

IVD and Bioanalytics in Berlin-Brandenburg

Potentials – Profiles – Perspectives

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IVD and Bioanalytics in Berlin-Brandenburg – Covering the Full Range of the Value Chain

During the last twenty years the Berlin-Brandenburg region has developed towards a healthcare location of Europe-wide importance. Its major strengths are a unique research landscape and a complex network of companies and institutions across all disciplines. Berlin-Brandenburg has extraordinary expertise in the areas of in vitro diagnostics and bioanalytics. About 100 companies and more than 20 research facilities are committed to IVD and cover the entire value chain – from biomarker identification to clinical validation, from developing cutting-edge platform technologies up to the production of innovative diagnostic tools.

Precise diagnoses are indispensable for targeted therapies. In the huge field of diagnostic procedures, in vitro diagnostics play a very prominent role to facilitate decision making of physicians of all specialties.

Basic research on the identification of biomarkers as indicators for biological and pathogenic processes – predominantly conducted at the numerous regional universities and academic institutions in Berlin and Brandenburg – often marks the start in the development of innovative diagnostics. Further steps involve also company engagement and include applied and translational research, technology development, clinical validation, scale-up for industrial production and finally the commercialization of a product ready for the market. The region is well-positioned to cover the entire value chain!

Due to the rapid progress and increasing use of high-throughput technologies in areas such as genomics, proteomics, metabolomics and glycomics, an increasing

number of biomarkers are available for use in new in vitro diagnostics techniques. In addition to its use to make or confirm a diagnosis, novel biomarkers allow for the stratification of patients or patient groups and diseases can also better be divided into sub-types. Both approaches contribute to a more targeted treatment in terms of personalized medicine. The advancing development of companion diagnostics to monitor therapy success is another promising strategy to improve patient outcome and to enhance healthcare efficiency.

One of the most representative examples of translational medicine in the capital region is the Berlin Institute of Health (BIH), which connects medical research by Charité – Universitätsmedizin Berlin and basic research from the Max Delbrück Center for Molecular Medicine (MDC) to strengthen translational research. By doing so, the systems medicine approach of the BIH combines biomarker research at a genomic and proteomic level with clinical patient data for specific indication areas.



Many modern diagnostic and bioanalytical techniques involve in-depth knowledge of disciplines beyond life sciences and integrating crosscutting technologies like informatics, optical technologies, microsystems technology, microelectronics, material sciences, nanotechnology, process technologies and engineering sciences is mandatory. Due to the excellent research environment, players in Berlin and Brandenburg are in the privileged situation that they find extraordinary expertise in these fields all around them. Short distances, various events and networking activities facilitate exchange and collaborative efforts which often result in cross innovation.

Another asset of the region is the extensive clinic landscape – including Charité – Universitätsmedizin Berlin, one of the largest university hospitals in Europe, and Vivantes, the largest municipal hospital group in Germany – and access to large patient populations for clinical trials and validation studies. According to a recent evaluation of the public study registry "clinicaltrials.gov" by the German Association of Research-based Pharmaceutical Companies (vfa), Germany is No. 2 worldwide in clinical trials. Nationwide, 532 trials started in 2016 and with 201 studies in Berlin-based medical facilities, Berlin leads the German ranking.

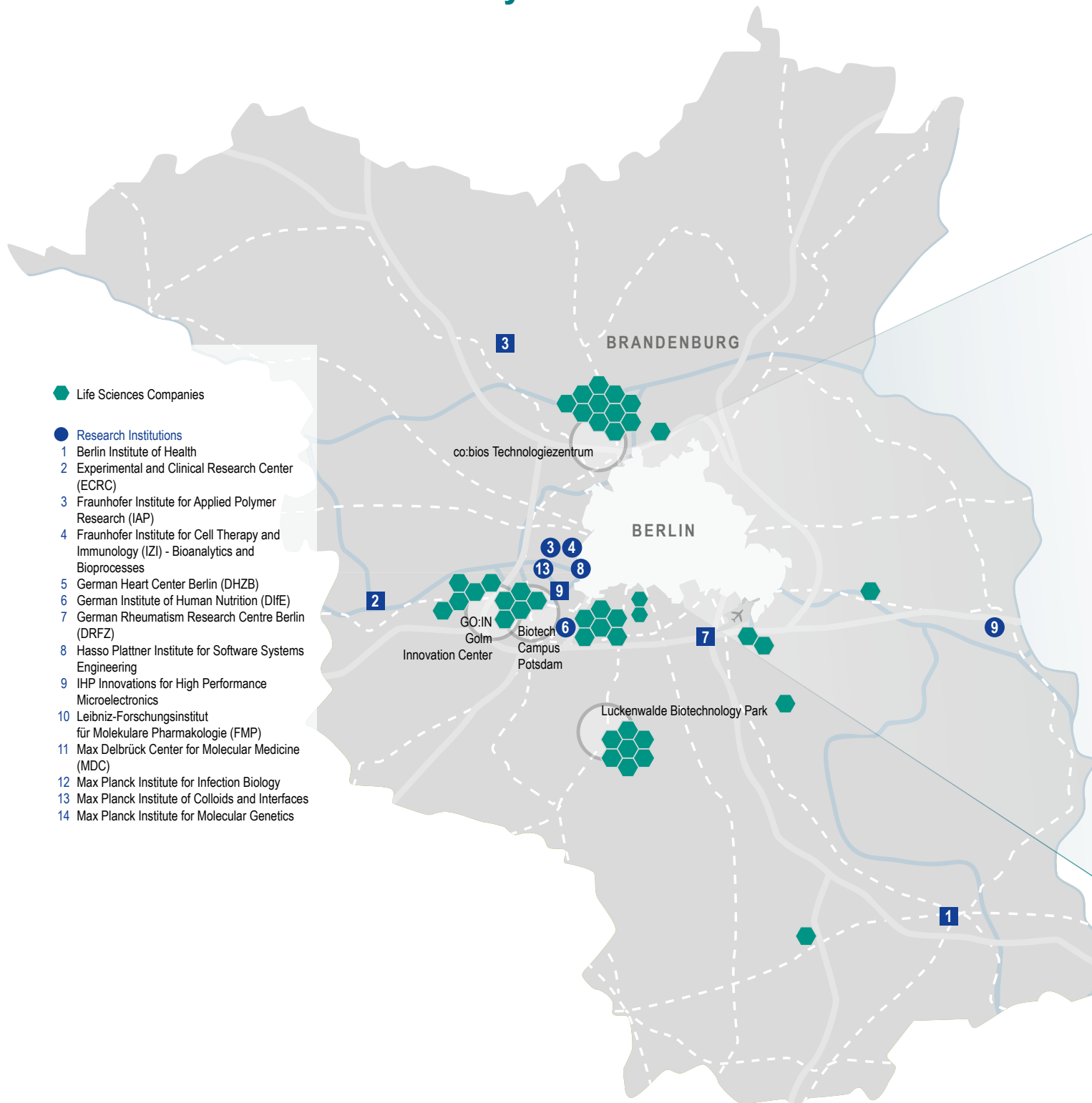
More than 100 companies – a considerable number of them spin-offs from regional universities and research institutions – benefit from this outstanding environment and have established successful businesses in the IVD and bioanalytics field. Besides providing dedicated products and services they have developed platform technologies to enable further progress in diagnostics and therapy. Epigenomic's proprietary DNA methylation biomarker technology to advance cancer diagnosis, Metanomics

