty-five samples, obtained from pregnant women in April 2019: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Ten samples from end-stage-renal-disease patients on dialysis: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Eight samples with high rheumatoid factor: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Eleven samples from healthy laboratory technicians with high concentration of virus antibodies VCA, EBV, Parvo, CMV etc.: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Fourteen samples from healthy pregnant women: neither IgM-Ab nor IgG-Ab detected (AU/ml < 10).
- Additional routine samples, anamnestic data requested from collection centers. Those data will be further evaluated, when clinical data are available.
- Five patients monitored. RT-PCR positive between 3 – 5 days after onset of symptoms. IgG-antibodies detected after 14 to 15 days, IgM-antibodies negative.

Summary: Specific and sensitive method. Implemented in routine testing. One iFLASH in use, will be run 24/7. Second iFLASH expected to be delivered on April 15th. To provide service to all of our associated laboratories in Germany, 33 in number, and our cooperating partner laboratories in Eastern Europe, we will have high demands for testing capabilities. Based on the actual incoming requests we may need 500.000 tests per month to cope with the testing requests.

Date: 04.04.2020

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MVZ Laboratory Dr. Limbach & Colleagues
Within the Limbach Group SE