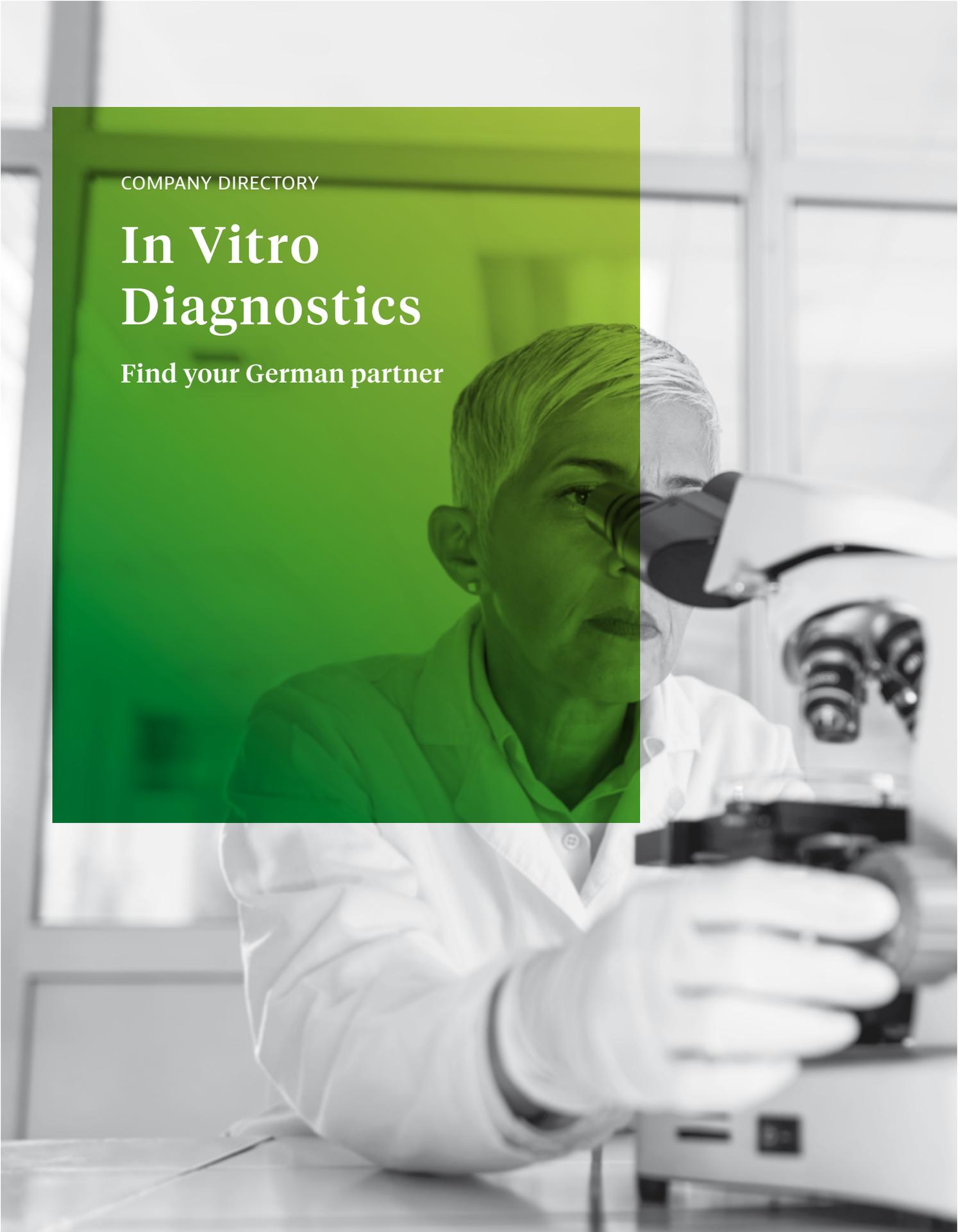


COMPANY DIRECTORY

In Vitro Diagnostics

Find your German partner





Dear Reader,

I am delighted to present our new "IN VITRO DIAGNOSTICS" publication. HEALTH MADE IN GERMANY has compiled this directory in order to give you an overview of companies active in the country's in vitro diagnostic (IVD) sector. The purpose of this directory is twofold: First, to provide a first point of orientation in the country's IVD market. And secondly, to serve as an aid that allows you to quickly find products and services of interest to your business. As such, the directory is an invaluable resource that also provides the tools necessary for you to take the next step – establishing contact with the appropriate partners in your area of activity.

Contact us to find out how we can help you grow your business in Germany's thriving health economy.

Yours,

A handwritten signature in blue ink that reads "Marion Lükemann". The signature is fluid and cursive.

Marion Lükemann, Director
HEALTH MADE IN GERMANY

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Summary

In vitro diagnostics (IVDs) are a crucial part of modern medicine: laboratory-based tests performed on biological samples provide information that is key for the prevention, treatment and management of disease. Today, around two thirds of all clinical diagnoses are made thanks to IVDs.

As life science technologies advance, clinical diagnostic tests have become an essential part of “precision medicine” that aims at treating patients according to their individual molecular make-up.

With more than EUR 2 billion in annual turnover, Germany represents the largest IVD market in Europe. This innovative industry develops and manufactures biological and chemical reagents, test kits, automated machines, and devices that are used to analyze bodily fluids.

The German IVD industry is dominated by medium-sized enterprises. This directory aims to give an insight into the diversity of the sector as well as throw a spotlight on small and medium-sized enterprises active in the IVD landscape.

A new EU regulatory framework will pave the way for dynamic market growth.



INTRODUCTION

In vitro diagnostics – the backbone of healthcare

Laboratory diagnostics are a crucial part of modern medicine. Testing body fluids and tissues is vital for making clinical decisions and managing disease.

Germany is not only the largest IVD market in Europe, but is also home to a high-tech industry providing innovative reagents and cutting-edge instruments.

Modern evidence-based medicine would not be the same without laboratory diagnostics. Such diagnostic tests provide us with vital information that is key for the prevention, treatment and management of disease. As bioanalytical technologies advance, clinical diagnostic tests have become an increasingly essential part of modern healthcare.

In vitro diagnostics are non-invasive tests performed on biological samples to diagnose or rule out a disease. Testing samples such as blood, urine and tissue outside of the human body provides valuable information about how the body is functioning and the patient's state of health. IVDs are a particularly safe medical product as the laboratory reagents needed for the testing procedure do not come into contact with the patient's body.

In vitro diagnostics are not only used for diagnosis, but can also prove useful in screening and monitoring diseases by therapeutic means. Today around two thirds of all clinical diagnoses involve IVDs. For that reason IVDs are referred to as the backbone of today's healthcare sector. This is reflected in their widespread application: IVDs can be found in hospitals, specialized laboratories, ambulances, and in the home.

Reagents and analyzers used in IVDs must ensure precise and reliable results. They can be used in a variety of areas ranging from sophisticated techniques performed in specialized clinical laboratories to user-friendly devices that are used by medical professionals, as well as simple self-tests that patients can use at home.

The German IVD industry develops and manufactures biological and chemical reagents, test kits,



automated machines and devices that are used to analyze bodily fluids. Most of the sector is comprised of small and medium-sized enterprises (SMEs). This directory aims to give an insight into Germany's innovative IVD sector – with a particular focus on SMEs. While it cannot be entirely comprehensive, it does aim to provide a thorough overview of the broad spectrum of products and services available in the field.

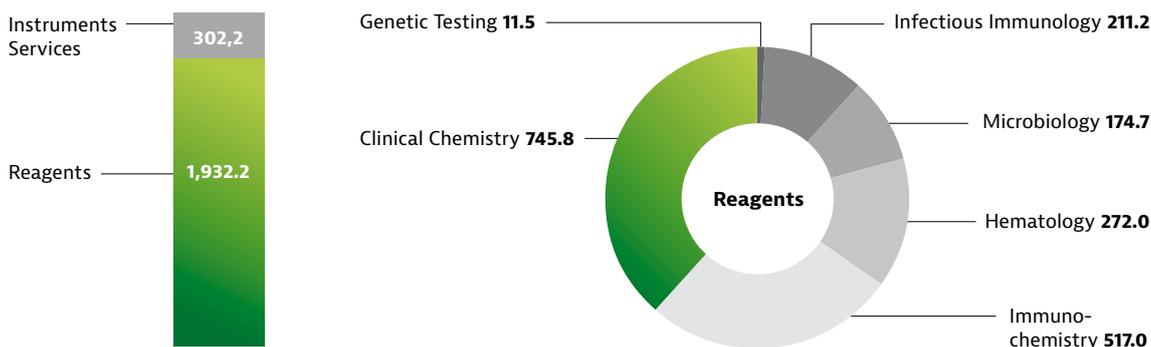
Strong and diverse market

The German IVD market is the largest in Europe. According to the German Diagnostics Industry Association (VDGH), turnover recorded in 2016 amounted to EUR 2.23 billion. This represents just a slight increase of 0.37 percent on the previous year. Companies generated the bulk of their turn-



Around two thirds of all clinical diagnoses are made using IVDs

IVD and reagent market turnover in Germany 2016 (in EUR million)



Source: German Diagnostics Industry Association (VDGH)



over with reagents (EUR 1.93 billion, 86.5 percent of turnover). Instruments and services totalled EUR 302.2 million (13.5 percent of turnover).

The European Diagnostic Manufacturers Association (EDMA) published the first IVD product classification in 1988. The aim was to improve the standardization and reliability of information on the European market. The market statistics program for IVD products was established at the European level, but has now become globally accepted. The system uses numerical codes that allow individual product areas to be defined separately. It supports the collection and analysis of market statistics. According to EDMA, in vitro diagnostics can be divided into six subsections:

- Clinical chemistry
- Immunochemistry
- Hematology
- Microbiological culture
- Infectious immunology
- Genetic testing

Clinical chemistry

In 2016, with a figure of EUR 745.8 million, clinical chemistry generated the highest turnover of the six IVD subsections in Germany. Clinical chemistry, also known as clinical biochemistry, refers to tests that are performed on chemical and biochemical analyses. These tests are mainly based on venous blood samples, but may also be conducted on other bodily fluids, such as urine and saliva.

Test kits are often available in the form of panels. They may refer to specialized tests for indicators such as the body's electrolyte balance, the status of single organs such as the electrolyte panel, and the comprehensive metabolic panel or the liver panel. Reagents used in clinical chemistry include various substrates, enzymes, electrodes, and biosensors. Tests commonly require sophisticated equipment in addition to reagents. Blood gas analyzers, electrophoresis and chromatography are used alongside self-testing equipment that enables patients to self-monitor different compounds.

Immunochemistry

Immunochemistry combines anatomical, immunological and biochemical techniques. Tests are generally protein-based as they detect antigen-antibody reactions. This branch of IVDs generated a turnover of EUR 517 million in 2016. It is made up of various sub-categories such as the evaluation of plasma protein dosages, anemia determination, therapeutic drug monitoring and the detection of drug abuse. In endocrinology, the identification of hormone levels refers to thyroid function, fertility levels and pregnancy. The tests can also be used to detect allergies and autoimmune diseases. Tumor marker tests allow for various sub-types and mutations of cancers to be identified.

Hematology

Hematology focuses on the analysis of blood and blood compounds. In 2016, this field generated



German IVD companies are major innovators in developing molecular tests

EUR 272 million in annual revenue. This subsection includes various tests for basic blood typing, including blood grouping or tissue typing. If a person is healthy, then the number, type and size of red and white blood cells is usually predictable. Anomalies measured provide information on different blood-related diseases or conditions; e.g. different kinds of anemia or blood cell cancers such as lymphoma and leukemia.

General histology tests and the evaluation of bone marrow also help to diagnose blood cell cancers. Blood plates (platelets) and proteins in the liquid component of the blood known as the plasma regulate blood clotting (coagulation). Anomalies can indicate blood disorders such as thrombocytopenia; a disorder whereby the pa-

tient has a reduced number of platelets that may result in a tendency toward abnormal bleeding. Prior to surgical intervention, coagulation and platelets tests are carried out at the pre-diagnostics stage. Blood cell counters, flow cytometers, hemoglobin analyzers and coagulation systems are just some types of analytical equipment found in hematological diagnostics.

Microbiological culture

With an annual turnover of EUR 174.7 million, microbiological culture represents an important part within the field of medical microbiology. Together with infectious immunology, the medical microbiology subsection has an annual turnover of around EUR 386 million. Microbiological tests help to identify infectious diseases, including bac-

Booming molecular diagnostics sector

Molecular diagnostics has emerged as one of the largest and fastest-growing sectors of the IVD industry. This development is fueled by the introduction of powerful techniques such as real-time polymerase chain reaction (PCR) and next generation sequencing (NGS), which allow the amplification and decoding of genetic and epigenetic information.

Quantitative real-time polymerase chain reaction (qPCR) is a method used to amplify genetic information encoded in RNA and DNA. This method is now used for diagnostics to rapidly detect nucleic acids of pathogens such as viruses and bacteria, cancer mutations and other genetic variations. The diagnosis of infectious diseases has been improved in particular. Quantitative real-time polymerase chain reaction allows the quantification and genotyping of viruses, such as the hepatitis B virus, by a characteristic melting curve without sequencing. Newly emerging pathogens, such as new strains of the influenza virus, can also be quickly discovered.

Advances in DNA sequencing have also revolutionized the industry. Since the first human genome was sequenced in 2001 (after more than a decade and a cost of around USD 3 billion), the technology has become much faster and much cheaper. Next generation sequencing (NGS) has enabled molecular biologists to

sequence a human genome within a timespan of one day at a total cost of around USD 1,000. In combination with powerful bioinformatics, genome sequencing is now entering medical practice. Genomics help to diagnose genetic diseases and disorders, particularly when it comes to finding the causes of rare diseases.

Testing for cancer mutations has become a hallmark of personalized medicine strategies in oncology. Next generation sequencing thereby enables tailored therapies that take the patient's individual genetic conditions or clearly identified pathogen strains into account. Other areas are human leukocyte antigen (HLA) testing – required for organ transplantation and pharmacogenetic testing – for the determination of drug response to toxicity. Forensics is also a field where molecular diagnostics is crucial. Testing signatures of the epigenome has emerged as a further area of application.

Companies based in Germany are proven innovators in developing molecular tests as well as high-tech instruments and consumables that are used in the bioanalytics of molecular information. Several of these companies have become world leaders in the field – particularly when it comes to infection diagnostics and molecular diagnostics for cancer. They are paving the way for personalized medicine.



teria, viruses, parasites, mycobacteria, and fungi. The identification of pathogens can either rely on microbiological cultures or on the body's immune response to these pathogens. The latter method is summarized in the subsection on infectious immunology. In order to investigate microbiological cultures, microorganisms are incubated in laboratories and analyzed by eye, by microscope, or treated with special agents such as antibiotics so as to identify antibiotic resistance. Apart from identifying antibiotic resistance, these microorganisms help to find the appropriate antimicrobial therapy.

Infectious immunology

Another area within medical microbiology is infectious immunology culture. This subsection concerns the immunological response of the host to various microbes, typically by antibodies. Diagnostic tests include infectious diseases caused by bacteria and other microorganisms. There are tests to determine viral infections which cause hepatitis and AIDS, as well as rubella, measles, herpes and the cytomegalic inclusion disease (CID). Mycological tests help to identify fungal infections and determine convenient agents. This subsection also includes diagnosing parasitic diseases such as toxoplasmosis.

Genetic testing

This dynamic area of IVDs focuses on the analysis and sequencing of a person's genetic code; either of ribonucleic acid (RNA) or desoxyribonucleic acid (DNA). Moreover, it includes the analyses of chemically modified nucleotides and proteins or metabolites that are the direct and sole consequence of their DNA template structure. Tiny fragments of DNA or RNA can usually be detected. In some cases, tests rely on original fragments. However, DNA is usually amplified in order to obtain a higher amount of genetic material for analysis.

Molecular tests and powerful sequencing methods have been developed to detect variations in specific parts of the genetic code. This method provides information about inherited or acquired traits. That is why this kind of diagnosis is often used in non-invasive prenatal diagnostics, to determine parenthood, and for forensic science during police investigations to identify a person by their 'genetic fingerprints'. Genetic testing can also determine the existence of specific genes in order to identify predisposition or the presence of diseases and can be used in pharmacogenetics.

Technology trends

Innovative developments in the IVD field are currently driven by four major trends: point-of-care testing, automation, digitalization and the concept of personalized medicine.