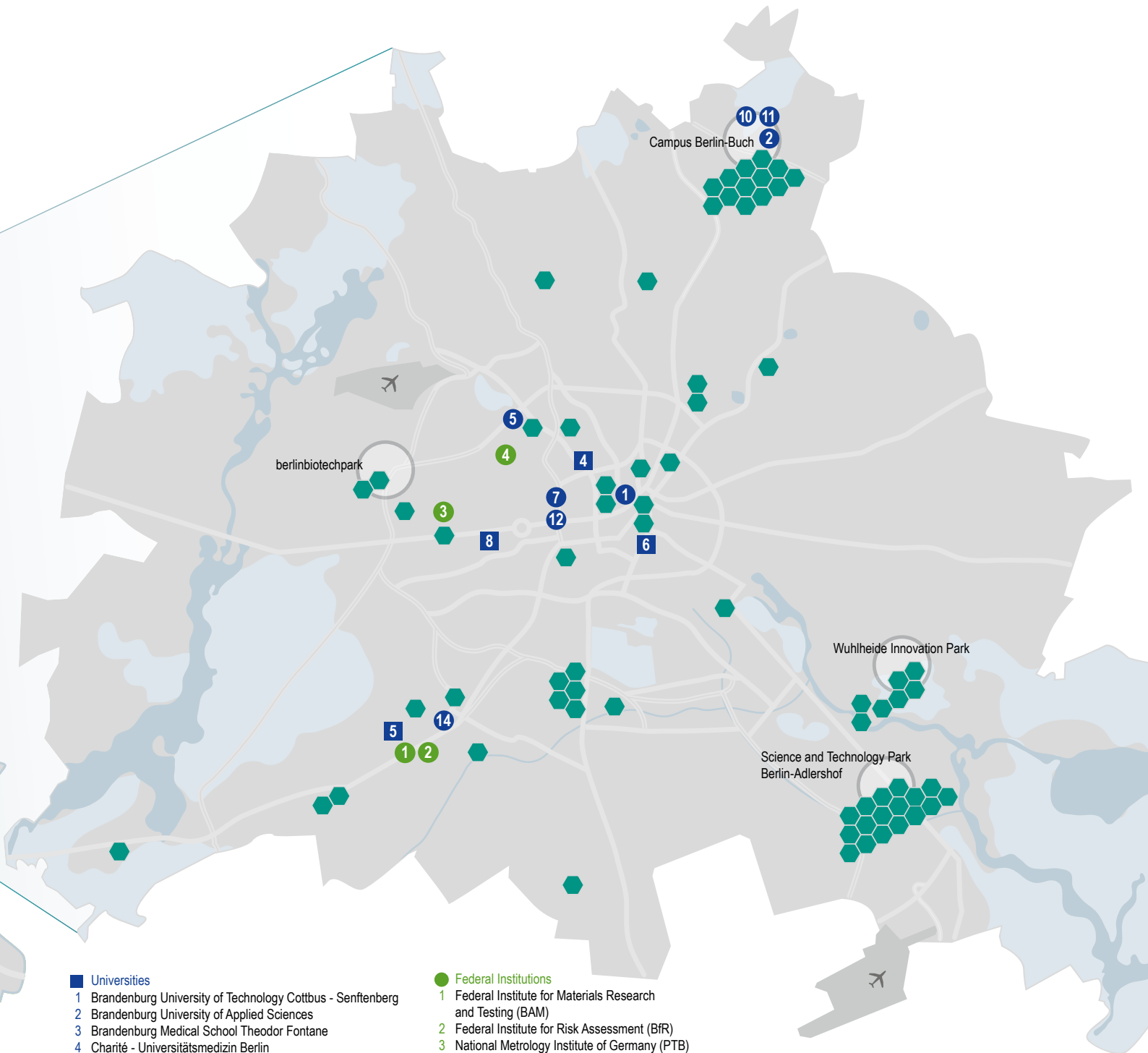
Health's metabolite profiling technology platform, Alacris' ModCell™ technology, a systems medicine modeling tool that offers individualized drug response predictions, SCIENION's sciFLEXARRAYER dispensing technology for non-contact ultra-low volume liquid handling, Medipan's fully automated system for standardized immunofluorescence imaging and data processing AKLIDES®, or Caprotec's Capture Compound Mass Spectrometry (CCMS) technology for the investigation of small molecule protein interactions are just a few examples to demonstrate the broad range of applications. Further examples of current developments from both, industry and academia, will be presented in greater detail on the following pages.

The development of the region into a number one location for in vitro diagnostics and bioanalytics has been continuously accompanied by a strong political commitment to enhance and support technology transfer and growth areas of healthcare – as e.g. reflected in the joint innovation strategy of Berlin and Brandenburg (Masterplan Gesundheitsregion Berlin-Brandenburg). Various initiatives and networks have been established to foster the exchange of expertise and collaborative efforts. The Diagnostik Berlin-Brandenburg e.V. network may serve as one successful example. The association – founded in 2007 – has brought together innovative companies, renowned international research institutions, laboratories and expert partners from Berlin-Brandenburg and six other federal states to jointly develop, manufacture, and sell in vitro diagnostic products. The network combines the diverse areas of expertise of its over 65 members, covering the entire value chain for in vitro diagnostics.



Overview Map of Regional Players Involved in IVD and Bioanalytics





- Universities**
- 1 Brandenburg University of Technology Cottbus - Senftenberg
- 2 Brandenburg University of Applied Sciences
- 3 Brandenburg Medical School Theodor Fontane
- 4 Charité - Universitätsmedizin Berlin
- 5 Freie Universität Berlin
- 6 Humboldt-Universität zu Berlin
- 7 Technical University of Applied Sciences Wildau
- 8 Technische Universität Berlin
- 9 University of Potsdam

- Federal Institutions**
- 1 Federal Institute for Materials Research and Testing (BAM)
- 2 Federal Institute for Risk Assessment (BfR)
- 3 National Metrology Institute of Germany (PTB)
- 4 Robert Koch Institute (RKI)

Committed to Improving Diagnostics and Bioanalytics – Key Areas of Research and Development

Research and development in IVD and bioanalytics cover a broad spectrum of applications. Academia and industry in Berlin and Brandenburg develop state-of-the-art solutions for next generation in vitro diagnostics and bioanalytics and have a proven track record of innovative products resulting from excellent and often jointly conducted research efforts.



The regional involvement in IVD & bioanalytics includes various approaches. Individual players in this huge field are tackling current challenges from very different starting points.

To provide a grouping of application areas, in this special issue a classification has been applied that clusters topics around **biomarkers and the impact of Omics**, **technology-based innovations** and **services** in the field of IVD & bioanalytics. However, innovative strategies usually involve the expertise of quite a few disciplines and therefore the activities of regional players often can be allocated to more than one of these subsections.

The development of in vitro diagnostics requires validated biomarkers as a prerequisite. The impact of Omics technologies, such as genomics, proteomics, metabolomics or glycomics for the identification of new biomarkers has been impressively demonstrated in recent decades. Further progress has been achieved by advanced high throughput screening technologies. Major regional players in this field include Charité – Universitätsmedizin Berlin, Institute

of Laboratory Medicine, Clinical Chemistry and Pathobiochemistry; Leibniz-Forschungsinstitut für Molekulare Pharmakologie; the MedLab of the Research Campus MODAL (Mathematical Optimization and Data Analysis Laboratories), a platform of Zuse Institute Berlin, Freie Universität Berlin together with 12 participating companies as well as several companies such as Alacris Theranostics GmbH, Metanomics Health GmbH, Metabolomic Discoveries GmbH and ATLAS Biolabs GmbH.

Players in Berlin and Brandenburg are developing technology-based innovations to provide novel in vitro diagnostics and other diagnostic methods. Universities, research institutes and companies have a strong position in latest developments in the field of Point-of-Care testing, Lab-on-a-Chip and Organ-on-a-Chip technologies, biosensors and multiparameter analytics.

These predominantly chip-based diagnostics are accompanied by other modern analytical technologies such as mass spectrometry and its distinctive advancements, e.g. CyTOF (Cytometry by Time of Flight) or CCMS (Capture Compound Mass Spectrometry) the latter having been developed by Caprotec bioanalytics GmbH.

With regard to in vitro diagnostics and bioanalytics services, laboratory medicine plays a significant role and the Institute of Laboratory Medicine, Clinical Chemistry and Pathobiochemistry of Charité – Universitätsmedizin Berlin is the key provider in this field. Berlin is also an important site for biobanks – on a national and European level. Biobanks like the Central and Interdisciplinary Biobank of the Charité (ZeBanC) collect a wide range of patient samples, support research projects with samples and data and offer various services for the processing and analysis of biomaterials.

Companies and research institutes in Berlin and Brandenburg offer a great variety of services which range from biomarker identification, next generation sequencing, over assay development to ISO-certified contract manufacturing of IVD tests.

Technological Advancements – Basis for Innovations

Technology-based innovations advance the development of next generation in vitro diagnostics. These innovations lead to the implementation of new diagnostic features, more reliable and rapid results, on-site testing, and will enable improved personalized medicine approaches. Current trends in miniaturization, automation and multi-parameter testing allow for cost reductions and will lead to more efficiency in the diagnostic laboratory routine.

Different technologies, same objective – Point-of-Care testing

The most striking advantage of Point-of-Care (POC) tests is that they empower physicians to make immediate decisions on patient-focused care wherever diagnostic testing is required. POC tests are often accomplished by portable handheld detection instruments providing rapid results. The EU-funded PoC-ID project (Platform for ultra-sensitive Point-of-Care diagnostics for Infectious Diseases) addresses the increasing demand for rapid and sensitive point-of-care diagnostics to reduce healthcare costs and increase the quality of life with a focus on infectious diseases. A user-friendly point of care (PoC) platform will be developed to target the need for early and fast detection of viral respiratory infections. Respiratory syncytial infection (RSV) are a major cause of disease in children but also a major diagnostics and management challenge in the daily practice. The PoC-ID project is coordinated by Leopold Georgi, Technische Universität Berlin, Research Center for Microperipheric Technologies. Additional Berlin-based members of the consortium are APTARION biotech AG and enablingMNT GmbH.

Frank Hufert and his team of the Institute of Microbiology and Virology, Brandenburg Medical School Theodor Fontane, focus on molecular diagnostics tools for fast on-site viral detection under field conditions. The group has developed more than 50 real-time PCR assays and more than 30 assays based on isothermal recombinase polymerase amplification (RPA). RPA represents a versatile alternative to PCR and allows real-time detection of viral and bacterial genomes within 10 minutes. A suitcase lab for rapid mobile genetic detection of emerging infectious diseases (EID) was already tested in a field trial in Africa. Current research addresses further applications in human and veterinary medicine.

The development of Point-of-Care tests is also a core area of the Department of Biosystem Integration and Process Automation of the Fraunhofer Institute for Cell Therapy and Immunology - Branch Bioanalytics and Bioprocesses IZI-BB in Potsdam-Golm. In the department of Frank Bier an in vitro diagnostics platform has been developed which is suitable for a broad range of point-of-care applications and which can be adapted to different diagnostic tests. The unique platform consists of a lab on-a-chip cartridge the size of a credit card and a base station for detection. Blood or other biological liquids can be applied directly onto



“In the PoC-ID project, 13 partners from 7 European countries and different fields of science have joined forces to develop new micro- and nanoelectronic-based sensing and integration concepts for advanced miniaturized in vitro diagnostic devices. Improved performance in terms of robustness, sensitivity and selectivity is achieved by a combination of innovative nanomembrane technology, molecular engineered capture molecules and two novel electronic sensing concepts. The PoC-ID project targets the diagnosis of respiratory syncytial virus infections and host responses in the pediatric context. Once successfully tested, the platform technology can easily be adapted to a variety of diagnostic or biosensing purposes.”

Leopold Georgi

Coordinator of PoC-ID H2020 project
Technische Universität Berlin, Research Center for Microperipheric Technologies

the cartridge and within 10–15 minutes, samples are analyzed automatically in the base station. Using microarrays, multiplex testing is possible by employing various capture molecules such as antibodies, proteins, peptides, glycans

or oligonucleotides. IZI-BB offers customers and partners the transfer of existing tests (e.g. ELISAs, DNA microarrays and others) to the IVD platform, including optimization and technical verification up to IVD approval.



Fraunhofer Institute for Cell Therapy and Immunology, Branch Bioanalytics and Bioprocesses IZI-BB

The Fraunhofer IZI-BB focusses on the development of platform technologies and biotechnological applications in agriculture, food safety and environmental testing as well as drug development and diagnostics. To provide flexible and easy-to use devices or solutions the key aspects of activities encompass complex sample preparations, data collection, miniaturization and automation. Moreover, the Institute also addresses functional protein production using innovative cell-free biosynthesis techniques and develops method for single cell manipulation. The site has the state-of-the-art infrastructure required for miniaturizing and automating biological processes. This includes various biosensor and biochip technologies, pipetting robots and micro and nano-dispensers, besides many different rapid-prototyping procedures.

Achieving improved efficiency – multiparameter testing

The advantages of multiparameter diagnostics are obvious. A single test run allows for the simultaneous analysis of many parameters of a given sample and thus provides more information for a reliable diagnosis. Multiplex tests save time, lead to improved efficiency in the diagnostic process and can advance personalized medicine approaches.

At the Brandenburg University of Technology (BTU) Cottbus-Senftenberg, research groups are developing automated multiparameter test methods for examining patient blood, serum and tissues. One major goal is the development of tissue section-based multiplex assays that can be applied in diagnostic laboratories or research facilities.

In the group “FISHng-FISH for tumor and pathogen diagnostic with VideoScan” of Peter Schierack and group leader Juliane Schiebel, scientists investigate genetic aberrations

in tumor tissues and microorganisms in infected tissues. Image-based multi-fluorescence detection involves the “VideoScan” technology, which was jointly developed with project partners. The platform can be used for various assay types based on cells, microparticles or solutions.

The group “Image-Based Assays” aims at refining the further development of microparticle and microfluidic systems for use in temperature-controlled conditions including microparticle-based multiplex real-time PCR and melting curve analysis as well as cell-based detection systems. In this project – an InnoProfile Transfer Initiative – Peter Schierack and group leader Stefan Rödiger focus on the combination of microparticle and cell-based detection methods enhanced with statistical bioinformatics for routine diagnostics. This work is concatenated to the research within the Gesundheitscampus Brandenburg (Ministry of Science, Research and Culture Brandenburg) where



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“Multiparameter analytics in the field of laboratory medicine deals with fast, high-precision and cost-efficient characterization of patient samples. Medical doctors can deduce appropriate therapies for patients. With our ultra-modern technical equipment at the Brandenburg University of Technology Cottbus-Senftenberg (BTU) we realize basic research and cooperative projects with regional partner companies. Our major interest focuses on biomolecule detection technologies including hardware, software and assay development and on Applied Statistical Bioinformatics. We educate students in cutting-edge topics of cell biology, microbiology, molecular biology and nanobiotechnology.”

Peter Schierack

Head of the Department of Multiparameter Diagnostics
at Brandenburg University of Technology (BTU) Cottbus-Senftenberg

the researchers aim to find novel digitalized diagnostic approaches in the "digilog project" and tools for a personalized medicine as part of the project "Consequences of age-associated cell and organ function".

Biosensors – providing better stability and sensitivity

Biosensors are analytical devices that convert a biological response into an electrical signal. Various types of biosensors have been developed in Berlin and Brandenburg, using nucleic acids, antibodies, enzymes or receptors to analyze its interaction with a given sample. These biosensors can be based on electrochemical, optical, piezoelectric or thermal mechanisms of signal transduction.

The history of BST Bio Sensor Technology GmbH reaches back to 1975 when a biosensor research group started at the former Berlin Academy of Sciences. As early as in 1982, the first biosensor based blood glucose device was launched on the European market. BST Bio Sensor Technology GmbH was founded by members of this group in 1991 and has become the market leader in multi-way biosensors in Europe. Core competences include the development, optimization and final production of biosensors of different generations (membrane type, thick film type, thin film type, sensor array) as well as the development and production of instruments based on biosensors.

The development of novel biosensors is also a core area of research at the Institute of Applied Life Sciences of the Technical University of Applied Sciences Wildau (TUASW). Fred Lisdat is Director of this Institute and Head of the Bioanalysis and Biosensors Laboratory. He and his group are working on several projects, many of them in collaboration with other research institutions in Germany and abroad. He is also presently the Chair of the Bioelectrochemistry Division of the International Society of Electrochemistry with more than 600 members worldwide.

Extensive research focuses on light-switchable sensors by using semiconductor nanoparticles or Quantum Dots – due to their unique photophysical properties – and combining them with the biocatalytic features of enzymes. This kind of biohybrid system provides a promising approach for the development of advanced bioanalytical devices allowing multi-analyte detection. Examples of applications include light-directed read-out of glucose and fructose oxidation and the detection of enzymatically produced nicotinamide

adenine dinucleotide (NADH). Both groups are cooperating closely and are working with other regional partners including Attomol GmbH, Medipan GmbH, PolyAn GmbH and GA Generic Assays GmbH.

A recent system demonstrates the feasibility to use photoactive proteins for the analysis of enzyme substrates.

In the direction of more applied research, collaborations with several companies have been established. For example, an optical test system was developed for the semi-quantitative determination of protein concentrations in cerebrospinal liquids with the company In.vent DIAGNOSTICA GmbH. The fast and simple detection system is based on gold nanoparticles and was designed for point-of-care diagnostics in emergency medicine by an early classification of neurological diseases.



Technical University of Applied Sciences Wildau (TUASW) Institute of Applied Life Sciences

The biosciences have developed into a major economic factor in the Berlin-Brandenburg region. Special regional expertise lies in molecular diagnostics, bioanalysis and medical technology. The TUASW has actively participated in these developments and since 2001 has not only set up an interdisciplinary course of studies in biosystems technology/bioinformatics, but has also established research laboratories focusing on various subjects of biosciences. The institute is presently comprised of 6 working groups.

Special competences include:

- the production of biomolecules and biological structures
- biochemical detection methods and the analysis of biological systems
- characterization of surfaces with biological components
- the development of hybrid systems at the interface between biology and technology, e.g. microreactors, microfluidic chips, biosensors, biofuel cells, photobioelectrodes etc.
- processing and high-performance computer-assisted analysis of bio-chemical and bioanalytical data

The Impact of Omics Technologies – Advancing the Development of New Diagnostics and Therapeutics

Genomics, proteomics, metabolomics and glycomics have become indispensable technologies to fathom the essence of life on a molecular basis. Combined with high throughput screening methods, “Omics” research leads to the identification of various new biomarkers and in turn contributes to the development of novel diagnostics and therapeutics.

Berlin has a longstanding reputation in genomics. Hans Lehrach, long-term Director at the Max Planck Institute for Molecular Genetics, was an early proponent of the human genome project. His scientific achievements are numerous and include his involvement in several genome sequencing projects, key work on protein microarray technologies and the development of personalized medicine approaches on the basis of ‘virtual patient’ models. Hans Lehrach has also been actively involved in accelerating the translation of scientific discoveries into the development of products and has co-founded several biotechnology companies. Many of these companies are in the Berlin-Brandenburg region and include Scienion, Atlas Biolabs, Alacris Theranostics, as well as the Dahlem Centre for Genome Research and Medical Systems Biology, a non-profit private research organization.

One of these companies, Alacris Theranostics GmbH, is a systems medicine company specialized in developing innovative approaches for cancer precision medicine and drug development. Alacris has developed the award-winning ModCell™ technology, a revolutionary systems medicine modeling tool that offers individualized drug response predictions and facilitates applications for the pharmaceutical/biotechnology industry, virtualizing a range of developmental pipelines. The company also offers one of the most comprehensive precision oncology analyses options on the

market today through its Comprehensive Molecular Tumor Analysis (CMTA) service. Alacris has also established innovative methodologies for identifying biomarkers, with applications as companion diagnostics and stratification of patients for targeted clinical trials. For further development and validation of its technologies, Alacris participates in a range of nationally and internationally funded research projects.



**Leibniz-Forschungsinstitut
für Molekulare Pharmakologie (FIMP)
Chemical Biology Platform**

FIMP & MDC provide a central open access Chemical Biology platform for EU-OPENSOURCE, the ChemBioNet, the Berlin Institute of Health (BIH), and the Helmholtz-Initiative für Wirkstoffforschung. The platform supports with state-of-the-art equipment for systematic screening of large compound or genome-wide RNAi libraries, and for medicinal and computational chemistry. It is funded by the EU, the Federal Ministry of Education and Research (BMBF), German Research Foundation (DFG) and also jointly financed by the Max Delbrück Center for Molecular Medicine (MDC) and the Berlin Institute for Health (BIH).