Placing diagnostics as close as possible to the patient and the healthcare professionals is a groundbreaking trend in the diagnostics sector. Point-of-care testing (POCT) means that tests are performed on-site, i.e. close to the bedside rather in a centralized laboratory. There is a diverse spectrum of applications for POCT – from the general practitioner to intensive and emergency care in hospitals.

POCT technologies deliver faster results as there are no longer delays caused by transportation. Similarly, there is no need for preparation of clinical samples, with biochemical test results available at the point of care. This could help speed up clinical decision making, with improved medical outcomes and lower costs also ensuing.

This is also true for technologies in genomics, transcriptomics, proteomics and metabolomics. High-throughput technologies have become ultra-



Around 11% of total IVD industry turnover is invested in R&D

The pillar of personalized medicine

Personalized medicine is a growing trend that is largely based on innovation in the field of diagnostics. The conventional approach for treating diseases, such as cancer, according to the organ or tissue of origin is gradually being replaced by a personalized approach. In this personalized approach, treatment is decided based on detailed knowledge of biomarkers that underlie the disease process. Also known as "precision medicine", this approach is defined by the US National Academy of Sciences as the use of genomic, epigenomic, exposure, and other data to define individual patterns of disease which could potentially lead to better individual treatment based on more specific – and less toxic – targeted therapies.

Personalized medicine always involves an upstream diagnostic test that provides information essential for the safe and effective use of a corresponding therapeutic product. Companion diagnostics (CDx) and therapy work in tandem to translate individual molecular fingerprints for use in personalized medicine. Precision medicine builds on reliable biomarkers: genetic, biochemical or other complex signatures that are specific indicators of a disease process. They must be validated in clinical studies.

At the time of publication there were 50 drugs that operate on the basis of a personalized strategy approved in Germany. This is more than double 2010 levels. According to the Association of Research-based Pharmaceutical Companies (vfa), a companion diagnostic test is required for 43 of these drugs, while a respective test is



recommended for seven of them. The bulk of tests provide information on the potential efficacy of a treatment; a low number checks on potential side effects. Oncology, in particular, relies on companion diagnostics – 36 of 50 personalized treatments fall into this category. One prominent example is the monoclonal antibody trastuzumab. It can be used as targeted treatment in 25 percent of all breast cancer patients that carry cancer cells with an overexpressed HER2 protein. A respective diagnostic test on a tissue sample provides the doctor with the information needed to choose the best therapeutic option.

As powerful bioanalytical technologies provide more and more information on possible targets, the number of companion therapies will increase. The development of biomarkers has become an integral part of the research and development activities of medical biotech and pharmaceutical companies in Germany.

Personalized medicine provides a good example of how the IVD industry can play a vital role in the public health sector. It increases the quality of life and care for patients as it can lead to fast and effective treatment. This not only leads to patient and clinical benefits, but economic benefits as well. German companies have an important role to play in this growing market.

Personalized therapies authorized in Germany

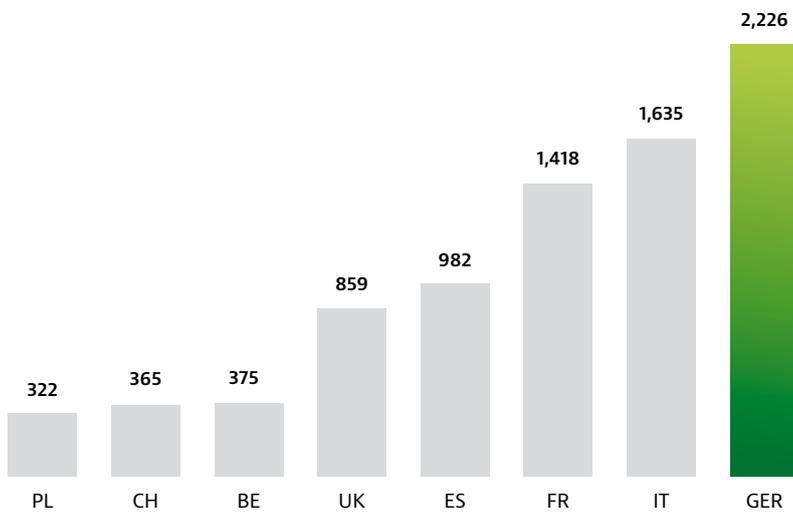
Number of mandatory or recommended CDx tests

Indication	mandatory	recommended
Oncology	36	2
Epilepsy	–	2
HIV	2	–
Immunology/ Transplantation	–	2
Metabolism	4	1
Musculoskeletal	1	–
Total	43	7

Source: vfa bio (as of June 2017)

European IVD market 2015

Diagnostics industry turnover in Europe (in EUR million)



United Kingdom: only companies which participate in GMDS
 France: data include only the central laboratory IVD market – Source: EDMA

sensitive and can be performed on tiny biological samples or just a cell. An emerging field is liquid biopsy, which enables, for instance, analysis for circulating tumor DNA in the blood.

Digitalization in the terms of Germany’s “Industrie 4.0” project is already underway in the IVD sector, with “Lab 4.0” being created by big data handling, cloud-based IT solutions, lab and production automation processes, and digital networking.

Innovative IVD sector

According to the German Diagnostics Industry Association (VDGH), there are around 150 companies in Germany that develop reagents and manufacture analysis systems. In 2014, a total of 22,500 people were employed in the German diagnostics industry. Small and medium-sized enterprises form the backbone of the sector. In 2014, 90.6 percent of German IVD companies fell under this category. Only 9.4 percent of companies employed over 500 people. Seventy-four percent of these companies carry out research or manufacture their products within Germany.

The German IVD sector is known for its capability for innovation. This is evidenced by the fact that approximately 12 percent of all employees are active in research and development (R&D). This percentage is remarkably high compared to other industries. Research and development expenditure is another important indicator of innovation: In 2016, the IVD sector invested 10.7 percent of its revenue into R&D projects; a figure that is topped by the pharmaceutical industry, which is the most research-intensive industry (13.4 percent).

The German life science industry is a major force driving innovation in the IVD sector. Advanced by developments in molecular biology, miniaturization and automation, companies have developed assays that are used in basic research but also in biomedical applications such as pharmacy, biotechnology, food analysis, and forensics. Biotech



and medtech companies invest great effort into making the latest findings from research available to patients. They have developed platform technologies, for example, that form the basis for the development of biopharmaceuticals or that foster research on rare diseases.

Public R&D support

The German Federal Government has identified innovations in life sciences and healthcare as decisive economic factors. A number of publicly funded programs at national and regional state levels have been made available to the IVD industry. As part of its new "High-Tech Strategy," the German Federal Government has identified personalized medicine as one of six action areas in its Health Research Framework Program. With the launch of an action plan, it has put a number of measures in place for the strategic funding of research in personalized medicine.

One example for this is a recent funding call published by the Federal Ministry of Education and Research (BMBF) that aims at improving diagnostics and therapy of bacterial infections. By funding initiatives such as *KMU-innovativ: Biotechnologie* and *KMU-innovativ: Medizintechnik*, the BMBF supports medium-sized companies in their R&D projects. All German federal states also have their own R&D grant programs in place.

Outlook

The IVD sector in Europe is currently concerned with adopting a new regulatory framework. The In Vitro Diagnostics Regulation (IVDR) was published in May 2017 and ensures that the approximately 40,000 laboratory tests in Europe have new guidelines for regulation. The IVDR replaces existing Medical Device Directives. Within a transitional period of five years – companies, as well as the notified bodies responsible for conformity assessment, have to adapt their quality management and technical documentation processes to fit the new reinforced criteria.

As Germany is the largest market in Europe, the new regulation is having an enormous impact on the IVD environment. The IVDR comes with the introduction of a new IVD risk classification system in line with international guidelines followed by stricter rules for the conformity assessment. It also reinforces the regulations on clinical evidence and strengthens post-market surveillance.



The companies expect that adapting their processes to the new regulation will require a great deal of effort on their part. The strength of the German IVD sector and its ability to innovate helps in facing these challenges.



More information:

www.health-made-in-germany.com

Company and technology overview

The table below gives an overview of the listed companies and their field of activity. Technologies areas are marked with a circle.

Company	Clinical chemistry	Immunochemistry
8sens.biognostic GmbH	●	●
altona Diagnostics GmbH		
AmplexDiagnostics GmbH		
ATLAS Biolabs GmbH		
Attomol GmbH		
BAG Health Care GmbH		
bio.logis Genetic Information Management GmbH		
bioactiva diagnostica GmbH	●	●
Bioanalytic GmbH	●	●
BioCheck GmbH	●	●
BioEcho Life Sciences GmbH		
BioGenes GmbH		●
BioRépair GmbH		
biotechrabbit GmbH		
BIOTECON Diagnostics GmbH		
CAMPTON Diagnostics UG	●	
CANDOR Bioscience GmbH		●
Carpegen GmbH		
CeGaT GmbH		
CellTrend GmbH		●
Centogene AG		
concile GmbH		●
Curetis NV		
DiaMex GmbH		
DiaSorin Deutschland GmbH		●
DITABIS	●	●
Dr. Seibt Genomics GmbH		
DRG INSTRUMENTS GmbH	●	
Epigenomics AG		
Eppendorf AG	●	●
Exosome Diagnostics GmbH		
GILUPI GmbH		
GNA Biosolutions GmbH	●	

Hematology	Microbiology	Infectious immunology	Genetic testing
	●		
	●		
			●
	●	●	●
●			●
●	●	●	●
●	●		●
	●		●
	●	●	
	●		●
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		●	●
●	●	●	●
●			●
	●		●
	●		●
	●		●

MATRIX

Company	Clinical chemistry	Immunochemistry
Greiner Bio-One GmbH	●	●
HS Diagnostica GmbH		
humatrix AG		
Immundiagnostik AG	●	●
in.vent DIAGNOSTICA GmbH	●	●
Institut Virion\Serion GmbH		
LDN	●	●
LifeCodexx AG	●	
Lionex GmbH		
Lipotype GmbH	●	
Lophius Biosciences GmbH		●
LRE Medical GmbH	●	●
medac		●
Mediagnost GmbH		
membraPure GmbH	●	
Microcoat Biotechnologie GmbH		●
Mikrogen GmbH		
Milenia Biotec GmbH		●
Minerva Biolabs GmbH		
Molzym GmbH & Co.KG		
mti-diagnostics GmbH	●	●
numares AG	●	
oncgnostics GmbH		
ORGENTEC Diagnostika GmbH		●
PROGEN – passion for research		
Promega GmbH		
Protagen AG		●
Q-Bioanalytic GmbH		
ravo Diagnostika GmbH		●
ScheBo® Biotech AG		●
SCIENION AG		
Seramun Diagnostica GmbH		●
Siemens Healthcare Diagnostics Products GmbH	●	●
sifin diagnostics gmbh		●
Sividon Diagnostics GmbH		
sphingotec GmbH		●
SpinDiag GmbH		
varionostic GmbH	●	
Viramed Biotech AG		
VIROTECH Diagnostics GmbH		
VivoSens Medical GmbH	●	
Zentrum für Humangenetik und Laboratoriumsdiagnostik	●	
ZytoVision GmbH		



COMPANY PROFILES

Find your German partner

The following pages provide detailed information about German companies active in the in vitro diagnostic sector.

For further information on your potential German partner please use the contact details provided in the company's profile.

8sens.biognostic GmbH

Robert-Rössle-Str. 10 · 13125 Berlin

Tel.: +49 (30) 9489-2116 · Fax: +49 (30) 9489-2117

Mail: ilka.renneberg@biognostic.de · Web: www.biognostic.de

Founded: 2000 · Employees: 12



8sens.biognostic GmbH - Development & Manufacturing of IVD

8sens.biognostic GmbH was founded in 2000 as an enterprise focused exclusively on research and development in the field of in-vitro diagnostics. Over its 17-year history the company has established itself as a specialist in the development and production of IVD.

8sens.biognostic has developed lateral flow assays for different application fields: Human & Veterinary Medicine, Food Industry, Drug Control. Our brand QuickSens® covers the medical field for human use. All tests are quantifiable with the reader system QuickSens®Omega100.

We do custom-made development of lateral flow tests from your ELISA. As a separate new development we also offer the realisation of complete projects on demand from our clients: from feasibility studies via test's development until declaration of conformities of complete test systems.

Our customers benefit from our experiences and high quality standards when we manufacture their products in our facilities.

All products are developed and manufactured in Berlin/Germany. We ensure high quality standards, cutting-edge development and production technology, highly qualified personnel, and collaborations based on trust and partnership with our national and international customers.

Instruments & Services

Reagents

altona Diagnostics GmbH

Mörkenstr. 12 · 22767 Hamburg

Tel.: +49 (40) 54806-760 · Fax: +49 (40) 54806-7610

Mail: petra.kampmann@altona-diagnostics.com · Web: www.altona-diagnostics.com

Founded: 2007 · Employees: 135



altona Diagnostics, founded in 2007 and based in Hamburg, Germany, is focused on developing, manufacturing and marketing molecular diagnostic test systems for the specific and fast detection of pathogens (viruses, bacteria and parasites) related to human infectious diseases. Besides a broad product portfolio for routine diagnostics, altona Diagnostics was one of the first companies to make reliable molecular diagnostic kits commercially available during outbreak situations for SARS, swine Flu, MERS, Ebolavirus and Zika virus. altona Diagnostics is an ISO 13485 certified company with 130 employees working in Hamburg to distribute its products worldwide in more than 30 countries.

altona Diagnostics has a wide network of scientific and industrial partners, and is associated with distinguished national and international institutes and reference laboratories. These relationships together with the technical expertise of the team contribute to a fast and competent development of reliable diagnostic tests for emerging pathogens.

Instruments & Services

Reagents

AmplexDiagnostics GmbH

Werkstr. 2 · 83555 Gars Bahnhof
Tel.: +49 (8073) 916-930 · Fax: +49 (8073) 916-9333
Mail: info@amplexdiagnostics.de · Web: www.eazyplex.com
Founded: 2002 · Employees: 10



Amplex develops, manufactures and distributes innovative molecular biological systems focusing on resistances in the medical microbiology. We are an expanding, international operating, independent and private-owned company.

The most innovative eazyplex® platform, based on a sophisticated combination of isothermal amplification and real time detection in a portable device uses lyophilized test reagents for a maximum on user-friendliness. The available kits include highly relevant resistances e.g. MRSA and CRE. All our tests can be performed out of clinical sample material without DNA extraction.

Instruments & Services

Reagents

ATLAS Biolabs GmbH

Friedrichstr. 147 · 10117 Berlin
Tel.: +49 (30) 3198966-0 · Fax: +49 (30) 3198966-19
Mail: customer-support@atlas-biolabs.com · Web: www.atlas-biolabs.com
Founded: 2006 · Employees: 14



ATLAS Biolabs is a leading European service provider of complex analyses in molecular genetics, including next generation sequencing, target sequence enrichment and microarray analyses supplemented by high-level statistics/bioinformatics support and RNA/DNA isolation from biological specimens. It was founded in 2006 as a spin-off of the RZPD, German Resource Center for Genomics, and the CCG, Cologne Center for Genomics. The company is located in Cologne and Berlin. ATLAS Biolabs' services are certified by Affymetrix, Agilent, and NimbleGen. Its customers include clinicians and registered doctors as well as pharmaceutical and biotechnological companies, and academic institutions both in Germany and abroad.

ATLAS Biolabs fulfills the requirements for designing and manufacturing in vitro diagnostics medical devices according to ISO 13485:2012/AC:2012. ATLAS Biolabs' processes are subject to rigorous quality control at all stages according to the international standards of ISO 9001:2008.

Instruments & Services

Reagents

Attomol GmbH – Molekulare Diagnostika

Schulweg 6 · 03205 Bronkow, OT Lipten
Tel.: +49 (35329) 5906-0 · Fax: +49 (35329) 5906-19
Mail: info@attomol.de · Web: www.attomol.de
Founded: 1997 · Employees: 16



Attomol GmbH has been supporting laboratory clinicians as developer, producer and distributor of test kits for 20 years.

The key issues of our work are: detection of mutations with allele-specific PCR and real-time PCR, detection of pathogens via real-time PCR, test strips for the detection of autoantibodies, and multiplex Beadassays for the detection of autoantibodies or pathogen-specific antibodies.

Our privately held company is shaped by the professional expertise of highly qualified motivated staff. That is why we are able to provide our customers with robust and reliable test systems and support them professionally in the work with our products. Our main technologies are patented. We continuously develop new tests in order to expand our

range. The focus lies on quick response customer service and high-quality test kits.

To fulfill the requirements for a documented production and quality control we follow DIN ISO 13485. Our products undergo internal and external performance evaluations in the course of CE marking process and participate regularly in proficiency testing.