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Bodo Lange
CEO Alacris Theranostics GmbH

“Next generation sequencing is currently revolutionizing omics-driven patient diagnostics in oncology as well as other genetic diseases. Single gene/gene variant biomarker detection has been a major step forward in patient stratification, but these markers cannot capture the complexity of genetic alterations that determine drug response and drug resistance. Recent advances in highly integrative, systems biology-driven approaches and the identification of complex biomarkers based on deep omics analyses are, however, helping to identify truly personalized therapy options and open up new solutions in precision medicine.”

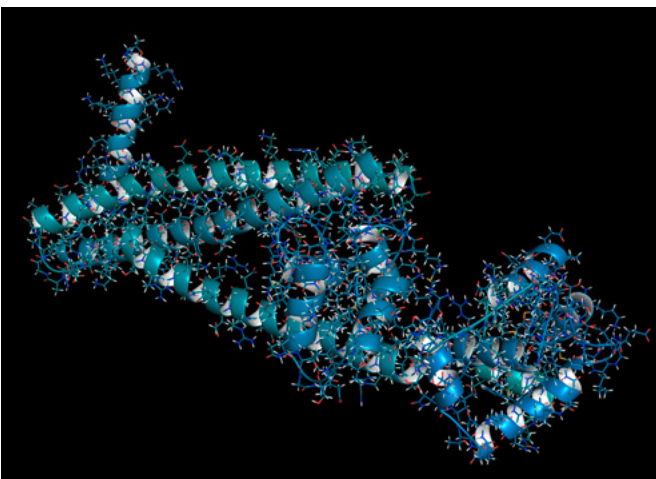


Mass spectrometry-based proteomics offers the possibility of measuring thousands of proteins in a single run and has fundamentally changed the way that biological systems are analyzed. Latest developments in liquid chromatography-tandem mass spectrometry (LC-MS/MS) have reduced the effort and instrument time necessary for the determination of global proteomes down to several hours. At the BIH Core Facility Proteomics, scientists employ and further

develop all commonly used approaches to accurately and precisely quantify proteins in complex samples. For proteome-wide discovery applications label-free, metabolic labeling and isobaric tagging approaches are used, while for targeted selected reaction monitoring (SRM) and parallel reaction monitoring (PRM) applications the group uses synthetic spike-in reference peptides for quantification.

Collaborations with other research groups span all areas of quantitative proteomics, from profiling different biological states in cells, tissues and body fluids, to measuring protein interactions with other proteins, drugs and nucleic acids, to determining the spatial information of proteins and also the identification of their post-translational modifications.

Metabolomics targets the analysis of the entirety of the intermediates and products of metabolism within cells, biofluids, tissues or organisms. Metanomics Health GmbH is one of the global key players in this field. The company hosts one of the world's largest metabolite profiling facilities with a broad range of gas-chromatography and liquid-chromatography coupled mass spectrometry instruments enabling unbiased and targeted metabolomics. Metanomics Health





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Tim Bölke

Managing Director, Metanomics Health GmbH

“The Metanomics Health GmbH technology platform, our scientific and clinical expertise, and the innovative and stimulating environment in Berlin-Brandenburg have helped us establish an outstanding proprietary clinical biomarker program: we identify and validate simple and complex novel metabolic biomarkers up to the prototype stage, then sub-license these to diagnostic partners with direct access to the health-care market.”

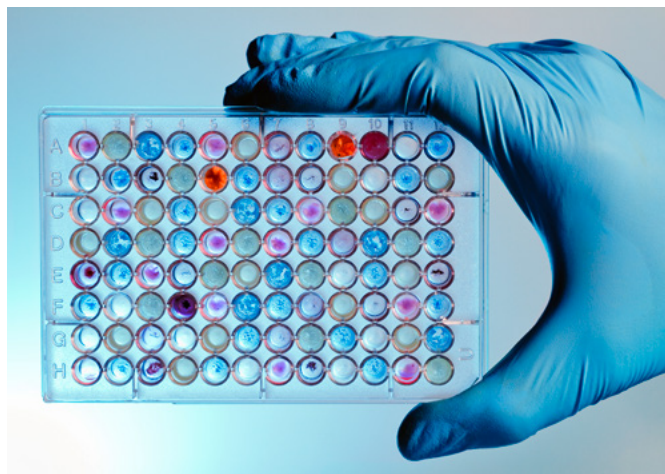
provides highly robust and reproducible analysis of metabolite pathways and their changes in response to disease, pharmaceutical intervention, and nutrition. The cutting-edge technology of the company includes state-of-the-art statistics, proprietary bioinformatics tools and biomedical expert interpretation of high quality data sets. Metanomics Health provides unique biomedical data that can accelerate drug development by reducing risk, increasing efficacy, and helping to identify therapy responders.

Although glycomics represents the youngest of the Omics technologies, it is increasingly garnering tremendous interest because carbohydrates are the most abundant biomolecules on Earth and have myriad of functions. Berlin and Brandenburg recognized the potential of glycosciences early on and regional academic institutions and companies cover the whole range of glycosciences – from basic research to advanced glycobio-technology applications.

The working group of Véronique Blanchard at the Institute of Laboratory Medicine, Clinical Chemistry and Pathobiochemistry, Charité – Universitätsmedizin Berlin is aiming to systematically analyze the glycome in the context of physiological mechanisms in human health and disease. The

identification and evaluation of glycan-based biomarkers represents a prominent field of research in Blanchard’s lab. One of the dedicated research projects – together with the Department of Gynecology of the Charité – focuses on serum glycome profiling to identify tumor markers for the diagnosis of epithelial ovarian cancer (EOC). Blanchard’s group is also working towards the next generation of stem cell markers.

Data integration of these diverse fields of Omics research remains a challenge for the future. In the MODAL (Mathematical Optimization and Data Analysis Laboratories) research campus, innovative methods for the extraction of information from large data sets and the construction of realistic models for complex processes are being researched. MODAL is a platform for public-private partnership for innovation built by Zuse Institute Berlin (ZIB) and Freie Universität Berlin together with 12 participating companies. More than 40 researchers of the campus will advance the data-driven development of pioneering modeling, simulation, and optimization methods. One of the most important goals of the MedLab group is the integrative analysis of already available patient information with the ever-growing data pools of modern Omics experiments.



Laboratory Medicine – Essential for Therapy Optimization

Laboratory diagnostics makes a central contribution to disease detection, therapy optimization and prevention. It is therefore of key importance for the healthcare system. Laboratory medicine institutions in Berlin and Brandenburg not only provide top laboratory diagnostics services for resident physicians and hospitals but are actively involved in the development of new diagnostic products.

About 100 companies and more than 20 research facilities in Berlin and Brandenburg are committed to in vitro diagnostics and cover the entire value chain – from biomarker identification to clinical validation, up to the production of in vitro diagnostics. They are developing innovative technologies and new biomarker strategies for medicine across the board.

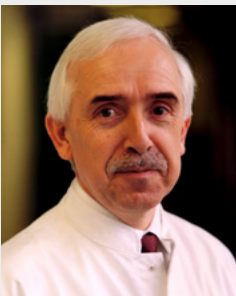
One of the major players in this area is Charité – Universitätsmedizin Berlin. The main research focus of the Institute of Laboratory Medicine, Clinical Chemistry and Pathobiochemistry is the investigation and utilization of pathobiochemical mechanisms for diagnostic, prognostic and therapeutic purposes. Research fields include inflammatory processes and biochemical signal transduction, the importance of carbohydrates, molecular oncology as well as developments of biomarkers.

Oncology is also a dedicated area of research at the Institute of Pathology of the Charité. A number of working groups use different approaches to elucidate specific biomedical aspects of oncology, e.g. the groups System Pathology, Experimental Hematopathology, Gastroenterologic Pathology, Translational Tumor Research and the joint Laboratory of Molecular Tumor Pathology. Current research of the latter focuses on systems-oriented tumor biology, particularly on signal transduction systems in cancer cells. The



objectives of research projects are aiming at a detailed understanding of the organization, regulation and biological features of signaling systems in order to integrate basic cancer research, molecular tumor diagnostics and predictive oncology.

Berlin also hosts the largest hospital laboratory in Europe: the Labor Berlin – Charité Vivantes GmbH. Beyond providing laboratory diagnostics for patient care of Vivantes and Charité hospitals at a total of 12 locations, Labor Berlin offers solutions for the diagnostics industry, for CROs as well as for companies from the life sciences and research facilities.



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Rudolf Tauber

Charité – Universitätsmedizin Berlin, Head of Institute of Laboratory Medicine, Clinical Chemistry and Pathobiochemistry

“Advances in basic biomedical research and the development of new analytical technologies and methods have led to an extraordinary increase in laboratory diagnostics over the last decades. Berlin-Brandenburg has developed into an internationally significant location for research & development in laboratory diagnostics and for conducting clinical trials. The diversity of hospitals as well as the university's high-performance medicine of the Charité enable access to patient groups of rural and urban populations from different ethnic origins, which largely cover all medical questions.”

High Quality Biobanks – Key for Biomedical Research

Professionally organized and centralized biobanks are responsible for the acquisition, processing and storage of biomaterials as well as related data and making them available for biomedical research. These biobanks guarantee the generation of reliable and reproducible research data based on well characterized biomaterials since quality management is of highest priority to them.

Central and Interdisciplinary Biobank of the Charité (ZeBanC)

The ZeBanC is the joint biomaterial bank of the Charité and the Berlin Institute of Health. It has a capacity of several million samples, which are mainly stored in the new biobank building at the Campus Virchow Klinikum of the Charité. The ZeBanC operates under certified conditions according to DIN EN ISO 9001: 2015.

In addition to the acquisition of a wide range of samples from Charité patients, the ZeBanC is responsible for a number of nationwide studies. ZeBanC has already supported numerous research projects with samples and data. Furthermore, the ZeBanC offers various services for the processing and analysis of biomaterials. The ZeBanC is also responsible in cooperation with the Charité Comprehensive Cancer Center (CCCC) for the acquisition of unfixed tumor tissue samples and corresponding blood samples for control. Since the CCCC is responsible for comprehensive documentation of related patient and medical records in pseudonymized form, these biomaterials and their clinical data may be integrated in scientific questions in order to strongly improve translational oncological research.

German Biobank Node

The German Biobank Node (GBN) is the central contact and exchange for the German Biobank community – not only for researchers, but also for politics, media, representatives of patients, industry and funding institutions. The GBN aims to create a better networking of national biobanks, to facilitate exchange of experience between biobanks and to develop standards for quality assurance. Other activities address the elaboration of an IT concept for sample and data exchange. The GBN also represents the interests of the German biobank community in the European network of biobanks (BBMRI ERIC)

National Register for Congenital Heart Defects

The National Register for Congenital Heart Defects provides a professional infrastructure for researching the epidemiological, clinical and genetic aspects of congenital heart defects. Its patient database is unique in Europe – a repository for tens of thousands of data sets. The Register is currently supporting a number of medical and epidemiological research projects seeking to answer outstanding questions regarding treatment, long-term prognosis and living with a congenital heart defect. The ZeBanC is responsible for the collection of DNA, blood and tissue samples from patients with congenital heart defects, their relatives and suitable control individuals which are made available for research purposes.



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“Due to increasing molecular subdivision of most diseases, even large biobanks cannot provide sufficient number of samples with very specific characteristics. Thus, networks like the German Biobank Alliance gain increasing importance in order to generate collections of sufficient size for research projects. This also requires IT-infrastructures to query for eligible samples and data in addition to biomaterials of comparable quality. The German Biobank Alliance is coordinated by the German Biobank Node and is currently setting up a national biobank network to be prepared for future challenges of advanced and reliable biomedical research. This complements the European biobank networks, activities in the context of BBMRI-ERIC for which the German Biobank Node is the focal contact point.”

Michael Hummel

Head Laboratory of Molecular Pathology, Charité – Universitätsmedizin Berlin

National Coordinator German Biobank Node (GBN), Director of the Central and Interdisciplinary Biobank Charité and BIH (ZeBanC)

Services – From Assay Development to Contract Manufacturing

Regional players in industry and academia offer a broad variety of first-class services in the IVD and bioanalytics fields. Services are provided along the entire value chain and range from biomarker identification, high throughput screening technologies, next generation sequencing, systems biology modeling, over assay development, technical optimization and software solutions to clinical validation studies and ISO-certified contract manufacturing of IVD tests.



In the Omics technology fields numerous services are available. Examples for next generation sequencing service providers are Alacris Theranostics GmbH and Atlas Biolabs GmbH. The Proteome Factory AG is specialized in professional proteomics and protein analysis. The company uses state-of-the-art technologies for differential proteomics studies and quantification and validation of regulated proteins, biomarkers and targets. Metanomics Health GmbH is one of the global key players in the field of metabolomics. The company hosts one of the world's largest metabolite profiling facilities and provides highly robust and reproducible analysis of metabolite pathways and their changes in response to disease, pharmaceutical intervention, and nutrition.

Lots of regional players support customers with assay development services based on different technologies, with many of them also providing manufacturing services. 8sens.biognostic GmbH offers custom-made development and production of immune-chromatographic lateral flow tests and microtiterplate-based assays. BST Bio Sensor Technology GmbH focuses on the conception, development and production of multi-way biosensors. Epiontis GmbH develops customized epigenetic assays and immune-monitoring services based on epigenetic markers for immune cells. CellTrend GmbH is a specialist for cell based bioassays with a focus on oncology and immunology. Glycotope

GmbH offers protein analysis and glycoprofiling services including high-throughput analysis of complex glycosylation patterns. The company also supports customers in the area of process transfer for upstream or downstream processes.

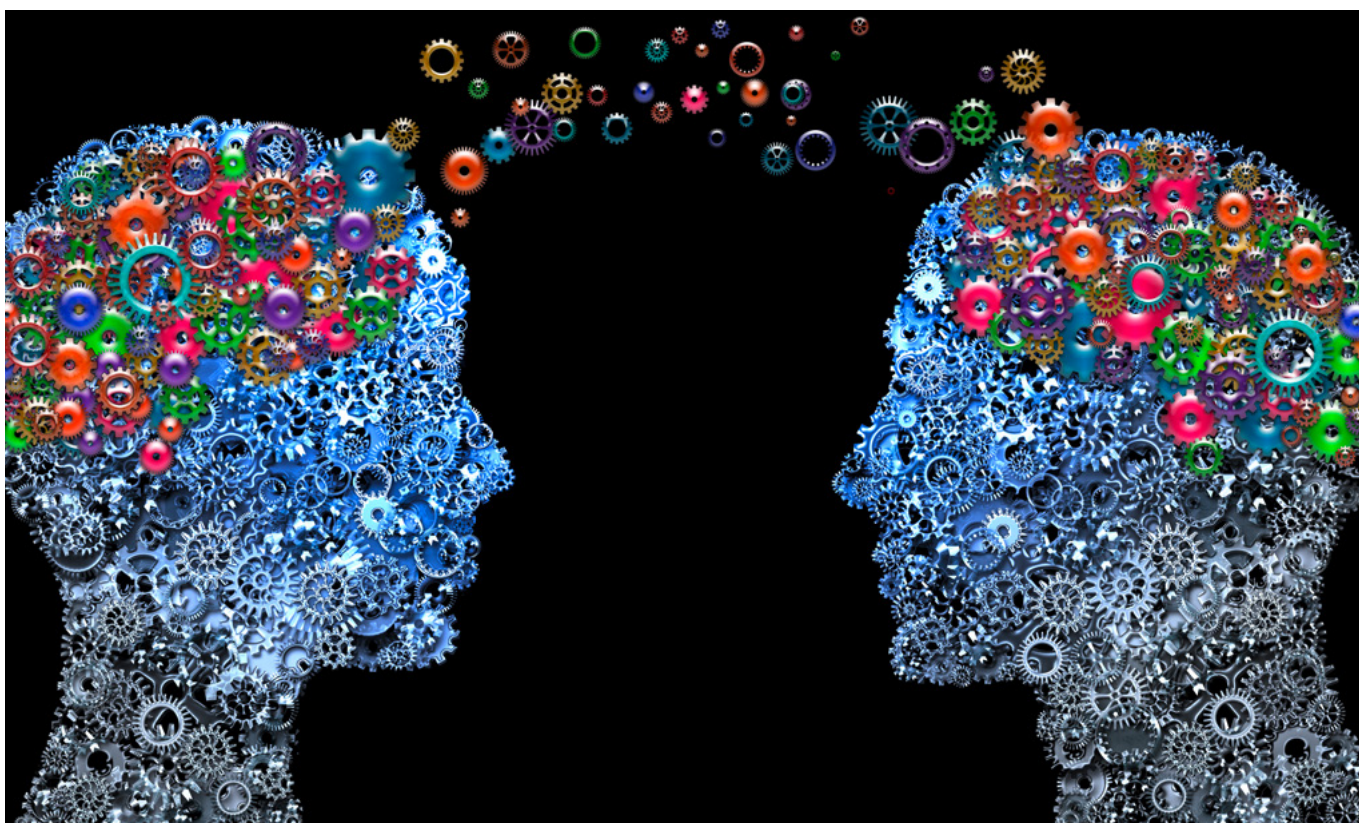
In addition to its hardware business, SCIENION AG offers services for IVD and RUO assay development and ISO-certified diagnostic test manufacturing services. Customers include several globally operating companies. Combining the expertise and technologies of two companies, the Spanish company GENOMICA S.A.U. and SCIENION have jointly developed a novel multiplex based detection kit for the identification and specific differentiation of 18 micro-organism causing sexually transmitted infections (STIs). SCIENION manufactures the microarrays for the test kit, utilizing its proprietary sciFLEXARRAYER non-contact printing technology.

Regional services comprise applications in the entire field of life sciences: BIOTECON Diagnostics GmbH offers microbiological testing of pharmaceuticals, cosmetics, food and beverages and BioTeZ Berlin-Buch GmbH provides mycotoxin and vitamin analysis as well as the development and production of ELISA tests and immunochemistry services. The ifp Institut für Produktqualität GmbH is an accredited service laboratory for modern food, feed and pharma analytics.

And finally, Berlin hosts the largest hospital laboratory in Europe: the Labor Berlin – Charité Vivantes GmbH. Beyond providing laboratory diagnostics for patient care of Vivantes and Charité hospitals, Labor Berlin offers solutions for the diagnostics industry, for CROs as well as for companies from the life sciences and research facilities.