In research and development we cooperate with the partners of the research association BioResponse e.V., DiagnostikNet-BB e.V., the institutes of BTU Cottbus-Senftenberg and Technische Universität Dresden.

Instruments & Services

Reagents

BAG Health Care GmbH

Amtsgerichtsstr. 1–5 · 35423 Lich
Tel.: +49 (6404) 925-0 · Fax: +49 (6404) 925-250
Mail: info@bag-healthcare.com · Web: www.bag-healthcare.com
Founded: 1947 · Employees: 250



We are the Experts for HLA and Blood Group Diagnostics

With more than 30 years of experience BAG Health Care is the specialist for HLA and blood group diagnostics. As an independent, globally operating company we offer permanent ongoing development of our products and services.

Our focal points in diagnostics:

Transplantation medicine
BAG Health Care offers a wide range of diagnostic procedures for HLA diagnostics – typing as well as HLA-antibody analysis. Matched to your individual laboratory requirements, you can choose between serological and molecular genetic methods. They can be applied flexibly for low test counts or automated high throughput rates.

Transfusion medicine

Determining the blood group antigens of donors and recipients is of decisive importance for safe blood transfusions. BAG Health Care offers numerous testing options and aids for serological and molecular genetic blood group diagnostics.

HLA disease associations

Many autoimmune diseases or hypersensitivity reactions of the immune system are related to certain HLA alleles. The determination of these associated alleles may help a lot in the diagnosis and choice of the best therapy for the patient. BAG Health Care offers a set of tests designed especially for this purpose.

Instruments & Services

Reagents

bio.logis Genetic Information Management GmbH

Altenhöferallee 3 · 60438 Frankfurt
 Tel.: +49 (69) 597970300
 Mail: info@biologis.com · Web: www.biologis.com
 Founded: 2013 · Employees: 25



About bio.logis GIM

bio.logis Genetic Information Management GmbH is part of the bio.logis Group and was founded in November 2013. Currently, a team of 50 highly specialized employees consisting of experienced physicians, scientists and IT-experts work for the bio.logis Group and its cooperating clinical institution, bio.logis Center for Human Genetics.

leverageable clinical knowledge for prompt application. GIMS supports physicians both in laboratories for automatically generating such expert content and diagnostic reports, and in hospitals with specific clinical suggestions.

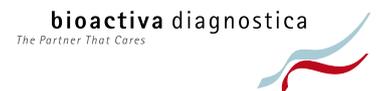
For more information visit our website:
<https://www.biologis.com>

bio.logis Genetic Information Management GmbH translates genetic data into leverageable medical information and makes it available to physicians and patients. To that end, it has developed a special "Genetic Information Management Suite (GIMS)" IT solution which, in the process chain required for genetic diagnostics, focuses on the "last mile" to physicians and patients by merging raw genetic data with

Instruments & Services	Reagents
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bioactiva diagnostica GmbH

Louisenstr. 137 · 61348 Bad Homburg
 Tel.: +49 (6172) 17102-0 · Fax: +49 (6172) 17102-29
 Mail: bioactiva@bioactiva.de · Web: www.bioactiva.de
 Founded: 2001 · Employees: 14



bioactiva is an experienced and innovative company focused on the manufacturing and distribution of in-vitro diagnostics especially PCR, ELISA, Rapid testing for infectious diseases. Customer orientation, high quality products, fast response to customer's needs are essential parts of our business.

We deliver high-quality products according to the newest state of science and technology.

We stand out by being highly client-oriented. Day after day, we aspire towards quality, reliability, promptness, flexibility, and efficiency for our clients. From the client's perspective, it could be said that bioactiva diagnostica GmbH is the reliable, fast and inexpensive source for covering the total need of high-quality laboratory diagnostics and tools.

Our Customers benefit from a long experience of specialists.

Steady quality, reliability and service stand on the top of our activities and action.

Our QM system is EN ISO 9001 and EN ISO 13485 certified.

The wishes of our customers and the legal demands in the distribution countries determine our business activities.

All company members fulfil the demands of the high-class management system and maintain its effectiveness in the distribution and in dealing with the customers.

We are happy that you are part of our successful story.

Instruments & Services	Reagents
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Bioanalytic GmbH

Waldmatten 10–13 · 79224 Umkirch

Tel.: +49 (7665) 5951 · Fax: +49 (7665) 5683

Mail: office@bioanalytic.de · Web: www.bioanalytic.de

Founded: 1978 · Employees: 9



Bioanalytic GmbH is a family-run company located in Umkirch close to Freiburg, Germany. Since 1978 we produce in vitro diagnostics, calibration standards, buffer and electrolyte solutions and complete test kits. Our portfolio includes device-specific OEM reagents and cleaning products for the medical, chemical and analytical-technical laboratories. Our customers are diagnostic and reagent manufacturers, global manufacturers of analyzers and measurement technology.

Bioanalytic GmbH has state of the art facilities for the production of high-quality reagents. Our scientific experience, our advice and strict quality standards have made us known as a reliable and competent business partner. Bioanalytic GmbH has the know-how to implement legal requirements and directives and is registered with the FDA.

We offer our customers individual OEM solutions. Our manufacturing capabilities allow great flexibility in terms of formulation, bottling and batch size. From manufacturing to ready to sale packaging including OEM labeling and safety data sheets, Bioanalytic GmbH offers an one-stop solution. Our ISO certifications (EN ISO 9001, EN ISO 13485) and our ongoing development of modern manufacturing processes ensure high-quality products and compliance with international quality standards.

Instruments & Services

Reagents

BioCheck GmbH

Vorbergweg 41 · 48159 Münster

Tel.: +49 (251) 2150-869 · Fax: +49 (251) 2150-870

Mail: office@polycheck.de · Web: www.polycheck.de

Founded: 1999 · Employees: 23



Polycheck® is a brand of Biocheck GmbH. It stands for a platform technology to facilitate serological multi-parameter testing in human allergies and autoimmune disorders as well as in veterinarian medicine. Quantitative screening of different parameters can be processed in one test approach. The procedure can be handled manually, half-automated or full-automated with its appropriate equipment. The user-friendly Biocheck Imaging Software evaluates the tests precisely. Result documentation can be printed in numerous languages and stored in a central LIS, including the raw data image.

Instruments & Services

Reagents

BioEcho Life Sciences GmbH

Nattermannallee 1 · 50829 Köln

Tel.: +49 (171) 2794631

Mail: contact@bioecho.de · Web: www.bioecho.de

Founded: 2016 · Employees: 7



Next generation products for the Life Sciences

BioEcho Life Sciences has been founded in 2016 by a team of experts in the field of genomic sample preparation. BioEcho develops state-of-the-art technologies and products towards more convenient, more robust and more sustainable molecular biology and diagnostics laboratory workflows.

BioEcho's EchoLUTION

genomic DNA Purification Technology

The BioEcho team has developed a break-through technology for the field of nucleic acid purification, an area where innovation hasn't been seen for decades. BioEcho's EchoLUTION Single-Step purification process allows DNA isolation and RNA isolation from various sample types in a fraction of the time compared to traditional methods, with much

less steps and with unmet extraction efficiency and sample purity. Our portfolio comprises kits for isolation of genomic DNA from tissues, blood and cultured cells and for concentration and clean-up of nucleic acids. Solutions for DNA and RNA isolation from FFPE tissue sections, bacterial samples, stool and for cell-free DNA from liquid samples as well as automated solutions are in preparation.

Instruments & Services

Reagents

BioGenes GmbH

Köpenicker Str. 325 · 12555 Berlin

Tel.: +49 (30) 6576-2396 · Fax: +49 (30) 6576-2397

Mail: service@biogenes.de · Web: www.biogenes.de

Founded: 1992 · Employees: 49



BioGenes GmbH, founded in 1992, is a worldwide acting full-service provider for customised immunoassay and antibody development with strong commitment to quality and service and has an unrivaled expertise in ELISA development, validation and production for several applications. Their extensive antibody know-how allows for complex antibody development.

- Custom Antibody Development
pAbs, mAbs, anti-idiotypic antibodies
- Custom ELISA Development
Host cell protein (HCP), diagnostic, immunogenicity, PK
- Generic HCP ELISA Kits
for CHO cells and E. coli
- Analytical Services
2D Western Blot, DIGE

Instruments & Services

Reagents

BioRépair GmbH

Kirchenstr. 5 · 74889 Sinsheim

Tel.: +49 (7261) 971760 · Fax: +49 (7261) 971761

Mail: trinkner@biorepair.com · Web: www.biorepair.com

Founded: 1997 · Employees: 6



BioRépair® founded 1997 in the innovative biotech cluster Rhine-Neckar close to Heidelberg.

In cooperation with universities and private institutes we develop and produce diagnostics for immunological, microbiological and parasitological detections. Our own research and development department guarantees for the output of new technics and innovative diagnostics.

BioRépair is ISO 9001 certificated and all our products are CE marked.

In our home market (Germany) we are selling through our own sales and marketing specialists. We cover the whole German market by using the most effective marketing in-

struments which are: direct visits to customers, key account management, telephone marketing, mail-shots and print- and electronic media.

Our customers are universities, hospitals, private laboratories, research laboratories and veterinarians.

In most of the european countries we are selling through our distributor network.

Our parasite concentration system is one of the leading products in Europe to detect parasites, larves and their eggs out of stool samples from human and animals.

Instruments & Services

Reagents

biotechrabbit GmbH

Neuendorfstr. 24a · 16761 Hennigsdorf

Tel.: +49 (3302) 207541-0 · Fax: +49 (3302) 207541-1

Mail: info@biotechrabbit.com · Web: www.biotechrabbit.com

Founded: 2011 · Employees: 20



biotechrabbit is a German biotechnology company which offers highest-quality reagents and optimized services for diagnostic and life science customers, with a focus on OEM supply and customized solutions.

Our offering includes ultra-pure enzymes for diagnostics, antibody production, innovative lyophilization as well as a comprehensive molecular biology product portfolio (PCR, qPCR, nucleic acid purification kits, cell-free protein synthesis kits, etc.).

biotechrabbit is a perfectly supporting partner for its customers throughout a project: be it the development of new products, providing services or the purchase of standard products. Our way of doing business combines the passion and pure curiosity of excellent researchers with the agile spirit of true entrepreneurs.

Instruments & Services

Reagents

BIOTECON Diagnostics GmbH

Hermannswerder 17 · 14473 Potsdam
 Tel.: +49 (331) 2300-200 · Fax: +49 (331) 2300-299
 Mail: bcd@bc-diagnostics.com · Web: www.bc-diagnostics.com
 Founded: 1998 · Employees: >80



BIOTECON Diagnostics focuses on the development and production of innovative, rapid detection systems for pathogens, spoilage organisms, genetically modified organisms (GMOs) and allergens by real-time PCR. Besides detection kits, the foodproof® and microproof® product lines also include kits for sample preparation.

As an international biotechnology company, BIOTECON Diagnostics markets its products worldwide. The company cooperates with sales experts from various countries, as well as an ever-growing, worldwide network of distributors and cooperation partners.

The accredited service laboratory of BIOTECON Diagnostics has many years of experience in microbiological analysis, especially for food and pharmaceutical industries.

Due to strong partnerships with the food manufacturing industry, BIOTECON Diagnostics is well aware of the microbial requirements of the manufacturers, and can therefore offer optimal solutions. New products are adapted and tested according to customer needs during development.

Business segments:

- Product development (PCR detection and sample preparation kits)
- Application development (automation, software)
- Microbiological services
- Contract development
- Further education (seminars, workshops and trainings)

Instruments & Services

Reagents

CAMPTON Diagnostics UG

Fraunhoferstr. 1 · 25524 Itzehoe
 Tel.: +49 (4821) 174-321
 Mail: blohm@campton-diagnostics.com · Web: www.campton-diagnostics.com
 Founded: 2016 · Employees: 4



Leading Scientists at the Fraunhofer Institute for Silicon Technology (ISIT) and at the CURIT Biotech Holding GmbH, both located in Germany, have developed a new Point-of-Care (POC) technology to identify cancer, infectious and autoimmune diseases in specialized medical practices or hospitals and clinics worldwide.

Portable diagnostic devices like the CAMPTON Biochip Reader™ offer a rapid test result, which would therefore be advantageous in the field of medical care. The advantage of the system for the end customer – as well as for our direct clients doctors and hospitals – is, that it is cheaper and more time efficient. It takes a few minutes to do the test and get the results immediately.

To facilitate the fast and reliable measurement of biomarkers, we intend to introduce the miniaturized automated POC system based on a cartridge with an integrated electrical biochip for ELISA-based decentralized detection of biomarkers. This system allows the detection of multiple biomarkers in a few microlitres of serum or whole blood during a few minutes using an ELISA directly on a gold electrode array. The sensitivity of this system is comparable with standard microtiter plate ELISAs, but the duration of the novel assay is a fraction of standard ELISAs.

Instruments & Services

Reagents

CANDOR Bioscience GmbH – The ELISA Experts

Simoniusstr. 39 · 88239 Wangen im Allgäu
Tel.: +49 (7522) 79527-0 · Fax: +49 (7522) 79527-29
Mail: info@candor-bioscience.de · Web: www.candor-bioscience.de
Founded: 2004 · Employees: 12



CANDOR Bioscience GmbH is an internationally oriented, innovative and profitable enterprise.

CANDOR develops, produces and distributes a comprehensive selection of premium solutions for immunoassays.

CANDOR offers more than 50 different products including optimizers, blockers, stabilizers and buffer solutions for immunoassays. By using these solutions the reliability of results can be improved, the assay can be simplified and process times can be reduced.

CANDOR quality comprises highest product quality, highest quality standards and demanding quality control in production in addition to comprehensive product support and customer service.

The company is certified according to DIN EN ISO 9001.

Instruments & Services

Reagents

Carpegen GmbH

Mendelstr. 11 · 48149 Münster
Tel.: +49 (251) 980-2320 · Fax: +49 (251) 980-2321
Mail: info@carpegen.de · Web: www.carpegen.de
Founded: 2001 · Employees: 10



Carpegen is an innovative life science company that specializes in developing molecular diagnostic assays and integrated systems based on real-time PCR.

As part of collaborations, contract development, and/or research projects, we develop modern diagnostic procedures and products, for example for the sensitive detection of infectious agents or for applications in human genetics. Among other areas, we focus on dental diagnostics.

For example, Carpegen has developed Carpegen® Perio Diagnostics, a powerful real-time PCR assay system that sets new standards in microbiological periodontal diagnostics. As an accepted diagnostic test, it is frequently used by German and European dentists to optimize the treatment of periodontal disease.

Funded by the German Federal Ministry of Education and Research, Carpegen has developed from 2007 to 2015 a proprietary point-of-care diagnostic system for nucleic acid analysis. In December 2016, the Gyronimo platform was sold to diagnostic specialist Curetis GmbH, Holzgerlingen. The worldwide rights for dental diagnostics, as well as environmental and food safety testing were retained by Carpegen.

Currently, Carpegen is conducting several development projects in addition to our operations, which receive funding support from government programs.

Instruments & Services

Reagents

CeGaT GmbH

Paul-Ehrlich-Str. 23 · 72076 Tübingen
 Tel.: +49 (7071) 565-4455 · Fax: +49 (7071) 565-4456
 Mail: info@cegat.de · Web: www.cegat.de
 Founded: 2009 · Employees: 60



CeGaT is a leading global provider of genetic diagnostics and mutation-related disease analyses. At CeGaT, we combine our next-generation sequencing (NGS) process and analysis pipelines with our medical expertise, where we are dedicated to identifying the genetic cause of disease and supporting patient management.

Genetic mutations can trigger a wide range of diseases, from epilepsy to Parkinson's. Through the use of NGS, it is possible to analyze all genes associated with a disease phenotype simultaneously – both fast and effectively. An interdisciplinary team of scientists and physicians evaluates the data and summarizes the findings in a comprehensive medical report. All services are performed in-house.

The use of NGS technology is of particular interest in the field of tumor diagnostics. Since each tumor may have several genetic driving forces, CeGaT can identify these alterations and help classify which mutations are causative. With the knowledge of these tumor-specific mutations, it is then possible to choose the most optimal therapeutic strategy.

CeGaT, founded in 2009 and based in Tübingen, Germany, is accredited according to CAP, CLIA and DIN EN ISO 15189:2014. The company provides human genetics services worldwide.