Creating Synergies – Combining Bioanalytics with Other Technologies Leads to Cross Innovation

Interdisciplinary cooperation and the transfer of expertise can lead to cross innovation in any given areas or industries and therefore, enabling cross innovation is a key topic of regional, national and international political agendas. One dedicated objective of the joint innovation strategy of Berlin and Brandenburg (Masterplan Gesundheitsregion Berlin-Brandenburg) aims at an increased utilization of cross-sectional technologies and to intensify cross innovation processes in the healthcare sector.



The development of modern in vitro diagnostics and bioanalytic tools involves the integration of several other disciplines such as informatics, optical technologies, microsystems technology, microelectronics, material sciences, nanotechnology, process technologies and engineering sciences, to mention the most important ones. Besides proven available outstanding competences in primarily healthcare-related disciplines like pharma, bioanalytics, biotechnology, biochemistry and medical technologies, the Berlin-Brandenburg region provides a unique sciences environment providing expertise in all the above mentioned fields. Key regional players of these cross-sectional technologies are often organized in separate networks – many of them broadening their activities with a specific focus on life sciences applications.

Exchange and collaborations between regional IVD players and scientists from other relevant disciplines have been established by individual contacts and have furthermore been fostered by various events and networking activities. The overall conditions in Berlin-Brandenburg have proved to be optimal for enabling cross innovation and thus to achieve a competitive edge.

Optical Technologies – virtually providing insights

Optical technologies have a long tradition in Berlin and Brandenburg and today *Photonics and Microsystems Technology* represents one of the five capital region clusters. Players in bioanalytics and diagnostics benefit from the extraordinary regional competence in optical technologies. In collaborative R&D efforts they are developing a great variety of biomedical and other bioanalytical applications – from sophisticated microscopy techniques to high-end optical sensors.

Innovations for the digital society of the future are the focus of research and development work at the Fraunhofer Institute for Telecommunications, Heinrich Hertz Institute, HHI. The Photonic Component Department develops semiconductor and polymer-based optoelectronic components, as well as integrated optical circuits for data transmission. Another focus is on infrared sensor systems, terahertz spectroscopy and high-performance semiconductor lasers for industrial and medical applications. Scientists have developed optical multi-sensors based on microring resonators which allow for label-free multi-parameter analysis. The cost-efficient silicon-based chip technology is suitable for applications in point-of-care diagnostics, food and drinking water control, as well as for the detection of hazardous substances.

The Federal Institute for Materials Research and Testing (BAM) is a senior scientific and technical federal authority with responsibility to the Federal Ministry for Economic Affairs and Energy (BMWi), with research, testing and consultation in the focus areas Infrastructure, Energy, Materials, Environment, and Analytical Sciences under one roof. The focus of the Biophotonics division, headed by Ute Resch-Genger, lies in multiparametric optical methods for the measurement and characterization of the interaction of

materials and light, for example in applications in materials research, bioanalytics, medical diagnostics, environmental chemistry, pharmaceuticals, bioengineering, and food technology. The research includes the design, traceable spectroscopic characterization, and application of functional organic, inorganic, and hybrid molecular and nanoscale chromophore systems and bioconjugates as well as signal enhancement and multiplexing strategies, absolute measurements of spectroscopic key performance parameters, and the development of reference materials for optical measurements.

Ilko Bald leads the Optical Spectroscopy and Chemical Imaging group which is situated both in the Physical Chemistry Department at the University of Potsdam, and BAM. The group combines different methods from DNA nanotechnology, optical spectroscopy and scanning probe microscopy in order to study physico-chemical processes at the single-molecule level. In several projects, DNA nanoscale folding techniques (Origami) are used as versatile tools for arranging functionalities with high local control to study molecular processes at a single-molecule level, e.g. to create highly-selective Förster resonance energy transfer (FRET)-based sensing tools or switchable photonic wires.

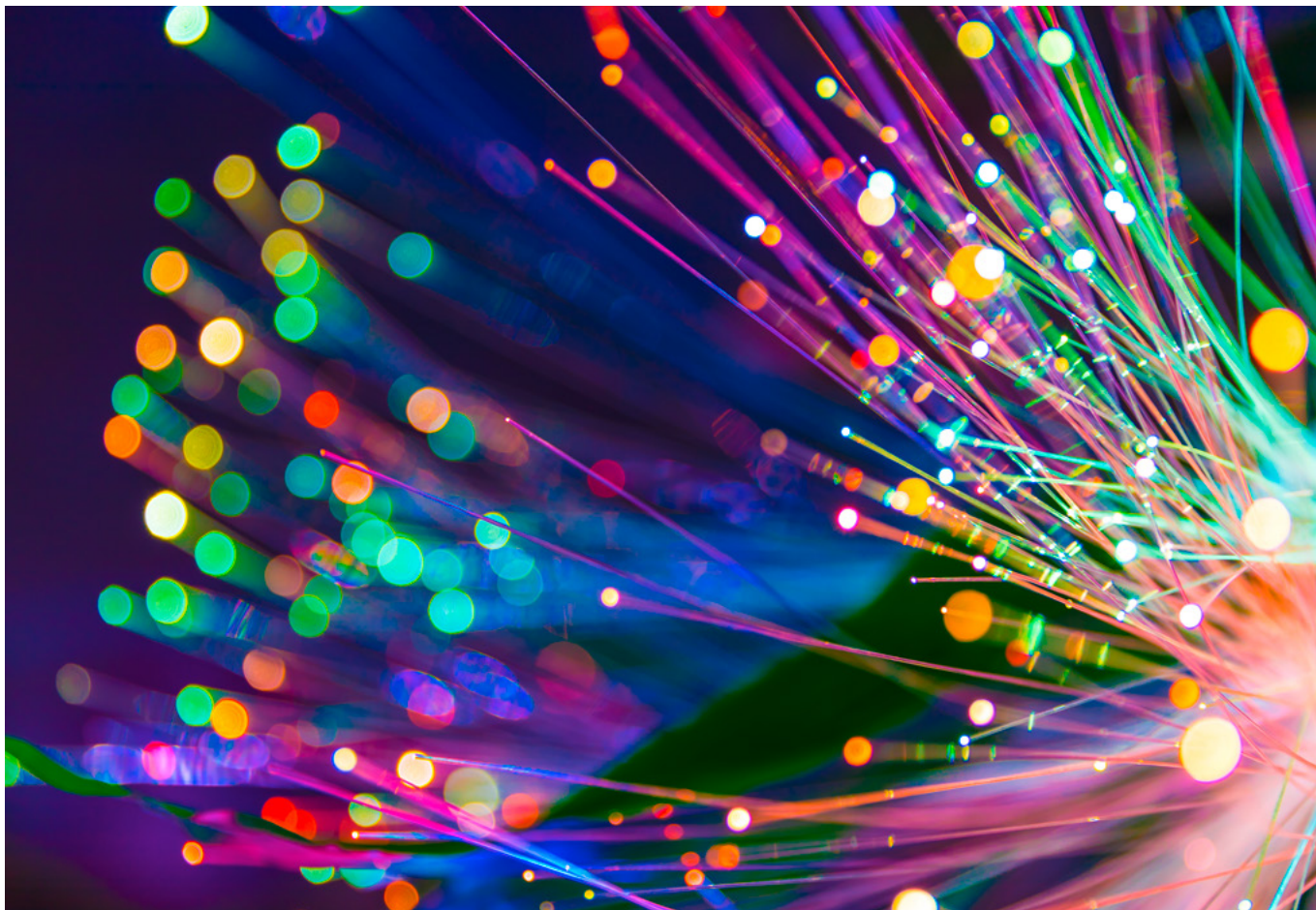


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“Accurate, reliable and comparable measurement data are more and more indispensable prerequisites and important components for emerging developments in the life sciences and health care, like precision and personalized medicine. Metrology for in-vitro diagnostic and bioanalytical procedures based on optical technologies provides support and enables solutions to this end. Practical work at PTB comprises the development and provision of reference measurement procedures to determine accurate target values in external quality assurance schemes for medical laboratories, to safeguard metrological traceability of accredited reference measurement laboratories, and to assign values to reference materials or measurement standards.”

Rainer Macdonald

Physikalisch-Technische Bundesanstalt
Head of Department Biomedical Optics



The working group of Fred Lisdat, Chair of Biosystems Technology and Director of the Institute of Applied Life Sciences, Technical University of Applied Sciences Wildau (TUASW), is focused on applying optical and electrochemical techniques in bioanalysis. Special competence is in the combination of nanostructures with biological molecules and photoelectrochemical detection systems. One example is an optical test to determine protein concentrations in cerebrospinal liquids. The fast, simple and sensitive point-of-care system based on gold nanoparticles was developed in collaboration with the companies LIMETEC Biotechnologies GmbH and In.vent DIAGNOSTICA GmbH.

Another project at TUASW addresses a combined solution for mobile microscopy and image analysis. The goal of Marcus Frohme's group at the Faculty of Engineering and Natural Sciences is to develop a system for mobile image processing including automated evaluation of microscopic images which are taken with the help of an optical attachment for modern end devices such as tablet PCs or mobile phones. First applications target the analysis of beer yeast to control the fermentation process. Successful results of this work have already led to the foundation of the spin-off Oculyze GmbH in 2016. Future applications range from agricultural monitoring to a point of care device for rural areas.

At the Biomedical Optics Department of the Physikalisch-Technische Bundesanstalt (PTB), the National Metrology Institute of Germany, measurement procedures are developed, examined and tested in the field of flow-cytometry, nano-flowmetry, quantitative microscopy and quantitative nucleic acid diagnostics of cells and (bio-) molecules. Research and development projects of the department headed by Rainer Macdonald are conducted in close cooperation with clinical, industrial and academic partners to support e.g. laboratory diagnostics. One goal of this work is the development of reference measurement procedures and values, to enable and support quality assurance schemes of tests in laboratory medicine. Non-invasive quantitative determination of important biomarkers (e.g. concentration of hemoglobin, oxygen saturation) in tissue, as well as in vivo imaging of pathological changes using fluorescence-labeled probes, round out the tasks of the department. For this purpose, opto-spectroscopic measurement and imaging techniques are developed and examined. Contact persons for flow cytometry and particle analytics are Jörg Neukammer, and Dirk Grosenick for optical medical imaging, respectively.

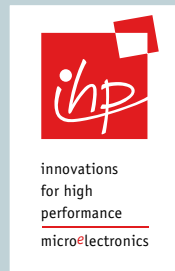
Microsystems Technology and Microelectronics – integral parts of miniaturized bioanalytical test systems

Microsystems technology is regarded as the key technology of the 21st century worldwide. The development of modern in vitro diagnostics is inconceivable without microsystems technologies as these tests are microsystems that combine different materials, components and technologies within a small space. Microsystems technology and microelectronics become even more important with regard to the growing demand for miniaturized test formats.

One research focus of the IHP Innovations for High Performance Microelectronics / Leibniz-Institut für innovative Mikroelektronik addresses smart solutions for the detection and quantitative determination of biomolecules by applying microelectronics technology. The “GlucoPlant” project, led by Mario Birkholz, focused on the development of an implantable glucose sensor chip to continuously monitor blood sugar. The chip was developed as a fully embedded microelectromechanical system (MEMS), in which the viscosity of a liquid is determined from the bending of an elastic cantilever. Modern micro technologies allowed the sensor chip to be fully operative at miniature dimensions of 1.3 x 0.4 x 0.2 mm only.

Microelectronics and biotechnology are currently involved in a convergence process bringing both disciplines closer together to integrate electronic systems in biological environments. Major developments are concerned with the field of biosensors, where the progressive miniaturization enabled the introduction of micro-sensors into biological systems. To better address these developments, the TU Berlin and the IHP founded the “Joint Lab Bioelectronics” in 2012. Current projects include research on new approaches for sensor-based metabolite monitoring, high-frequency impedance spectroscopy for cell monitoring, cell handling by dielectrophoresis or the optimization of semiconductor interfaces to improve biocompatibility.

Scientists of the Faculty of Engineering and Natural Sciences at the Technical University of Applied Sciences Wildau and from the IHP have developed a hybrid-waveguide ring resonator for on-chip biochemical sensing. By combining a low-loss strip-waveguide and a highly sensitive slot-waveguide integrated in a silicon photonic platform, the new test system achieves an increase in sensitivity, while maintaining low optical losses. Thus, this resonator structure may represent a promising alternative approach for future integrated biochemical sensing applications.



IHP Innovations for High Performance Microelectronics/ Leibniz-Institut für innovative Mikroelektronik

The IHP performs research and development in the fields of silicon-based systems, highest-frequency integrated circuits, and

technologies for wireless and broadband communication. The focus of research at the institute is oriented towards issues relevant for business, resulting in applications for telecommunications, semiconductor and automotive industries, aerospace, telemedicine, and automation technologies.

The IHP provides an important bridge between academia and industry. The Joint Labs with universities in the Berlin-Brandenburg region have been particularly successful in this cooperation. A steadily increasing number of international users of the Multi-Project Wafer and Prototyping Services demonstrate the recognized competence of the IHP.

Process Technologies – accompanying life sciences from R&D to manufacturing

Process Technologies are cross-sectional technologies involved in almost all fields of biotechnological production. They are an integral part of any bioanalytical procedures and key for controlling complex and highly automated bioprocesses in various areas, including recombinant drug manufacturing, cultivation of cells, as well as biogas and biomass production. Regional experts of bioprocess engineering are committed to accelerating the development of bioprocesses and to meeting current trends for improved process automation and Quality by Design approaches.

The successful development of cell-derived products requires a combination of deep scientific knowledge and a thorough understanding of process engineering. Peter Neubauer, Chair of the Bioprocess Engineering Department at Technische Universität Berlin, clearly claims that consistent application of process engineering strategies which are focusing directly on the industrial scale should already be in use in early product development. This idea is also reflected in the Quality by Design (QbD) concept which postulates several quality tests as early as the product development process to enable a more targeted error identification and a more efficient error reduction is to be made possible. This concept as an integral part of quality management was first outlined by Joseph M. Juran and is used by different industries. With regard to the production of pharmaceuticals, the application of QbD principles are mandatory after they have been included into regulatory guidelines of the U.S. Food and Drug Administration (FDA) in cooperation with the European Medicines Agency (EMA).

The working groups at Neubauer's department address several challenges of current life science-related process engineering. They aim to advance bioprocess scale-up and scale-down, process analytical technologies (PAT), dynamic modelling and optimization of biological systems as well as automated bioprocess development. Additionally, they work to optimize cell and systems biology applied to microbial bioprocesses and biocatalysis applications.

PAT projects include the development of novel monitoring methods for process development and production. Multiposition and multiparameter sensors (MMS) allow for real time in situ monitoring of process performance in bioreactors, while the development of novel optical sensors is aimed at in situ monitoring of cell population homogeneity and cell viability for various applications, e.g. brewing or biogas production.



© Olga Sheshukova

“Characterization of industrial reactors, scale up and scale down technologies, and a higher degree of automation in bioprocess development urgently need new analytical technologies, such as a broader range of non-invasive and multiposition on-line sensors and model-based soft sensors. While our Bio-PAT Berlin-Brandenburg network on Process Analytical Technologies (PAT) integrates partners from different fields, miniaturized silicon based new analytical tools are developed in our Joint Lab Bioelectronics together with the IHP Leibniz Institute Frankfurt/Oder. The vision of integration of automation and computation is established in the Lab of the Future that is closely related to our BioPilot plant where the processes are validated in an environment that is close to industry.”

Peter Neubauer

Head Bioprocess Engineering, Department of Biotechnology, Technische Universität Berlin

Material Sciences – enhancing bioanalytics by use of functional polymers

The integration of material sciences into bioanalytics offers new and improved test methods. Pursuing innovative approaches using tailor-made functional polymers leads to novel product features and can overcome limitations of conventional analytical tools.

Polymer surface chemistry for biologically active materials represents one core area of the research at the Fraunhofer Institute for Applied Polymer Research IAP. The group of Andreas Holländer develops technologies that allow surface properties – in particular polymer surfaces – to be adapted to meet application requirements. Dedicated research efforts targeted the functionalization of surfaces used in quality control in the food industry. The scientists have successfully developed materials for the quality control of beverages. Functionalized polymer powders speed up the sample preparation for the detection of bacteria and yeasts. The method shows clear advantages compared to traditional membrane filtration methods and can be applied for large sample volumes.

In addition, several regional companies are active in polymer research – often in joint projects with academic institutions – and are developing specialized products for life science applications. PolyAn is a nanotechnology company specialized in the modification of surfaces using Molecular Surface Engineering. The company is a leading supplier of functionalized microarray slides, coverslips and membranes for molecular diagnostics and life science research applications. PolyAn offers a portfolio of polymer microparticles for multiplex bead assays, calibration of flow cytometers and calibration of fluorescence imaging systems.

With PolyAn's production process up to two fluorophores are incorporated into the beads during the polymerization process – thereby ensuring a homogeneous distribution of the dyes within the beads. Beads are offered in different sizes and can be equipped with a wide range of functional surfaces.

The key technology of Surflay Nanotec GmbH is its proprietary Layer by Layer (LbL) technology with charged polymers (polyelectrolytes). Using this technology, macroscopic as well as colloidal surfaces are functionalized on a nanoscale. The combination of physicochemical functions and biological properties separated by nanometer-thick layers allows the unique modification of the surface without any great difficulty. Areas of application include modern separating materials, substance encapsulation, enzyme immobilization as well as sensory or diagnostic beads. The company also offers a broad range of fluorescent labeled polymers.

Further regional R&D efforts towards functional materials target applications beyond bioanalytics, e.g. polymer-based antimicrobial coatings, novel systems for drug delivery and polymer-based materials for applications in tissue engineering and regenerative medicine.



© Fraunhofer IAP, Fotografin Manuela Zytar

“The separation and enrichment of cells and microorganisms are a major problem in diagnostics, especially if there are large sample volumes and small concentrations, or viscous or solid-laden samples. At the Fraunhofer IAP in Potsdam, a polymer powder with a functionalized surface was developed together with the company GEN-IAL from Troisdorf. This powder is used to bind microorganisms from beverages such as beer and juices. The powder can be separated easily and the microbes can be identified and quantified using techniques such as PCR. The time for incubation can be reduced substantially compared with traditional techniques.”

Andreas Holländer

Senior scientist at Fraunhofer Institute for Applied Polymer Research IAP

More Innovation through Cooperation – Networks Facilitate Collaborative Efforts

Efficient networking advances research and its transfer into innovative products. Several networks in Berlin and Brandenburg serve as platforms for intense interaction to promote cooperations and the integration of different areas of expertise.