Instruments & Services

Reagents

CellTrend GmbH

Im Biotechnologiepark · 14943 Luckenwalde
 Tel.: +49 (3371) 681-290 · Fax: +49 (3371) 681-312
 Mail: info@celltrend.de · Web: www.celltrend.de
 Founded: 1998 · Employees: 8



CellTrend is an innovative certified ((ISO 9001, ISO 13485, GMP) biotech company. We offer the following technologies and services:

- Development, production and distribution of immunoassays for diagnostic and research
- Cell culture assays for drug research (bioactivity assays): Screening, lead optimization, drug development

All know-how is available for contract services:

- Development of assays and kits
- Contract research
- Contract production (OEM)
- Contract analysis

CellTrend developed together with clinical partners (e.g. Charité Berlin) a new class of biomarkers: autoantibodies against G protein-coupled receptors (GPCR). CellTrend established some unique, patent-protected kits for these markers: beta1-receptor, beta2-receptor, muscarinic receptors, angiotensin II receptor 1, endothelin receptor A, alpha-adrenergic receptors, etc.

Instruments & Services

Reagents

Centogene AG

Schillingallee 68 · 18057 Rostock

Tel.: +49 (381) 20365-0 · **Fax:** +49 (381) 203652-219

Mail: office@centogene.com · **Web:** www.centogene.com

Founded: 2006



CENTOGENE is a worldwide leader in the field of genetic diagnostics for rare hereditary diseases – with the largest test portfolio worldwide. Testing samples from over 110 different countries allows CENTOGENE a unique insight into epidemiological basis of hereditary disorders, which is crucial in the medical result interpretation process.

The company is strictly focusing on offering quality molecular genetic diagnostics, underlined by its multiple international accreditations (ISO, CAP, CLIA). CENTOGENE's in depth medical expertise is supported by the application of cutting-edge technologies including next generation sequencing, whole exome sequencing (CentoXome®), whole genome sequencing (CentoGenome®) and innovative biomarkers for selected diseases. CENTOGENE has developed a compre-

hensive mutation database (CentoMD®) that is pivotal to offering high quality diagnostic reporting and medical interpretation; thoroughly interpret each patient's sequence data. In addition to diagnostic services for individual patients, CENTOGENE is also a pivotal partner for multiple renowned industrials worldwide. CENTOGENE has affiliations in Germany, India, Canada, Austria, and the United Arab Emirates.

Instruments & Services

Reagents

concile GmbH

Kronenmattenstr. 6 · 79100 Freiburg

Tel.: +49 (761) 151474-10 · **Fax:** +49 (761) 151474-19

Mail: info@concile.de · **Web:** www.concile.de

Founded: 2010 · **Employees:** 19



concile is a manufacturer of a reader device and quantitative as well as qualitative point-of-care tests for cancer, cardiac, infectious and hormone disorders.

The concile Ω100 is a novel device for immediate point-of-care diagnosis (POCT) in the office laboratory. Because of its built-in high-performance battery, decentralized use on hospital wards, during home visits and in rescue vehicles is also possible. The device meets the requirements for a device for immediate point-of-care diagnosis with unit-use reagents in the Guidelines for Quality Assurance of Medical Laboratory Examinations of the German Medical Association (RiLiBÄK).

Available quantitative rapid tests for the reader are PSA, fPSA, UBC Rapid, Neopterin, CRP, h-FABP, Testosterone, TSH, FSH, LH, β-HCG, Vitamin D, sPLA2-IIA, CEA, CA19-9, CA15-3, CA125, AFP.

Instruments & Services

Reagents

Curetis NV

Max-Eyth-Str. 42 · 71088 Holzgerlingen
Tel.: +49 (7031) 49195-10 · Fax: +49 (7031) 49195-19
Mail: contact@curetis.com · Web: www.curetis.com
Founded: 2007 · Employees: ca. 100



Founded in 2007, Curetis is a molecular diagnostics company which focuses on the development and commercialization of reliable, fast and cost-effective products for diagnosing severe infectious diseases. Curetis' Unyvero Solution enables rapid multi-parameter pathogen and antibiotic resistance marker detection in only a few hours, a process that today can take up to days or even weeks with other techniques.

Curetis offers tests for pneumonia, implant and tissue infections, blood stream infections and intra-abdominal infections and continuously expands its Unyvero Cartridge pipeline. To date, Curetis has raised EUR 44.3 million in an IPO on Euronext Amsterdam and Euronext Brussels and private equity funds of over EUR 63.5 million. Furthermore, Curetis has entered into a debt financing facility with EIB for up to

EUR 25 million. The company is based in Holzgerlingen near Stuttgart, Germany.

Curetis collaborates with Heraeus Medical, pharmaceutical companies, and has entered into several international distribution agreements covering many countries across Europe, the Middle East and Asia.

Instruments & Services

Reagents

DiaMex GmbH

Siemensstr. 38 · 69123 Heidelberg
Tel.: +49 (6221) 894669-40 · Fax: +49 (6221) 894669-90
Mail: info@diamex.com · Web: www.diamex.com
Founded: 2012 · Employees: 10



DiaMex GmbH as a producer of diagnostics offers high quality controls for the medical laboratory and Lyme disease assays based on the Luminex technology. DiaMex GmbH is certified according to DIN EN ISO 13485.

See also: www.diamex.com

Instruments & Services

Reagents

DiaSorin Deutschland GmbH

Von-Hevesy-Str. 3 · 63128 Dietzenbach
Tel.: +49 (6074) 401-0 · Fax: +49 (6074) 401-209
Mail: info@diasorin.de · Web: www.diasorin.com
Founded: 2002 · Employees: 160



The Diagnostic Specialist

DiaSorin is an Italian multinational Group and a global leader in the market for in vitro diagnostics. For over 40 years, the Group has been developing, producing and commercializing diagnostic tests for a wide range of clinical areas. DiaSorin tests are designed for hospital and private testing laboratories, in the markets of immunodiagnostics and molecular diagnostics.

Consistent with its commitment to innovation, DiaSorin is constantly renovating and expanding its product line, focusing on the specialized segments of infectious diseases, endocrinology and autoimmune diseases and developing new technologies. DiaSorin strongly believes in the importance of strengthening its direct presence and steadily works to broaden the coverage of its distribution organization.

In 2002 DiaSorin acquired Byk-Sangtec and founded the German subsidiary. Today around 160 employees work in production, research & development, quality assurance, sales and service at DiaSorin Deutschland GmbH.

Instruments & Services

Reagents

DITABIS – Digital Biomedical Imaging Systems AG

Freiburger Str. 3 · 75179 Pforzheim
Tel.: +49 (7231) 2986-300 · Fax: +49 (7231) 2986-301
Mail: contact@ditabis.de · Web: www.ditabis.de
Founded: 1996 · Employees: 31



DITABIS stands since 1996 for custom development and production of devices and system components in the strongly regulated markets of medical and life science industry. Our OEM partners from diagnostics, medical and laboratory equipment value our applicative knowledge and our technical expertise which is reflected in clever inexpensive device concepts. We manufacture the developed devices in our own series production with the highest quality – for worldwide successful products!

You define the customer requirements for the diagnostic, laboratory or medical equipment and we provide first design proposals. The commonly defined requirements including our innovative solutions will be finalized in a well concerted system requirements and specifications document. Now DITABIS

performs the detailed development of mechanics, electronics, optics and software upon completion. After mutual verification and validation of the prototypes the transfer into series production is complemented by all certifications (CE, FDA, etc.) according to international standards of your target markets. All processes are supported by a comprehensive risk management. Subsequently the OEM series production starts within the product life cycle including future product modifications.

Instruments & Services

Reagents

Dr. Seibt Genomics GmbH

Joseph-Schumpeter-Allee 15 · 53227 Bonn
 Tel.: +49 (228) 33-888-70 · Fax: +49 (228) 33-888-780
 Mail: info@dr-seibt-genomics.com · Web: www.dr-seibt-genomics.com
 Founded: 2014 · Employees: 8



Dr. Seibt Genomics is an innovative company in Bonn/Germany with a multi-disciplinary team. Dr. Seibt Genomics offers individually solutions in the field of pharmacogenomics and predictive gene diagnostics.

Aim of Dr. Seibt Genomics is to offer individualized drug therapy with optimized drug doses. Reduce toxic effects and avoid drugs which won't work because of genetics. For greater safety and prevention Dr. Seibt Genomics analyzes the DNA for the risk of genetic diseases.

In the field of Nutrigenomics they analyze food intolerances. Dr. Seibt Genomics is specially known for Deluxe-Whole-Genome-Sequencing including interpretation. The Team utilizes state of the art technique and latest methods e.g. panel di-

agnostics and Next-Generation-Sequencing. The company is able to provide the "Dr. Seibt Genomics Kit", which contains a buccal swab to collect the DNA, to all continents.

Further information: <https://www.dr-seibt-genomics.com>

Instruments & Services

Reagents

DRG INSTRUMENTS GmbH

Frauenbergstr. 18 · 35039 Marburg
 Tel.: +49 (6421) 1700-0 · Fax: +49 (6421) 1700-50
 Mail: drg@drg-diagnostics.de · Web: www.drg-diagnostics.de
 Founded: 1973 · Employees: 60



DRG – Diagnostics that perform!

DRG, founded in 1970, is a multinational specialty medical equipment and diagnostics manufacturer and distributor, with successful representation in over 110 countries through a network of DRG subsidiaries and local distributors.

The German division, DRG Instruments GmbH, founded in 1973, is located in Marburg and specializes in the development and production of innovative ELISAs and CLIA assays, both for routine and research applications, in the fields of diabetes diagnosis, endocrinology, prenatal/neonatal supervision, thyroid function and many more.

At the end of 2008, DRG began development of a closed system, our DRG:HYBRiD.XL, a fully automated analyzer for

the simultaneous determination of immunoassays, as well as clinical chemistry.

NEW: DRG:HYBRiD-XL® – Fully Automated Combi Analyzer for Immunoassays and Clinical Chemistry including an interesting test panel:

25-OH Vitamin D, Renin, Aldosterone, Androstenedione, Free Testosterone, 17-OH Progesterone, Calprotectin, TSH rec Ab, anti-CCP, Anti-DGP (Gliadin), Anti-Tissue Transglutaminase, HbA1c, NT-proBNP, D-dimer, TM-CA 72-4, PSA, Toxoplasma and many more.

NEW ELISAs: DHT-optimized, Hepcidin 25 (bioactive) HS, Salivary Progesterone HS ELISA

Instruments & Services

Reagents

Epigenomics AG

Geneststr. 5 · 10829 Berlin

Tel.: +49 (30) 243450 · Fax: +49 (30) 24345-555

Mail: contact@epigenomics.com · Web: www.epigenomics.com

Founded: 1998 · Employees: 45

epigenomics

Epigenomics is a molecular diagnostics company focused on blood-based detection of cancers using its proprietary DNA methylation biomarker technology. The company develops and commercializes diagnostic products across multiple cancer indications with high medical need. Epigenomics' lead product, Epi proColon[®], is a blood-based screening test for the detection of colorectal cancer. Epi proColon has received approval from the U.S. Food and Drug Administration (FDA) and is currently marketed in the United States, Europe, and China and selected other countries. Epigenomics' second product, Epi proLung[®], is in development as a blood-based test for lung cancer detection. For more information, please visit www.epigenomics.com.

Instruments & Services

Reagents

Eppendorf AG

Barkhausenweg 1 · 22339 Hamburg

Tel.: +49 (40) 53801-0

Mail: eppendorf@eppendorf.de · Web: www.eppendorf.com

Founded: 1945 · Employees: 2,930

eppendorf

Eppendorf is a leading life science company that develops and sells instruments, consumables and services for liquid handling, sample handling and cell handling in laboratories worldwide. Its product range includes pipettes and automated pipetting systems, dispensers, centrifuges, mixers, spectrometers and DNA amplification equipment as well as ultra-low temperature freezers, fermentors, bioreactors, CO₂ incubators, shakers and cell manipulation systems. Consumables such as pipette tips, test tubes, microliter plates, and single-use bioreactor vessels complement the range of highest-quality premium products.

Eppendorf products are most broadly used in academic and commercial research laboratories, e.g., in companies from the pharmaceutical and biotechnological as well as the chemical and food industries. They are also aimed at clinical and environmental analysis laboratories, forensics and at industrial laboratories performing process analysis, production and quality assurance.

Eppendorf was founded in Hamburg, Germany in 1945 and has more than 3,000 employees worldwide. The company has subsidiaries in 26 countries and is represented in all other markets by distributors.

Instruments & Services

Reagents

Exosome Diagnostics GmbH

Am Klopferspitz 19a · 82152 Martinsried
Tel.: +49 (89) 416-17270 · **Fax:** +49 (89) 416-17269
Mail: munich@exosomedx.com · **Web:** www.exosomedx.com
Founded: 2010 · **Employees:** 13



Exosome Diagnostics is developing revolutionary biofluid-based diagnostics for personalized healthcare. The company's exosome-based technology platform, ExoLution™, and point of care instrument for protein capture and analysis, Shahky™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored.

The company's ISO15189 accredited European Clinical Diagnostic and Product Development Lab in Munich is servicing customers and clinical samples from Asia, Europe, the Middle East and Russia.

Exosome Diagnostics flagship diagnostic test for prostate cancer, ExoDx Prostate Intelliscore (EPI), is indicated for

patients with a PSA in the gray zone (2–10 ng/mL), to determine whether to proceed with a biopsy. Each year, millions of prostate biopsies are performed, with most results indicating no- or low-grade cancer that could be monitored, rather than require radical treatment. Complications associated with prostate biopsies range from discomfort, incontinence or impotence, to hospitalization for serious infections.

EPI was designed to reduce unnecessary prostate biopsies and the associated overtreatment. EPI only requires a simple urine sample with no prior invasive examination and is completely non-invasive.

Instruments & Services

Reagents

GILUPI GmbH

Hermannswerder 20a · 14476 Potsdam
Tel.: +49 (331) 58184-782 · **Fax:** +49 (331) 58184-780
Mail: info@gilupi.com · **Web:** www.gilupi.com
Founded: 2006 · **Employees:** 14



GILUPI GmbH is a medical device company founded in 2006 with focus on the development and production of innovative products for the in vivo isolation of rare cells from the blood circulation. Currently, the main focus of GILUPI is the diagnostics market for cancer.

Individual oncological targeted therapies will become more and more important in tomorrow's personalized medicine. The identification of the right drug for the specific patient is the upcoming challenge. To address this medical need, the application of the GILUPI CellCollector® enriches rare cells (circulating tumor cells – CTCs) by directly "fishing" them in the patient's bloodstream. By using special diagnostic analyses, these isolated cells can be characterized and/or analyzed at a molecular level.

The GILUPI CellCollector® is the first in vivo CTC isolation product worldwide that is CE approved.

For further information visit www.gilupi.com

Instruments & Services

Reagents

GNA Biosolutions GmbH

Am Klopferspitz 19 · 82152 Martinsried
Tel.: +49 (89) 998207-180 · Fax: +49 (89) 998207-188
Mail: info@gna-bio.com · Web: www.gna-bio.com
Founded: 2010



GNA Biosolutions is developing diagnostic instruments and assays for robust, ultra-fast detection of important pathogens based on its proprietary Laser PCR(R) technology. The world's fastest thermal cycles for DNA amplification and detection can be achieved by ultra-fast laser-heating of nanoparticles within the sample solution, an optothermal technology that allows heating and cooling rates many orders of magnitude faster than other PCR methods. The localized nano heating technology makes ultra-fast DNA-based tests possible within 15 minutes or less.

Instruments & Services

Reagents

Greiner Bio-One GmbH

Maybachstr. 2 · 72636 Frickenhausen
Tel.: +49 (7022) 948-0 · Fax: +49 (7022) 948-514
Mail: info@de.gbo.com · Web: www.gbo.com/bioscience
Founded: 1868 · Employees: 1,800



greiner bio-one

Greiner Bio-One specialises in the development, production and distribution of high-quality plastic laboratory products. The company is a technology partner for hospitals, laboratories, universities, research institutes, and the diagnostic, pharmaceutical and biotechnology industries.

The BioScience division of Greiner Bio-One ranks among the leading providers of specialised products for the cultivation and analysis of cell and tissue cultures. Drawing on decades of experience with cryogenic sample storage, Greiner Bio-One also offers solutions for automated storage systems in biobanks. In addition, we continue to utilise our expertise in the development and production of microplates for high-throughput screening, thereby allowing extremely fast and efficient drug screening for both industrial and research ap-

plications. The entire development, manufacturing and sales operations are controlled from the German headquarters of the BioScience division in Frickenhausen.

Greiner Bio-One Diagnostics – also part of the BioScience division – specialises in the development of new molecular biology analysis methods. The field of application of 'DNA arrays' as a key technology ranges from human diagnostics to food technology.

Instruments & Services

Reagents

HS Diagnostics GmbH

Wrangelstr. 11–12 · 12165 Berlin

Tel.: +49 (30) 7978-6110 · Fax: +49 (30) 7978-1731

Mail: info@hsdiagnostics.de · Web: www.hsdiagnostics.de

Founded: 2012 · Employees: 7



HSDiagnostics is a Berlin based company founded in 2012. We are specialists in T-cell receptor profiling by ultra-deep sequencing. With our proprietary technology called TCRsafe, tested and optimized in hundreds of samples, we can display the T-cell receptor repertoire in blood and tissue samples in maximal resolution, up to the single cell level and up to every single nucleotide and translated peptide of the TCR. Within days we can deliver ultra-deep T-cell receptor profiles starting from tissue, blood samples or DNA, a key to understanding of the adaptive immune system. Our service is available for human and mouse samples.

In the last 2 years we developed a unique method to identify tumor reactive T cell receptors from patient samples, which we are planning to optimize in future cooperations with the

goal to establish novel individual cancer therapies based on T-cells.

Our Services:

- Ultra-deep T cell receptor (TCR) profiles from blood, tissue, DNA samples
- Comparison of TCR profiles in time series or multi-sample studies to find common elements
- Systematic analysis of T cell response under various conditions
- Identification of tumor reactive TCRs

Instruments & Services

Reagents

humatrix AG

Reißstr. 1a · 64319 Pfungstadt

Tel.: +49 (6151) 60159-0 · Fax: +49 (69) 60159-11

Mail: info@humatrix.de · Web: www.humatrix.de

Founded: 2001 · Employees: 10



humatrix AG is a biotechnology company specialized in the analysis of human DNA. In the field of paternity testing, humatrix has been one of the leading companies for many years and has set qualitative standards. In the meantime, the strategic focus of the company lies in the area of personalized medicine. Here, humatrix develops and offers pharmacogenetic test systems and test panels to prevent inefficient therapies adverse drugs effects to improve the quality of life.

Instruments & Services

Reagents

Immundiagnostik AG

Stubenwald-Allee 8a · 64625 Bensheim

Tel.: +49 (6251) 70190-0 · Fax: +49 (6251) 849430

Mail: info@immundiagnostik.com · Web: www.immundiagnostik.com

Founded: 1986 · Employees: 80



Closing the Gaps in Diagnostics

Immundiagnostik – founded in 1986 – is a diagnostics company with focus on the development and production of innovative immunological tests (ELISA, EIA) and other analytical detection methods such as HPLC, LC-MS/MS and PCR) for routine and research in medicine. The aim is to provide high quality, innovative and effective tools for the prevention, differential diagnosis and treatment monitoring. Focus is on gastroenterology/nutrition, cardiovascular/kidney, bone metabolism, oxidative stress, complementary medicine/preventive medicine, clinical immunology.

The product portfolio is complemented by a wide range of antigens and antibodies for research purposes.

Business connections exist to clinical diagnostic laboratories and academic research institutions in the form of contract work, especially for the conduct of clinical trials. Collaborations with the pharmaceutical industry and memberships in scientific societies form the basis for a successful business development.

The portfolio is continuously supplied from the pipeline of proprietary research and development. Examples: IDK Calprotectin for IBD Monitoring, Vitamin D Analytics (ELISA, HPLC, LCMS/MS), IDK Extract for stool analytics.

Instruments & Services

Reagents

in.vent DIAGNOSTICA GmbH

Neuendorfstr. 17 · 16761 Hennigsdorf

Tel.: +49 (3302) 55199-11 · Fax: +49 (3302) 55199-10

Mail: info@inventdiagnostica.de · Web: www.inventdiagnostica.de

Founded: 2001 · Employees: 40



Human Bio-Materials | Diagnostic Clinical Studies | Controls | Bio-Storage + Bio-Hub | Contract Development

in.vent DIAGNOSTICA GMBH is a medical diagnostic company based at the biotech campus in Hennigsdorf near Berlin.

According to our mission "Targeted procurement of human Bio-Materials" in.vent is Europe's leading specialist for procurement of high class, highly qualified human Bio-Materials. We procure a wide range of clinically defined samples of small volumes up to bulks in normal and disease state, predominantly autoimmunity and allergy. in.vent is active in the field of diagnostic clinical studies which are key for valuable diagnostics. Diagnostic clinical studies cover the complete value chain of IVDs incl. requirements of the

new IVDR. in.vent also manufactures kit-internal controls for IVD-manufacturers and is supplier of kit-external controls for proficiency test and control manufacturers. Additionally we offer Bio-Storage and Bio-Hub to our customers, by which we are able to store & ship all volumes of human Bio-Materials down to -180 °C.

Regarding contract development in the range of assays in.vent develops ELISAs and rapid tests for luminescence-, enzyme- and nanoparticle-based detection for proteins and antibodies in urine, sera and whole blood.

Instruments & Services

Reagents

Institut Virion\Serion GmbH

Friedrich-Bergius-Ring 19 · 97076 Würzburg
Tel.: +49 (931) 3045-0 · **Fax:** +49 (931) 3045-100
Mail: dialog@virion-serion.de · **Web:** www.virion-serion.de
Founded: 1978 · **Employees:** 130

virion\serion

Institut Virion\Serion GmbH, founded in Germany in 1978, is one of the leading companies specializing in the manufacture of in vitro diagnostics products for infectious disease serology. The company offers a selection of test systems to aid in the diagnosis of viral, bacterial, parasitic and fungal diseases. Our product portfolio comprises of various analytical methodologies, such as complement fixation tests, SERION ELISA classic and SERION ELISA antigen products as well as laboratory automated systems.

With our product line SERION ELISA classic we cover a broad range of serological investigations including diagnosis of respiratory infections, gastrointestinal infections, children's diseases, ToRCH diagnostics, immune status control and CSF

diagnostics. Furthermore we provide a large panel of control materials for various applications.

In 2013, Virion\Serion has additionally founded their independent business unit SERION Immunologics. SERION Immunologics offers various highly purified native and recombinant antigens to detect pathogen specific antibodies from viral, bacterial and fungal origins. The product portfolio is complemented by corresponding disease state plasma, different raw materials (e.g. BSA) and customer specific services such as Lyophilization or ELISA coating.

Instruments & Services

Reagents

LDN – Labor Diagnostika Nord GmbH & Co. KG

Am Eichenhain 1 · 48531 Nordhorn
Tel.: +49 (5921) 8197-0 · **Fax:** +49 (5921) 8197-222
Mail: info@ldn.de · **Web:** www.ldn.de
Founded: 1996 · **Employees:** 40

LDN[®]

Since its foundation in 1996 LDN has been devoted to the development, production and supply of speciality in-vitro diagnostics test systems and innovative technologies to the clinical and research laboratory markets.

The product focus is on immunoassays for Biogenic Amines, Neuroscience, Food Safety and Endocrinology – the techniques used are ELISA, RIA, colorimetric and lateral flow.

LDN products are distributed worldwide by a network of OEM partners and distributors and in North America through our daughter company Rocky Mountain Diagnostics (www.rmdiagnosics.com).

Instruments & Services

Reagents

LifeCodexx AG

Line-Eid-Str. 3 · 78467 Konstanz
Tel.: +49 (7531) 97694-60 · Fax: +49 (7531) 97694-80
Mail: info@lifecodexx.com · Web: www.lifecodexx.com
Founded: 2008



Headquartered in Konstanz, Germany, LifeCodexx AG has been developing innovative and clinically validated non-invasive diagnostic tests based on the newest molecular analytical methods since 2010. With the PrenaTest® launched in 2012, LifeCodexx AG has been changing prenatal diagnostics considerably. The PrenaTest® is Europe's first non-invasive prenatal test (NIPT) for the determination of the most common chromosomal disorders in unborn children. The test method is based on the analysis of cell-free DNA in the pregnant woman's blood and can be performed from the ninth month of pregnancy (9+0 p.m.). The PraenaTest® is a safe test that does not present any risks to the unborn child. It determines very accurately whether or not any of the chromosome disorders, such as Down Syndrom, tested are present. The test may help relieve pregnant women concerns

and worries about possible health problems in the child if these are unsubstantiated. The test is performed within Germany in strict conformity with the highest quality standards as per the European Directive on In-vitro Diagnostic Medical Devices. The PrenaTest® is available at select gynecological practices and prenatal diagnostic clinics in various countries throughout Europe, Asia, and the Middle East.

Visit www.lifecodexx.com.

Instruments & Services

Reagents

Lionex GmbH

Salzdahlumer Str. 196 · 38126 Braunschweig
Tel.: +49 (531) 2601-266 · Fax: +49 (531) 2601-159
Mail: info@lionex.de · Web: www.lionex.de
Founded: 1999



LIONEX Diagnostics & Therapeutics GmbH is a German biotech company active in the fields of biomedicine and human health with special emphasis on TUBERCULOSIS (TB). Our focus is on research and product development for infectious diseases and cancer. LIONEX is actively participating and/or coordinating a number of research projects funded by the European Union, The WHO, FIND, German Federal Ministry for Research and Education (BMBF), German Federal Ministry of Commerce (BMWi). Research fields include diagnostics, vaccine and drug development, bladder cancer biomarkers and bladder cancer therapeutics.

LIONEX is developing novel Diagnostics for Tuberculosis and HIV based on a series of proprietary platforms. Our aim is to manufacture cost-effective but high quality, rapid tests for diseases endemic countries. LIONEX is ISO9001 and ISO13485 certified and has excellent, state-of-the art infrastructure including molecular biology CAT.-1, and CAT-II laboratories with access to CAT.III labs. Manufacturing machines and facilities for Large scale Lateral Flow Tests as In-Vitro-Diagnostics (IVD) are available at LIONEX.

LIONEX produces and supplies one of the largest numbers of mycobacterial antigens and monoclonal antibodies for research world-wide.

Instruments & Services

Reagents

Lipotype GmbH

Tatzberg 47 · 01307 Dresden

Tel.: +49 (351) 796-5345 · Fax: +49 (351) 796-5349

Mail: info@lipotype.com · Web: www.lipotype.com

Founded: 2012 · Employees: 11



Lipotype is a spin-off company from the Kai Simons and Andrej Shevchenko labs of the world-renowned Max-Planck-Institute of Molecular Cell Biology and Genetics in Dresden, Germany. Drawing on many years of cutting edge research experience, Lipotype delivers comprehensive, absolutely quantitative lipid analysis services for clinical and biological samples on a high-throughput scale. Lipotype offers high quality lipid analysis services for applications such as clinical screening, biomarker identification (pharmacodynamic, pharmacokinetic, CDx) and mode-of-action studies for clinical researchers, pharma and biotech companies.

Advantages of Lipotype lipid analysis are:

- Broad coverage (~ 2,300 lipids)
- Absolute quantitation (internal standards)
- Sensitivity: sub- μ M
- Technical variation < 10%
- High-Throughput: 200 samples per day
- Minimal sample amount (1 μ l of blood plasma, 60,000 cells)
- Data delivery within 2 weeks

Instruments & Services

Reagents

Lophius Biosciences GmbH

Am BioPark 13 · 93053 Regensburg

Tel.: +49 (941) 6309-197-0 · Fax: +49 (941) 6309-197-9

Mail: info@lophius.com · Web: www.lophius.com

Founded: 2002 · Employees: 20



Lophius Biosciences is a privately-held German biotechnology company focusing on the development and marketing of innovative immune diagnostic systems to improve therapy control and personalized treatment of patients in the area of transplantation, infectious and autoimmune diseases.

The company's developments are based on its expertise in cell-mediated immunity as well as on its proprietary T-activation[®] and Reverse T Cell Technology platforms. Whereas the T-activation[®] technology platform allows an efficient stimulation of a broad spectrum of clinically-relevant immune effector cells to accurately measure the cell-mediated immunity, the Reverse T Cell Technology platform can distinguish between active and memory T cells to develop innovative diagnostics.

With its T-Track[®] CMV leading product, based on T-activation[®] technology, Lophius offers a highly sensitive, reliable and standardized CE-marked in vitro diagnostics solution to measure the functionality of CMV-specific cell-mediated immunity. T-Track[®] CMV assists clinicians in the risk stratification of CMV disease in immunocompromised patients, toward an improved and individualized patient management.

Instruments & Services

Reagents

LRE Medical GmbH

Georg-Brauchle-Ring 89 · 80992 München
Tel.: +49 (89) 358803-47 · Fax: +49 (89) 358803-67
Mail: strehle@lre.de · Web: www.lre.de
Founded: 1961 · Employees: 200



LRE Medical GmbH is a leading contract developer and manufacturer of medical, in vitro diagnostics (IVD, analytical and life sciences instrumentation for OEM customers. LRE focuses on products for Handheld, Point-of-Care/Use and Laboratory markets based on a variety of technologies including solutions for molecular diagnostics. For more than 50 years looks for ways to optimize product design and manufacturing processes that improve product quality, reliability and performance, reduce overall program and product costs and shorten the time to market.

LRE provides full turnkey projects "One Stop Shopping" solutions (Engineering, Manufacturing, After Sales Service and Lifetime Product Support) for the Development and Manufacturing of innovative Devices in compliance with ISO 13485, ISO 14001 and FDA CFR Part 820 for Class I-III Medical Devices.

Instruments & Services

Reagents

medac – Gesellschaft für klinische Spezialpräparate mbH

Theaterstr. 6 · 22880 Wedel
Tel.: +49 (4103) 8006-9111 · Fax: +49 (4103) 8006-8934
Mail: contact@medac.de · Web: www.medac.de
Founded: 1970



medac is a privately held global pharmaceutical company with a successfully growing therapeutics and diagnostics business.

Established in Hamburg, Northern Germany, medac provides a wide range of high-quality standard products as well as special therapeutics and innovative diagnostics. Being specialised in the treatment of haemato-oncological, urological and autoimmune diseases, medac is dedicated to the refining of existing and the development of new diagnostic and therapeutic products providing patients with essential and individualised treatments.

In the field of diagnostics medac develops, produces and distributes innovative products for customers including

physicians and histotechs in private and public laboratories as well as biotech and pharmaceutical companies. The currently available products range from the enzyme activity and anti-drug-antibody ELISA for therapeutic monitoring to serologic, immunohistochemistry, cytology and PCR products. One future focus of medac's diagnostics division lies on the development of test systems for autoimmune diseases and cancer.

Further information about the company and its products can be found online at www.medac.de

Instruments & Services

Reagents

Mediagnost GmbH

Aspenhastr. 25 · 72770 Reutlingen

Tel.: +49 (7121) 5148-40 · Fax: +49 (7121) 5148-410

Mail: contact@mediagnost.de · Web: www.mediagnost.de

Founded: 1985 · Employees: 25



Mediagnost, Gesellschaft fuer Forschung und Herstellung von Diagnostika GmbH, founded in 1985, is a research based company dedicated to the development and manufacture of in-vitro diagnostic test systems and cell culture derived biological reagents (viral antigens and antibodies). Main focus lies on designing innovative diagnostic tools (Endocrinology, Virology, Diagnostic of Infections, Nucleic Acid Technology) in a swift transfer from the scientific research base directly to the customer.

Mediagnost has established state-of-the-art laboratories, certified by the German authorities and in conformity with the laws relating to medical devices, pathogens and genetic engineering. The laboratories in two security levels (L1/S1+L2/S2) are approved for handling human pathogens.

The manufacturing processes, adhering to the GLP and GMP standards, are managed by scientists with qualified expertise in immunology, endocrinology, virology and infectiology.

Mediagnost is certified according to ISO 13485. All test systems for clinical diagnostics are in compliance with the European Medical Device Directive 98/79/EC and are CE-labeled.

The entire company expertise is available as service!

Instruments & Services

Reagents

membraPure GmbH

Wolfgang-Küntschner-Str. 14 · 16761 Hennigsdorf

Tel.: +49 (3302) 201 20-0 · Fax: +49 (3302) 201 20-21

Mail: info@membrapure.de · Web: membrapure.de

Founded: 1993 · Employees: 50



We manufacture systems for water purification, TOC measurement, amino acid analysis and ion chromatography. Offering an outstanding level of technology and quality such as EDI, post column derivatization with Ninhydrin. Our Amino Acid Analyzer is a vital system for detection of inherited metabolism errors in new born screening around the world. All eluents for this IVD analyzer are made under ISO 13485 in our new premises which we built in 2015 to enlarge our production capacity.

With the recently published results in Diabetes 2 studies, our IVD kit could be used to support the prediction of Diabetes 2 and will also have a supporting role in prediction of cardiovascular diseases. We constantly improve and develop new applications and increase the sensitivity of our Amino Acid

Analyzer to promote this method for other industries like pharma where it was introduced as the valid method in the last edition of pharmacopeia.

We sell our equipment world-wide through a network of distributors and our own sales offices in Beijing/PR China, Kuala Lumpur/Malaysia and Latin America. Our head office and our new production hall is located in Hennigsdorf near Berlin/Germany. Please contact us if you have any questions about our equipment or its applications.

Instruments & Services

Reagents

Microcoat Biotechnologie GmbH

Am Neuland 3 · 82347 Bernried

Tel.: +49 (8158) 9981-0 · Fax: +49 (8158) 9981-10

Mail: a.graentzdoerffer@microcoat.de · Web: www.microcoat.de

Founded: 1992 · Employees: 126



Microcoat offers a wide range of individual and specialized services for the diagnostic and pharmaceutical industry. In close cooperation with our customers, we aim for best performance building on a complete range of advanced technologies and uncompromised quality standards.

Contract Manufacturing

Microcoat is an approved original equipment manufacturer (OEM) for diagnostic test kits, bulk and finished components according to ISO and IVD standards. Since all critical test components are produced and modified in-house, we are able to control quality at all points of the production process.

Custom Development

We offer unique expertise in diagnostic assay and product development. A broad spectrum of methods, skilled staff and intensive communication with the customer are the cornerstones for successful project realization.

Laboratory Services

Microcoat conducts a broad spectrum of services to support drug development starting from early development to post-marketing surveillance. Assay validation and sample analysis is performed according to GLP and GCP standards. Sample panels can be analyzed for routine IVD parameters on automated laboratory analyzers or for any ELISA or PCR parameter which is commercially available.

Instruments & Services

Reagents

Mikrogen GmbH

Floriansbogen 2-4 · 82061 Neuried

Tel.: +49 (89) 54801-0 · Fax: +49 (89) 54801-100

Mail: mikrogen@mikrogen.de · Web: www.mikrogen.de

Founded: 1989 · Employees: 128



MIKROGEN is a global provider of system solutions for medical laboratory diagnostics. The company's success factors are the combination of excellent genetic engineering know-how with scientific background and consistent customer orientation. We offer a wide range of system solutions for the detection of different human pathogens based on serology and real-time PCR (e.g. HIV, HCV, HEV, EBV, ZIKA, Toxoplasma, Helicobacter pylori, HPV). Our focuses are on the serology of bacterial, fungal, viral and parasitic infections as well as on autoimmune and cancer diseases. Our own developed and high quality recombinant antigens are well known and unique in the Dx market. Mikrogen has got an excellent worldwide reputation for the development and manufacturing of Line Blot, Elisa and Multiplex test systems based on recombinant antigens, serving global needs.

MIKROGEN's philosophy is to develop high-value products providing additional benefits for our customers. More than one hundred staff members work continuously on the implementation of latest scientific results. Competent consulting and support as well as specialized sales representative make MIKROGEN the partner of choice in the diagnostic laboratory.

Instruments & Services

Reagents

Milenia Biotec GmbH

Versailler Str. 1 · 35394 Gießen

Tel.: +49 (641) 948883-0 · Fax: +49 (641) 948883-80

Mail: info@milenia-biotec.de · Web: www.milenia-biotec.de

Founded: 2000 · Employees: 16



Milenia Biotec is dedicated to the development, production and sales of lateral flow immunoassays. The main business areas are food diagnostics and inflammatory diseases.

Instruments & Services

Reagents

Minerva Biolabs GmbH

Köpenicker Str. 325 · 12555 Berlin

Tel.: +49 (30) 2000-4370 · Fax: +49 (30) 2000-4379

Mail: info@minerva-biolabs.com · Web: www.minerva-biolabs.com

Founded: 1999 · Employees: 18



Minerva Biolabs GmbH founded in 1999 is a leading biotechnology company for the development, manufacturing, and marketing of detection & elimination kits for the control of microbial contamination.

Minerva Biolabs is a contract manufacturer specialized in IVD kits, molecular biological reagents, PCR assays, and sample preparation kits. With our flexibility and experience as contract manufacturer of complex assays and kits for various notable customers, we are an ideal partner for you and your product. We will reliably handle small to large batch sizes according to your needs.

As a contract manufacturer, we offer our service and experience of more than 15 years in producing various molecular

biological reagents and kits. Our special asset is to manufacture lyophilized molecular biological components and PCR kits, including in vitro diagnostics. In addition, we will help you to make your product successfully marketable.

We are certified according to ISO 13485 with a proven record as contract manufacturer serving customers around the world.

Leverage our expertise in formulation and manufacturing

- Reduce expenditure on facilities, technology and personnel
- Focus on your core competencies
- Reduce risk
- Increase flexibility
- Clean room facility
- More than 15 years of experience

Instruments & Services

Reagents

Molzymb GmbH & Co. KG

Mary-Astell-Str. 10 · 28359 Bremen

Tel.: +49 (421) 696 162-0 · Fax: +49 (421) 696 162-11

Mail: info@molzym.com · Web: www.sepsitest.com

Founded: 2003 · Employees: 16



Molzymb develops innovative solutions to serve biological research and the in-vitro diagnosis of infectious diseases. This comprises new processes enabling and facilitating the molecular diagnosis of infectious diseases caused by bacteria and fungi. Molzymb manufactures ultra-clean reagents and kits for microbial nucleic acid extraction and amplification processes. In particular, reagents and consumables are supplied free of contaminating microbial DNA. Molzymb's unique technology of the removal of human DNA, a well-known factor negatively influencing sensitive PCR and microbiome analysis at low microbial loads, allows the precise detection and monitoring of infectious diseases in humans and animal models. DNA contamination-free assays for the broad-range amplification of parts of the 16S and 18S rRNA genes of bacteria and fungi are available for PCR analysis at 40

cycles without false-positive signals. The products are useful for pathogen detection and precise analysis of microbial communities (microbiomes). The walk-away robotic system, SelectNA™plus, enables the automated extraction of microbial DNA from clinical and other materials with a minimum of hands-on time. Molzymb offer kits approved for the routine in-vitro diagnosis of a variety of infectious diseases.

Instruments & Services

Reagents

mti-diagnostics GmbH

Limburger Str. 45 · 65510 Idstein

Tel.: +49 (6126) 959-5262 · Fax: +49 (6126) 959-5262

Mail: info@mti-diagnostics.com · Web: www.mti-diagnostics.de

Founded: 1990 · Employees: 10



mti-diagnostics GmbH has been active in the field of clinical chemistry since 1990. We differ from the competition by our flexibility. Customer requirements and short delivery times are our target target.

The variety and high quality of our products are our business and philosophy. The mti-diagnostics GmbH is certified in accordance to DIN EN ISO 9001:2008 and DIN EN ISO 13485:2012. Optimized processes with continuous checks during all steps within the process combined with high delivery reliability emphasizes our quality standards we set for ourselves.

We look forward to your inquiries

Instruments & Services

Reagents

numares AG

Am Biopark 9 · 93053 Regensburg
 Tel.: +49 (941) 280 949-00 · Fax: +49 (941) 280 949-50
 Mail: info@numares.com · Web: www.numares.com
 Founded: 2004 · Employees: 70



numares, a fast growing commercial stage diagnostics company, is developing software-based test systems for high throughput use in clinical routine and life science research. Its AXINON® system features a range of analytical and diagnostic applications using nuclear magnetic resonance spectroscopy to evaluate metabolomic biomarker networks. As metabolomics is used for the identification of biomarker networks, numares offers an easy-to-operate and modular platform with high degree of standardization and robustness. This enables clinical research to take the critical step from bench to bedside and position metabolomics as the second important pillar in precision medicine next to genomics.

In Europe, numares has recently launched renalTX-SCORE®, a metabolomics test for diagnosis of renal-allograft rejection. renalTX-SCORE® is a non-invasive urine test and therefore offers many advantages over renal needle biopsy, which is the current gold standard. The company is developing tests in cardiovascular diseases, nephrology, oncology and neurology.

numares AG is headquartered in Regensburg, Germany, with offices in Boston and Singapore.

Instruments & Services	Reagents
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oncgnostics GmbH

Winzerlaer Str. 2 · 07745 Jena
 Tel.: +49 (3641) 508456 · Fax: +49 (3641) 508451
 Mail: kontakt@oncgnostics.com · Web: www.oncgnostics.com
 Founded: 2012 · Employees: 9



oncgnostics develops – based on proprietary epigenetic biomarkers - highly reliable molecular in vitro diagnostics (IVD) tests for screening, follow-up care and therapeutic decisions in cancer diagnostics. DNA methylation constitutes a naturally occurring chemical modification, which may be involved in the epigenetic silencing of certain genes. Cancer cells display specific DNA methylation patterns, and these provide the basis for the molecular cancer diagnostics provided by oncgnostics. For the first diagnostic field cervical cancer, a set of six DNA methylation markers was validated using >2000 well-characterized patient samples in several studies. GynTect®, oncgnostics' first test based on these results, reliably clarifies which women with abnormal Pap smear and/or HPV-infection require invasive diagnostics and treatment. Reliable markers for cervical cancer diagnostics are patented

in Europe (EP2478117B1), the US (US8575326B2; US9228238B2), Japan (JP5491631B2), pending in Canada, rights held by oncgnostics. In the IVD market oncgnostics acts in the field of molecular diagnostics: estimated worldwide market volume of 6.5 bn USD in 2016; compound annual growth rate 9%.

Instruments & Services	Reagents
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ORGENTEC Diagnostika GmbH

Carl-Zeiss-Str. 49-51 · 55129 Mainz

Tel.: +49 (6131) 9258-0 · Fax: +49 (6131) 9258-58

Mail: orgentec@orgentec.com · Web: www.orgentec.com

Founded: 1988 · Employees: 130



ORGENTEC Diagnostika – A Global Leader in Specialty Diagnostics

Headquartered in Mainz, Germany, ORGENTEC Diagnostika offers one of the industry's most comprehensive portfolios in diagnostics of autoimmune and infectious disease diagnostics, with additional strengths in cardiovascular and organ function testing.

Our in-house research department has a clear focus on the development of novel biomarkers for early recognition of rheumatoid arthritis and companion diagnostics.

Alegria®, the automated instrument for autoimmune and infectious disease serology enables labs to complete multiple assays and deliver faster results at minimum cost.

With our US branch Corgenix in Denver, and sales subsidiaries in Austria, Hungary, France, and China, as well as an established global network of distribution partners, ORGENTEC's products are benefitting patients in over 100 countries around the world.

Instruments & Services

Reagents

PROGEN – passion for research

Maaßstr. 30 · 69123 Heidelberg

Tel.: +49 (6221) 8278-0 · Fax: +49 (6221) 8278-23

Mail: info@progen.com · Web: www.progen.com

Founded: 1983 · Employees: 21



Since 1983, PROGEN has been an established manufacturer and supplier of premium antibodies, in vitro diagnostics, and reagents for the global life science research community. While PROGEN's antibodies are among the most published antibodies in biomedical and cell biology literature, its ELISA kits aim at niche markets. Building on its core-competency in immunochemistry, the company has expanded its collaborations and business in recent years to access new research markets with innovative immunological products. The activities of the DIN EN ISO 13485 certified company focus on the development of ELISA tests for the determination of adeno-associated virus titers in gene therapy research and development. Since 2012, PROGEN has been a 100% subsidiary of the R-Biopharm AG.

Instruments & Services

Reagents

Promega GmbH

High-Tech-Park · Schildkrötstr. 15 · 68199 Mannheim
 Tel.: +49 (621) 8501-0 · Fax: +49 (621) 8501-222
 Mail: de_custserv@promega.com · Web: www.promega.com
 Founded: 1997 · Employees: 75



With a portfolio of more than 3,000 products covering the fields of genomics, molecular diagnostics, protein analysis and expression, cellular analysis, drug discovery and genetic identity, Promega is a global leader in providing innovative solutions and technical support to life scientists in academic, industrial and government settings.

Promega products are used by life scientists who are asking fundamental questions about biological processes as well as by scientists who are applying scientific knowledge to diagnose and treat diseases, discover new therapeutics, and use genetics and DNA testing for human identification.

Promega holds significant intellectual property rights and licenses in several key areas that form a foundation for its diverse portfolio including:

- Bioluminescence, including engineered luciferases, luciferase reporter vectors and luciferase substrates
- Short tandem repeat (STR) detection for STR-based cell line authentication, human identification, cell and tissue characterization, and mixed sample detection
- HaloTag® protein labeling and capture technology

Instruments & Services

Reagents

Protagen AG

Otto-Hahn-Str. 15 · 44227 Dortmund
 Tel.: +49 (231) 9742-6300 · Fax: +49 (231) 9742-6301
 Mail: bd@protagen.com · Web: www.protagen.com
 Founded: 1997 · Employees: 21



Protagen AG specializes in Pharma development services and novel companion diagnostics, in the field of immuno-oncology and autoimmune disease. Via co-development projects with its strategic partners, Protagen enables effective, targeted immuno-therapeutic development for improved patient care.

Protagen is at the forefront of immuno-profiling and the discovery of novel biomarkers using its proprietary immuno-profiling platform (SeroTag®), and stratification arrays based on biomarker panels (NavigAID) to screen patient serum specimens, Protagen is able to provide:

- Better disease activity assessment
- Improved response prediction
- Patient monitoring
- Early detection of immune-related adverse events (irAEs)

Protagen's NavigAID portfolio of patient stratification arrays is available for SSc, SLE, RA and SJS. Protagen's SeroTag® technology is also applied to the field of immuno-oncology to identify and monitor a number of issues currently hindering the successful development and broader application of certain cancer immunotherapies, such as low response rates and irAEs.

To find out how Protagen can support your therapeutic development project to enable better response prediction, patient monitoring and early detection of adverse events contact us now.

Instruments & Services

Reagents

Q-Bioanalytic GmbH

Fischkai 1 · 27572 Bremerhaven

Tel.: +49 (471) 4832-440

Mail: info@q-bioanalytic.com · Web: www.q-bioanalytic.com

Founded: 2003 · Employees: 20



bioanalytic

Q-Bioanalytic is a producer of a CE IVD marked Real-Time PCR Test kit for MRSA detection. In addition, the company produces test kits for the detection of microorganisms in food samples. The latter test kits are in complete accordance with the ISO 20838.

The following bacterial species can be detected:

Salmonella spp., Listeria monocytogenes, MRSA (Food), Staphylococcus aureus, Cronobacter sakazakii, Clostridium perfringens, E. coli, Campylobacter jejuni, EHEC (stx1, stx2, eaeA), E. coli, EHEC, EPEC, EIEC, Shigella, Vibrio vulnificus, Vibrio parahaemolyticus, Vibrio cholerae, Vibrio alginolyticus, Legionella pneumophila, Legionella spp., Pseudomonas aeruginosa. In addition to the identification of species, toxicity

markers of Vibrio species are also available. Vibrio cholerae (tox), Vibrio parahaemolyticus (tdh /trh).

A monitoring using the Vibrio parahaemolyticus test can be used to prevent the acute hepatopancreatic necrosis disease (AHPND) of shrimp aquaculture.

Instruments & Services

Reagents

ravo Diagnostika GmbH

Oltmannsstr. 5 · 79100 Freiburg

Tel.: +49 (761) 407-488 · Fax: +49 (761) 407-477

Mail: info@ravo.de · Web: www.ravo.de

Founded: 1995 · Employees: 9



ravo Diagnostika is a privately held company which was founded in 1995 by Prof. Dr. med. Arnold Vogt, former director of the Department of Immunology in the Institute of Medical Microbiology and Hygiene, Albert-Ludwigs-University in Freiburg, Germany, and two of his co-workers, Dr. rer. nat. Christiane Rasiah and Prof. Dr. med. Sebastian Rauer.

Our team focusses on development and production of immunoassays for the diagnosis of infectious and autoimmune diseases and we lay great value on good quality and support.

Our customers are medical laboratories all over the world.

The product range comprises indirect haemagglutination assays (IHA), ELISA, ISAGA, DIFA and Line Assays.

We have implemented a Quality Management System according to DIN EN ISO 13485 and the Council Directive 98/79/EC, Annex IV.

Instruments & Services

Reagents

ScheBo® Biotech AG

Netanyastr. 3 · 35394 Gießen

Tel.: +49 (641) 4996-0 · Fax: +49 (641) 4996-77

Mail: schebo@schebo.com · Web: www.schebo.de

Founded: 1988 · Employees: 46



ScheBo® Biotech AG is an innovative biotech company that is active in the fields of development, production and marketing of diagnostics. ScheBo® Biotech AG's mission is to improve quality of health care by providing the best diagnostics with a focus on QUALITY, CLINICALLY RELEVANT INNOVATION and SIMPLICITY.

ScheBo® Biotech AG was founded by the biochemists and molecular biologists Ursula Scheefers-Borchel, Ph.D., and Hans Scheefers, Ph.D.

Subsidiaries:

ScheBo® Biotech UK Ltd., founded: 1999

ScheBo® Biotech USA Inc., founded: 2001

The Company:

- is completely privately funded and independent,
- operates internationally,
- develops innovative diagnostics.

R&D and manufacturing led to the successful launch and sales of the following products:

- ScheBo® Pancreatic Elastase 1 Stool Test, · ScheBo® Pancreatic Elastase 1 Serum Test, · ScheBo® Tumor M2-PK™ EDTA Plasma Test, · ScheBo® Elastase Canine Test, · ScheBo® Quick-Prep™, · ScheBo® Tumor M2-PK™ Stool Test*, · ScheBo® Brainostic™ GFAP ELISA, · ScheBo® M2-PK Quick™ (lateral flow test), · ScheBo® 2in1 Quick™ (M2-PK + Hb) (lateral flow test), · ScheBo® Pancreas Elastase 1 Quick™ (lateral flow test), · ScheBo® Pancreas Elastase 1 Quick™ Canine (lateral flow test), · ScheBo® Hb Smart™, · ScheBo® Lactoferrin Smart™

Instruments & Services

Reagents

SCIENION AG

Volmerstr. 7b · 12489 Berlin

Tel.: +49 (30) 6392-1700 · Fax: +49 (30) 6392-1701

Mail: support@scienion.de · Web: www.scienion.com

Founded: 2001 · Employees: 45



SCIENION offers complete solutions for precise liquid dispensing applications enabling high throughput production of multiparameter assays in diagnostics, and life and material sciences. Addressing the dynamically increasing needs for miniaturization and multiplex analyses, SCIENION offers a unique technology portfolio that has been continuously expanded for over 15 years. SCIENION provides flexible solutions for research and development, wherein solutions for production purposes are customized. Systems and software are characterized by their versatility, precision and robustness. The company is a renowned specialist for ultra-low volume liquid handling, particularly for the handling of precious and sensitive compounds of biological or chemical origin. SCIENION's dispensers allow for contact-free and precise drop spotting in the pico- to micro-liter range and

are optimally suited for microarray based analytics – such as for tests with DNA, oligonucleotides, peptides, proteins, antibodies, glycans or for dispensing cells onto various substrates. The company operates from two sites in Germany, Dortmund and Berlin, and has subsidiaries in New Jersey, USA, and Lyon, France.

Instruments & Services

Reagents

Seramun Diagnostica GmbH

Spreenhagener Str. 1 · 15754 Heidesee OT Wolzig
Tel.: +49 (33767) 791-10 · Fax: +49 (33767) 791-99
Mail: info@seramun.com · Web: www.seramun.com
Founded: 1992 · Employees: 52



Seramun Diagnostica GmbH was founded in Brandenburg (near the capital Berlin) more than 20 years ago and has established itself as a competent manufacturer and developer of reagents for immunoassays like ELISA, blot and microarrays and for in-vitro diagnostic kits in the field of autoimmune and infectious diseases.

The product range of reagents comprises chromogenic substrates for HRP and AP for the application in ELISA, Blot and Microarray – reagents and stabilizers for enzyme conjugates, proteins and proteohormones.

Our reagents and services are used worldwide by IVD manufacturers and scientific institutions. An internationally distributed product range of more than 90 CE marked IVDs for

the diagnosis of infectious and autoimmune diseases is also based on the company's own reagents and developments.

Seramun's services include production, purification and labeling of monoclonal and polyclonal antibodies, production and purification of recombinant proteins and cultivation and preparation of bacterial pathogens at the company's premises.

The new automatable technology platform SeraSpot® offers microarrays on the basis of microtitration plates with up to 25 different parameters in one well for the application in human and veterinary diagnostics.

Instruments & Services

Reagents

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring-Str. 76 · 35041 Marburg · Tel.: +49 (6421) 39-5124
Mail: communications.hclldmar.team@siemens-healthineers.com
Web: www.healthcare.siemens.com/laboratory-diagnostics
Founded: 1914 Behringwerke GmbH · Employees: 1,300



Siemens broad spectrum of immunoassay, chemistry, hematology, molecular, urinalysis, and blood gas testing systems, in conjunction with automation, informatics and services, can serve the needs of laboratories of any size – today and tomorrow.

Instruments & Services

Reagents

sifin diagnostics gmbh

Berliner Allee 317–321 · 13088 Berlin
 Tel.: +49 (30) 927030-0 · Fax: +49 (30) 927030-30
 Mail: info@sifin.de · Web: www.sifin.de
 Founded: 1992 · Employees: 75



sifin diagnostics gmbh is a privately owned company, manufacturing and distributing worldwide a broad range of microbiological and immunological products:

Blood grouping serological products: Bedside cards, ready-to-use reagents, ready-to-use reagents as bulk and concentrates, ready-to-use reagents for blood grouping on PK® instruments

Bacteriological test reagents: Shigella diagnostics, Yersinia diagnostics, Salmonella diagnostics, Coli diagnostics

Culture media and supplements: Dehydrated culture media, supplements and additives, ready-to-use culture media, base materials, detection reagents

Immunoassays: Detection of rabies virus

Monoclonal antibodies: We offer monoclonal antibodies for research or further use in your own technique

Contract manufacturing: Blood grouping monoclonal antibodies, production of culture media, bacteriological test reagents may be supplied as bulk reagents

Microbiological system MICRONAUT from MERLIN Gesellschaft für mikrobiologische Diagnostika mbH: System for the phenotypic identification and susceptibility testing of bacteria and yeasts – and exclusively available at sifin diagnostics gmbh

Instruments & Services

Reagents

Sividon Diagnostics GmbH

Nattermannallee 1 | S19 · 50829 Köln
 Tel.: +49 (221) 669-56100 · Fax: +49 (211) 669-56199
 Mail: info@sividon.com · Web: www.sividon.com
 Founded: 2010



Sividon Diagnostics is a management buy-out of Siemens Healthcare and was founded in July 2010. Sividon's position in molecular oncology is marked by the long-term experience of the staff, the extensive patent portfolio and the preparations going back to the year 2004, conducted in collaboration with renowned experts.

Sividon's first product is the EndoPredict test. In two independent clinical studies it was shown that EndoPredict can identify those patients with primary breast cancer that can be expected to have a chance of more than 95 % for more than 10 years of tumour-free survival under solely anti-hormonal treatment, i.e. without chemotherapy.

In early 2014, Sividon Diagnostics and Myriad Genetics entered into an exclusive co-marketing agreement. On May 31, 2016, Myriad Genetics acquired Sividon diagnostics and its lead product EndoPredict®. The test is the foundational product of the newly initiated kit-based strategy and allow Myriad to leverage its global oncology distribution to bring this important test to patients worldwide.

Instruments & Services

Reagents

sphingotec GmbH

Neuendorfer Str. 15A · 16761 Hennigsdorf
Tel.: +49 (3302) 2056-50 · Fax: +49 (3302) 2056-555
Mail: info@sphingotec.de · Web: www.sphingotec.com
Founded: 2002 · Employees: 9



sphingotec GmbH is a German biotech company located in Hennigsdorf, northwest of Berlin, with its facilities in the Technology Campus, one of the largest industrial parks in Berlin and Brandenburg.

sphingotec actively researches, develops and markets innovative diagnostic methods for prediction, diagnosis and monitoring of several relevant disease states. With these biomarkers we cover the fields of sepsis, heart failure and kidney function.

Furthermore, we envision that the medicine of the future will rely on diagnosing sub-clinical conditions or risk factors early to initiate disease-prevention strategies avoiding future manifestation of diseases way before they actually

occur. In order to realize this vision sphingotec has developed reliable immunoassays for the prediction of widespread and life-impacting diseases like breast cancer, Alzheimers, diabetes and obesity.

Our CE-marked commercially available assays and their medical utilities are extensively validated in thousands of patients worldwide.

Our constantly growing network of key opinion leaders in the medical field and our complete patent protection further enhance the awareness of our innovations.

Instruments & Services

Reagents

SpinDiag GmbH

Engesser Str. 4 · 79108 Freiburg
Mail: info@SpinDiag.de
Web: www.SpinDiag.de
Founded: 2016



The SpinDiag GmbH was founded in 2016 as a spin-off from the research institute Hahn-Schickard, one of the world's leading research institutes for microsystems. SpinDiag develops a test system for the fast, broad and affordable screening of patients for antibiotic-resistant bacteria during their admission to hospitals. This is crucial because worldwide millions of patients get infected in hospitals by other colonized or infected patients every year. SpinDiag's system will be designed to be operated at the point of care e.g. on the ward to rapidly generate test results on more than 25 possible antibiotic resistances directly from patient's swab samples in just 30 minutes, instead of as before in 24-72 hours. Through this early knowledge of resistances, colonized or infected patients can be treated in isolation, which will allow to significantly reduce the number of unnecessary infec-

tions of other patients. Hospitals will not only benefit from this increase in patient safety but will be able save costs for pre-emptive isolations and of outbreaks, which will render the use of SpinDiag's tests highly economically.

Instruments & Services

Reagents

varionostic GmbH

Lise-Meitner-Str. 8 · 89081 Ulm

Tel.: +49 (731) 36080756 · Fax: +49 (731) 36080754

Mail: info@varionostic.de · Web: www.varionostic.de

Founded: 2006 · Employees: 6



varionostic is Europe's leading expert for DNA methylation analysis using newest platforms of Pyrosequencing and MassARRAY. We offer our customers from industry and academia outstanding tailored services from assay design to data analysis. Scientists can also profit from our predesigned methylation assays developed within our own research facilities. Our unique specialised competence is the basis for highest quality in epigenetic research.

Clinical-chemical rapid tests are produced in-house, including handheld devices for POC and reagents. Beside a reliable and environmentally safe test for haemoglobin we offer 16 more relevant clinical parameters to be analyzed within seconds to minutes. Easy to use, secure in handling and biochemistry.

Instruments & Services

Reagents

Viramed Biotech AG

Behringstr. 11 · 82152 Planegg

Tel.: +49 (89) 899-336 · Fax: +49 (89) 859-9949

Mail: viramed@viramed.de · Web: www.viramed.de

Founded: 1983



Since 1983, Viramed® is one of the leading biotechnology companies for medical laboratory diagnostics. With more than 30 years of experience in the field of infectious and autoimmune serology, Viramed® is a successful enterprise, specialized in the development, production and worldwide distribution of high quality diagnostics.

Viramed® offers a broad range of serologic in vitro-diagnostic assays for antibody detection based on ViraChip® microarrays, ViraStripe® immunoblots and ELISA test kits. For fully automated processing, reading and interfacing to LIS, Viramed® provides microarray processors, ViraChip® Reader systems and ViraChip® software solutions to the clinical laboratory. Viramed® customized services include protein preparation and antigen purification for biotechnological

and diagnostic companies. Additionally, Viramed® serves as a distributor for IFA, ELISA and rapid test kits from internationally renowned manufacturers.

Viramed® has an excellent service record characterized by a solution-driven, highly motivated professional team with in depth scientific experience to quickly support the customers.

Instruments & Services

Reagents

VIROTECH Diagnostics GmbH

Löwenplatz 5 · 65428 Rüsselsheim

Tel.: +49 (6142) 6909-0 · Fax: +49 (6142) 966613

Mail: info@virotechdiagnostics.com · Web: www.virotechdiagnostics.com

Founded: 1986 · Employees: 90



VIROTECH Diagnostics GmbH with its head office, development- and production site in Germany, emerged in December 2016 from Sekisui Virotech GmbH. Since then the company is acting again as German firm with more than 30 years of experience in the diagnostics business. The basis of its success is to strictly adhere to the concept of the so called "System Diagnostics" and the steady redesign and expansion of its Infectious Disease ELISA- and Immunoblot product ranges. The company has combined these two product lines with products of other international manufacturers to provide an almost complete portfolio to its German customers. An own sales force sells these product lines throughout Germany. On international basis VIROTECH Diagnostics GmbH trades with more than 30 distributors world-wide to whom they offer their own manufactured products as well as an enteropatho-

genic range. The company develops and manufactures also for other companies and is always searching for new cooperations in this area. VIROTECH Diagnostics stands for high quality, customer-orientated service and innovative products in the field of human- and veterinary diagnostics.

Instruments & Services

Reagents

VivoSens Medical GmbH

Engertstr. 9 · 04177 Leipzig

Tel.: +49 (341) 3558-7895 · Fax: +49 (341) 3558-7899

Mail: info@vivosensmedical.com · Web: www.vivosensmedical.com

Founded: 2011 · Employees: 8

VivoSensMedical

VivoSensMedical GmbH is a med-tech startup dedicated to women's health. With OvulaRing the company has developed a modern e-health solution that is able, for the first time, to map the entire female cycle and therefore to precisely determine ovulation and the fertile window, ideal for medical cycle diagnostics, optimizing conception and natural contraception. Based on 40 years of medical research, OvulaRing combines wearable (vaginal biosensor) for measuring the body-core temperature with mobile software/app and medical algorithms for data evaluation within a medical approved device. With 288 measuring points daily, the patent-protected OvulaRing is the only product on the market that is able to map the entire female cycle and therefore enabling a profound analysis of the patient's cycle health. Further the fertile window and ovulation can precisely be determined

with reliabilities higher than 99%. Based on algorithms an ovulation prognosis for the following month can be given. We are addressing the markets fertility, contraception and cycle diagnostics with 110 million women in Europe and the USA with an overall sales potential higher than 10 billion Euros.

Instruments & Services

Reagents

Zentrum für Humangenetik und Laboratoriumsdiagnostik

Lochhamer Str. 29 · 82152 Martinsried

Tel.: +49 (89) 895578-0 · Fax: +49 (89) 895578-780

Mail: info@medizinische-genetik.de · Web: www.medical-genetics.de

Founded: 1998 · Employees: 120

CENTER FOR HUMAN GENETICS AND LABORATORY DIAGNOSTICS
Dr. Klein, Dr. Rost and Colleagues



The Center for Human Genetics and Laboratory Diagnostics in Martinsried is specialized in advanced laboratory testing in genetics, clinical chemistry and immunology (in particular: HLA testing). The laboratory is accredited according to DIN EN ISO/IEC 17025 and ISO 15189. The institution's clinical consultation focuses on pediatric genetics, infertility and inherited diseases. Among the applied technologies are: PID, NIPT (Prenatalis®), Next Generation and Sanger Sequencing as well as Array technologies, Blotting, FACS, FISH, HPLC, pyrosequencing, real-time PCR and tandem mass spectrometry. One of its newly established tests is the molecular genetic analysis of the human microbiome (enteralis).

The highly qualified medical, scientific and technical staff offers comprehensive and individual support services for physicians regarding all clinical and diagnostic questions. The patient's services include genetic counseling for children with developmental delay, rare diseases and prenatal testing in Munich, Martinsried, Augsburg and Kempten, as well as infertility counseling and immunization consultations.

Instruments & Services

Reagents

ZytoVision GmbH

Fischkai 1 · 27572 Bremerhaven

Tel.: +49 (471) 4832-300 · Fax: +49 (471) 4832-509

Mail: info@zytovision.com · Web: www.zytovision.com

Founded: 2004 · Employees: 50



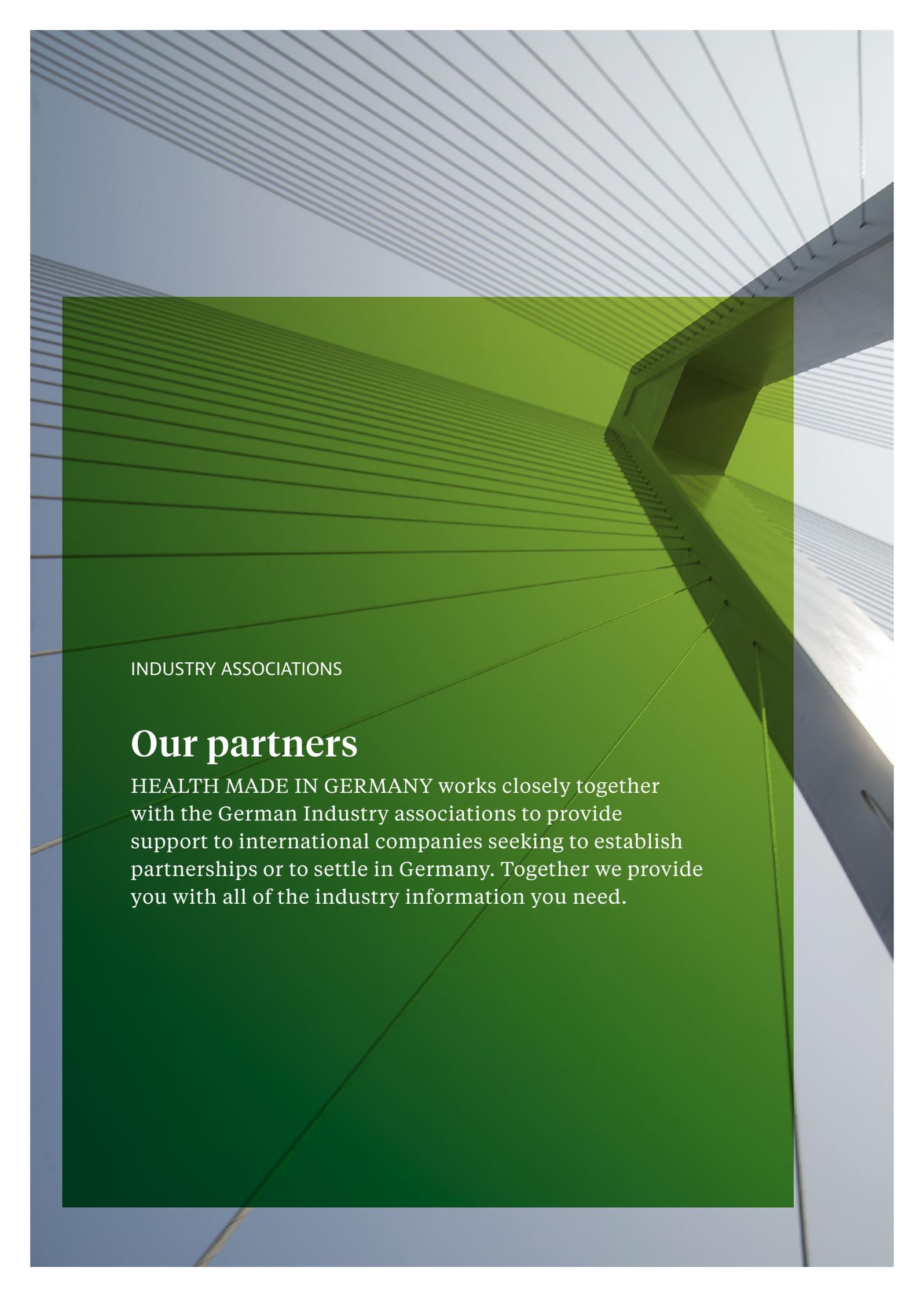
ZytoVision had been founded in May 2004 as a limited company, i.e. German GmbH, and has since the beginning a clear focus on the development and production of probes to be used in Fluorescence in situ-hybridization (FISH) and Chromogenic in situ-hybridization (CISH). So far, ZytoVision GmbH is selling worldwide more than 300 different products for in situ-hybridization (ISH); most of the products are aimed at the detection of chromosomal aberrations in tumours as for example ERBB2 amplifications in breast and Ros1 or ALK translocations/inversions in lung cancer. The products are manufactured according to ISO 9001 and 13485, and are labeled as CE-certified in vitro diagnostics (IVDs). In addition, ZytoVision had been able to get the IVD approval in a number of Non-European countries like India, China, and Australia. The company did grow to a size characterized by

50 employees. The products are marketed nationally and internationally by a mature and powerful distributor network, established over 13 years, composed of worldwide roughly 90 distributors most of them acting exclusively for ZytoVision. ZytoVision is also acting as a central lab, performing FISH or CISH analyses (GCLP compliant), in clinical trials in order to support the establishment of companion diagnostics.

Instruments & Services

Reagents





INDUSTRY ASSOCIATIONS

Our partners

HEALTH MADE IN GERMANY works closely together with the German Industry associations to provide support to international companies seeking to establish partnerships or to settle in Germany. Together we provide you with all of the industry information you need.

BIO Deutschland e. V.

Contact: Dr. Claudia Englbrecht

Am Weidendamm 1a · 10117 Berlin

Tel.: +49 (30) 72625-130 · **Fax:** +49 (30) 72625-138

Mail: info@biodeutschland.org · **Web:** www.biodeutschland.org

BIO DEUTSCHLAND

Biotechnologie-Industrie-Organisation Deutschland e. V.

The *Biotechnologie-Industrie-Organisation Deutschland* (BIO Deutschland) is an independent organization for innovative biotechnology companies in Germany. At its offices in Berlin, the association is developing and supporting an innovative industry based on modern life sciences. Founded in October 2004, BIO Deutschland currently has more than 320 member companies and several supporting members and sector partners. To support its members BIO Deutschland engages in a broad range of activities, including lobbying, public relations, and offering business development opportunities. Using a wide range of political initiatives, BIO Deutschland lobbies for improvements to legal parameters for innovative small and medium-sized enterprises. The association is also very active in a broad range of events with the aim of providing biotechnology with a platform for discussion and interaction. The German Biotechnology Days, a yearly national forum for biotechnology with more than 800 attendees, is organized jointly by BIO Deutschland, the Council of the German Bioregions and regional hosts. BIO Deutschland is governed by a managing board of CEOs, CFOs and Managing Directors of companies that represent the German biotech sector. This committee comprehensively represents the various fields in the sector.

BIO Deutschland's member companies and their experts are organized in working groups that deal with a variety of subjects relevant to the biotech sector and small and medium sized companies. The groups meet regularly to discuss current developments, to draft position papers, to exchange ideas and to network. A total of twelve working groups and one network for communication and PR are active in the association.

Working groups for the following topics are currently installed:

Big data and Bio-IT, Diagnostics, Finance and Taxation, German-US Cooperation, Licenses and Technical Contracts, Regulatory Affairs, 'Entrepreneurship, Innovation and Jobs', Human Resources, Industrial Bio-Economy, Industrial Cell Technology, Health Policy and Technology Transfer.

BIO Deutschland is also partner of several other associations such as BVMW, The German Association for Small and Medium-sized Businesses, Biosingapore, bts – Biotechnology Student Initiative, BVIZ – German Association of Innovation, Technology and Business Incubation Centers, EAPB – European Association of Pharma Biotechnology, EUCOPE – European Confederation of Pharmaceutical Entrepreneurs, German-Sino Healthcare Group, ICLS- International Council for the Life Sciences and VBIO – German Life Sciences Association. Additionally BIO Deutschland administrates the head office of the Council of German Bioregions.

BIO Deutschland is Germany's biotechnology sector representative at the European association, EuropaBio, in Brussels. BIO Deutschland also collaborates closely with other biotech organizations in Europe and the USA in order to lobby for the interests of the sector in an internationally coordinated way. It is a founding member of the International Council of Biotechnology Associations (ICBA) and (affiliated) member of the Biotechnology Innovation Organization (BIO) USA.

Association of German Biotech Companies (VBU)

in DECHEMA e.V.

Contact: Dr. Andreas Scriba

Theodor-Heuss-Allee 25 · 60486 Frankfurt am Main

Tel.: +49 (69) 7564-124 · **Fax:** +49 (69) 7564-169

Mail: scriba@dechema.de · **Web:** www.v-b-u.org · www.dechema.de



For a culture of innovation

Innovation is at the bottom of it all. Innovation has not only set the basis for the industrial development in Germany, it has also enabled for Germany to stay at the very top so far in the increasing global competition.

Scientific publications and patent registration are often taken as the indicator of the innovative power of a society. But this is not the whole truth. Innovation requires more than the development of a new industrial design, and it means more than research results and even more than a brilliant idea. Innovation implies that this idea or result is brought to real life, that it finds an expression in new products or services that meet a market demand.

A more positive entrepreneurial culture

Germany has excellent academic research, yet it is not really known as a country with a lively founding scene. And yet, the number of new businesses decreases from year to year. For businesses requiring higher investment and a longer development period – typical for industrial processes – the situation is even more bleak. Why is that so? The report states that education in schools with regards to founding needs to be improved, societal values and standards need to be adjusted for a more positive entrepreneurial culture, and labor supply needs to be increased for new and growing businesses.

In short: Motivating more people to set out on the big adventure of founding a new business is not so much a question of the financial and institutional framework, it is a question of culture and societal values. While in some other countries the founding of a business is seen as a chance for success, for growth and in any case a valuable experience, in Germany founding is regarded more suspiciously – it contradicts widely accepted values such as security, firm structures, and a potential failure is regarded as a stain in one's CV rather than an interesting feature.

Visibility for founders

The challenges have been identified, though, and countermeasures are being taken. A large number of initiatives are dedicated to technology transfer; universities and other research institutions have established technology transfer

agencies that scout academic research groups for marketable technologies. Competitions and funding programs such as the GO Bio Initiative of the German Federal Ministry of Research and Education or the Science4Life competition provide financing, advice and visibility for founders, and their number is increasing. Last year, for example, the AICHEM Gründerspreis was awarded for the first time to innovative entrepreneurs active in the fields of energy, industrial biotechnology and analytics. The nine finalists had the unique opportunity to present their concepts to industry experts from all over the world. This is an invaluable chance as many founders report that one of the hardest tasks is to identify and approach the right people in large companies in order to position themselves as potential suppliers, customers or development partners.

Our mission: innovation

From its beginning, the VBU Vereinigung Deutscher Biotechnologieunternehmen set out to enable technology transfer and facilitate networking between academic research and industry. With a special focus on small and medium sized enterprises, the VBU offers advice and organizes events tailored to give information and support to start-ups during their growth and expansion phase, both nationally and internationally. Being a part of DECHEMA, the large network for chemical process technology and biotechnology, it is the home for people active in research whether in universities, independent research institutions, start-ups or "big businesses". The activities of VBU supplement the approximately 120 topical working groups within DECHEMA, around 20 of them covering biotechnology from Omics and Cell Culture to Bio-processing and Single-Use Technologies. The mission of VBU is as up-to-date as it was 20 years ago, and as long as there are people with brilliant ideas, it will always be up-to-date.

GERMAN ASSOCIATION OF BIOTECHNOLOGY INDUSTRIES

within the German Chemical Industry Association

Contact: Dr. Ricardo M. Gent (Executive Director) · Stanislaus Koch (Manager Biotechnology)

Mainzer Landstr. 55 · 60329 Frankfurt am Main

Tel.: +49 (69) 2556-1504 · **Fax:** +49 (69) 2556-1620

Mail: info@dib.org · **Web:** www.dib.org



The German Association of Biotechnology Industries (DIB) and its national, European and global networks are the voice and leading industry representation for the innovative and dynamic biotechnology industry that operates in and from Germany.

DIB is the biotechnology division of the Association of the German Chemical Industry Association (VCI).

DIB is supported by 10 member associations and sector groups of the VCI.

- German Crop Protection, Pest Control and Fertilizer Association
- German Diagnostic Manufacturers Association
- German Cosmetics and Detergents Association
- VCI Sector Group Food Additives
- German Association of Research-Based Pharmaceutical Companies
- German Association for Food Law and Food Sciences
- German Medical Technology Association
- Association of the German Pharmaceutical Industry
- German Animal Health Association
- Association of the German Chemical Industry Association

Member companies and the above listed industry associations and sector groups are members of DIB. They constitute all in all about 95 % of the biotechnology business operating in and from Germany. This includes many different industry sectors such as polymers, plastics, fine and specialty chemicals, crop protection, plant breeding, enzymes, pharmaceuticals, diagnostics, animal health products, personal care products, detergents, animal feeds, foodstuffs, renewables and derived products. DIB is one of the largest biotechnology industry representations worldwide.

Role of DIB

DIB's mission is to advocate national, EU and international policies and legislation that uphold a natural science and risk-based approach, foster innovation, operate in a predictable and proportionate way, enable the industry to perform efficiently, protect intellectual property and reward the introduction of new technologies and practices.

- DIB contributes to the creation of internationally competitive framework conditions for use of biotechnology in research, development, production and products.
- DIB represents the political-economic interests of companies that use biotechnology in order to strengthen sustainable growth and the international competitiveness of biotechnology in Germany.
- DIB represents the interests of their members vis-à-vis high-level representatives of legislative bodies, political decision-makers, regulatory authorities, public administration, media and the general public, both nationally and internationally.
- DIB contributes to further strengthening Germany as an industry location.

DIB is a member of the European biotechnology association EuropaBio and appoints one member to the board.

German Diagnostics Industry Association (VDGH)

Contact: Dr. Robert Haustein (Head of Governmental Affairs)
Neustädtische Kirchstr. 8 · 10117 Berlin
Tel.: +49 (30) 200-599-46 · **Fax:** +49 (30) 200-599-49
Mail: haustein@vdgh.de · **Web:** www.vdgh.de



The German Diagnostics Industry Association (VDGH) is the trade association of the manufacturers of in vitro diagnostics (IVDs) and life science research firms active in Germany.

The VDGH represents the interests of about 100 member companies. They research, develop, manufacture and sell these laboratory analytical products and their precursors as well as products for patient self-testing. In vitro diagnostics can help discover health risks, identify illnesses, gauge the effectiveness of medicines before they are administered, and draw up therapeutic plans. The products of the life science research companies are instruments, reagents, test systems, and consumables that serve research in the life sciences.

The companies in the VDGH represent about 90 percent of domestic sales of diagnostics. Two third of the companies are engaged in research and development and have production sites in Germany. The diagnostic industry employs about 12 percent of its workforce in the area of research and development.

The VDGH supports its members by engaging in a wide range of activities from lobbying to providing the latest information to its members on all relevant political, economic, and regulatory topics. The VDGH also offers continuing education events for its members for various topics including regulatory and reimbursement.

The VDGH also provides various committees for the discussion of a large variety of subjects, relevant for IVD manufacturers and life science research companies. The different working committees of the VDGH meet regularly to discuss the current developments in the area of interest, to exchange idea, and to work on position papers for various stakeholders. Currently, VDGH members can choose to participate in the following working committees and working groups (AGs).

Working committees of the VDGH:

- Diabetes and Self-management
- Market and Communications
- Quality Management Systems
- Regulatory Affairs
- Environmental Affairs
- Science and Technology

Working committees of the VDGH Life Sciences

Research Department:

- Customer Communication
- Market Research
- Scientific Dialogue

In addition, there are a number of working groups (AGs) that report to specific committees

- AG Devices
- AG Licensing and Registration
- AG Animal By-products
- AG Vigilance
- AG Market Research
- AG IT-Security



HEALTH MADE IN GERMANY

Germany is one of the world's most important providers and exporters of healthcare products and services. The country's innovative medical products set international standards for quality, safety and reliability. German manufacturers and service providers in all health and life sciences segments attract overseas customers and partners and deliver leadership in healthcare innovation.

HEALTH MADE IN GERMANY is the export initiative for the German healthcare industry. It supports international companies and organizations that are interested in establishing contact with potential German partners and suppliers. Set up by the German Federal Ministry for Economic Affairs and Energy (BMWi), the initiative bundles expert market intelligence for easy market entry. One of the initiative's main goals is to promote the German healthcare sector through international networking activities for the mutual benefit of international partners and German companies alike.

HEALTH MADE IN GERMANY does this by providing proactive support (including market and regula-

tory insight), introductory services, and networking platforms including trade events at home and abroad. The initiative serves four major industries active in the international medical market: pharmaceuticals, medical technology, medical biotechnology, and digital health care.

HEALTH MADE IN GERMANY also works closely with 16 major German industry trade associations and is part of the BMWi's MITTELSTAND GLOBAL umbrella program for small and medium-sized enterprises. The initiative is ideally placed to provide access to German healthcare market information and to help overseas businesses identify potential German partners.

The HEALTH MADE IN GERMANY initiative is implemented by Germany Trade & Invest, the economic development agency of the Federal Republic of Germany, on behalf of the BMWi.



For more information:

www.health-made-in-germany.com

Our support for your business:



We publish market briefs and in-depth market studies of the German healthcare industry and its different sectors.



Our calendar is regularly updated with the latest industry events in Germany and overseas.



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Expert Advice



Axel Lohse is the manager responsible for the medical biotechnology and pharmaceutical industries at HEALTH MADE IN GERMANY. He is your point of contact for expert advice in those fields and looks forward to receiving your inquiries and requests.

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