DiagnostikNet-BB

The Diagnostik Berlin-Brandenburg e.V. network bundles the competencies of innovative companies, renowned international research institutions, clinics and laboratories to jointly develop, manufacture, and sell in vitro-diagnostic products. DiagnostikNet-BB combines the diverse areas of expertise of more than 70 members, covering the entire supply chain for in vitro diagnostics. Since its foundation in 2007, the association has brought together partners from Berlin-Brandenburg and six other federal states.

Highly specialized partners take a stake in the network covering the whole technology spectrum:

- sample delivery, biobanking
- biomarker finding, development, and validation (genetic, epigenetic, proteins & cell-based markers)
- platform-independent assay development
- detection systems, biosensors, devices
- biochips, microarrays, multi-parameter bioassay
- point-of-care testing, companion diagnostics
- software, bioinformatics, data management
- laboratory automation
- certification, accreditation
- services in clinical chemistry and molecular diagnostics

All member companies are certified according to the required ISO norms and hence guarantee quality. Renowned partners with expertises in the area of certification, approval, reimbursement and patent law complete the portfolio.

In addition to human medicine diagnostics, other fields of application include veterinary diagnostics, mobile health, food, and agriculture & environment. Clients profit from individualized, user-oriented product solutions.

The network's subsidiary, Diagnostik BB GmbH, is a professional seminar and workshop provider and supplies various consulting and project management services specialized on the in vitro diagnostics area.

www.DiagnostikNet-BB.de

DiagnostikNet | BB

NETZWERK DIAGNOSTIK BERLIN-BRANDENBURG e.V.

www.diagnostik-bb.de

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Frauke Adams

Office Manager DiagnostikNet-BB

“The DiagnostikNet-BB combines the expertise of outstanding medium-sized diagnostics companies, laboratories, research institutes and competence partners, which are exemplary for the strength and innovation potential of the Berlin-Brandenburg region. With members in now eight federal states, the network goes far beyond the capital region. All partners have more than 6,000 employees and a turnover of more than 300 million euros per year. Additionally, the number of network collaborations is quite remarkable: about 500 projects have been initiated since the foundation of the network in 2007.”

PolyMed

The PolyMed network was founded by 10 companies (SME) and the Technical University of Applied Sciences in Wildau along with other associated research partners in 2014. Its main focus relies on the combination of new technologies in plastics engineering, automation technologies and medical technologies.

Our partners strive to achieve new products, new processes and technologies to offer unique as well as custom tailored solutions to customers. Examples of the cooperation between the partners are the development of a sophisticated sampling and storage device with integrated pre-sample filtration fully automated and customizable. Another focus lies on the printing of individual human organs based on tissue-like plastic materials.

Our partners are:

- Abacus Analytical Systems GmbH
- Analytical Control Instruments GmbH
- bbi-biotech GmbH
- Christmann Kunststofftechnik GmbH
- Cybertron GmbH
- Herotron Medical Device Sterilization
- HumanX GmbH
- Motzener Kunststoff- und Gummiverarbeitung GmbH
- Polymerics GmbH
- RoweMed AG-Medical 4 Life

www.polymed.info



European Diagnostic Clusters Alliance (EDCA)

The European Diagnostics Clusters Alliance (EDCA) is the association of public and private clusters focusing on the development and production of new solutions for in vitro diagnostics.

The purpose of the association is:

- to promote competitiveness of European industry in the area of medical diagnosis. To this end, the association will enhance the synergies between academics research, clinical research, health authorities and diagnostic companies;
- to facilitate the growth of European SMEs in medical diagnostic;
- to promote the development of diagnostic clusters and competitiveness clusters in Europe;
- to promote cooperation between diagnostic clusters (inter-cluster) in order to help build European collaborative projects.

www.edc-alliance.eu



Future Opportunities and Challenges – a Perspective

The global in vitro diagnostics market accounted for more than \$60 billion in 2016 and leading market research companies expect this market to grow at a CAGR of 4.6–5.4% in the next five years. Key drivers of this development include the aging population, the identification of new biomarkers, the increasing demand for diagnostics enabling personalized therapy approaches, and the expansion of IVD companies to emerging markets. Advancements in point-of-care testing and companion diagnostics also contribute to the growth rate, and finally a better informed public results in patient-driven demands. However, inadequate reimbursement policies and strict regulatory requirements for IVD production will remain to be challenging issues in the future.

Steady progress in the Omics technologies will lead to an increasing number of new biomarkers with distinct features enabling personalized medicine. These developments will be further accelerated by a better integration of genomic, proteomic, metabolomic and glycomic information.

Point-of-Care (POC) testing will continue to be a field of expansion in the future. On the one hand, POC tests will move closer to the patient or consumer and personal mobile diagnostics facilitating disease management as known for diabetes will expand to other diseases as well. On the other hand, there is a great demand for low cost diagnostics platforms for deployment worldwide, especially in resource-limited settings. Current trends targeting miniaturization and multiparameter testing will be ongoing and will contribute to cost reduction and more efficiency.

Berlin-Brandenburg has extraordinary expertise in the areas of in vitro diagnostics and bioanalytics. About 100 companies and more than 20 research facilities are committed to IVD and cover the entire value chain. Due to the excellent research environment and various networking activities, the integration of cross-cutting technologies like informatics, optical technologies, microsystems technology, microelectronics, material sciences, nanotechnology, process technologies and engineering sciences works smoothly. Regional players develop solutions for next generation in vitro diagnostics and bioanalytics such as sensor-actor molecules and autonomous biosensors, DNA-, protein- and glycan-based multiplex analytics. Techniques include state-of-the-art microarray and bead technologies, Lab-on-a-chip technologies as well as several proprietary platform technologies are enabling further progress in diagnostics and therapy.



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“Berlin and Brandenburg is a traditional hot spot for the development of in vitro diagnostics. The discovery of new biomarkers, the development of innovative technologies and their implementation in medical applications are not done separately, but in close cooperations with all stake holders in R&D. This is one of the most important advantages of the capital region, where projects along the entire value chain are possible. The initiation and performance of those collaborations are strongly supported by the cluster management of Health Capital. Therefore, the Berlin-Brandenburg region is your first point of contact for the development of next-generation in vitro diagnostics.”

Christine Mißler

Cluster Healthcare Industries Berlin-Brandenburg HealthCapital,
Project Manager Biotech I Pharma



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THE GERMAN CAPITAL REGION
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Directory of Regional Players Involved in IVD and Bioanalytics

Companies	
3B Pharmaceuticals GmbH	
3B Pharmaceuticals GmbH (3BP) is a privately held pharmaceutical R&D company based in Berlin, Germany. The company is dedicated to the development of peptide-based pharmaceutical and diagnostic products. 3BP is pursuing projects in hemophilia and nuclear medicine.	3b-pharma.com
8sens.biognostic GmbH	
8sens.biognostic develops, produces and sells rapid tests (lateral-flow) and ELISAs for different markets (human and veterinary diagnostics, food control). Our products are the QuickSens®-tests for h-FABP, Tropl, CRP and hs-CRP and the Reader for quantification QuickSens®OMEGA. Development-on-demand, feasibility studies and production-on-demand are also offered.	biognostic.de
Acuros GMBH	
Development of osmotic micropumps for medical or microfluidic applications. The innovative technology enables new options in liquid handling – from disposable micropumps for drug delivery to precision micropumps for lab-on-a-chip development.	acuros.de
Adrenomed AG	
Adrenomed AG is a privately financed, clinical stage biopharmaceutical company focusing on endothelial dysfunction and impaired vascular integrity. We develop safe first-in-class therapies for the treatment and prevention of impaired vascular integrity, which is one underlying pathophysiology of a variety of critical care conditions like septic shock and acute congestive heart failure. Lead candidate Adrecizumab is a humanized monoclonal Adrenomedullin-specific antibody, currently investigated in a Phase-II study in patients with early septic shock stratified for the bioactive target expression by a proprietary IVD assay.	adrenomed.com
AFOSA GmbH	
Development, production and marketing of diagnostics (ELISA kits), primarily for use in veterinary medicine.	afosa.com
AJ Innuscreen GmbH	
The AJ Innuscreen GmbH is a young life science company working in the field of biotechnology and boosts the life science unit of Analytik Jena AG. Innovative technologies and products are developed and produced for the isolation and purification of nucleic acids. Reagent systems for molecular biology, as well as technologies and products for molecular diagnostics, are also included in the product portfolio. The company is EN ISO 9001:2008 and EN ISO 13485:2003 + AC:2009 certified.	aj-innuscreen.de
Alacris Theranostics GmbH	
Alacris Theranostics GmbH is a systems medicine company based in Berlin specialized in developing innovative approaches for cancer precision medicine and drug development. With its award-winning portfolio of technologies – ModCell™, NGSight™ & Oncovar™ – Alacris delivers a unique combination of deep molecular insight and predictive modelling that is set to shape the cancer care landscape, from diagnosis and treatment to targeted drug development. Alacris has built up a highly qualified network of collaborators including renowned clinics, academics and pharmaceutical companies, to accelerate the translation of research innovations and technologies into direct benefits for patients.	alacris.de
Alcat Europe GmbH	
Alcat Europe GmbH is the daughter of the US company Cell Science Systems, the original developer of the Alcat test technology. The company is specialized to identify intolerant reactions of the leucocytes to foreign substances like foods, drugs or chemicals.	alcat-europe.com
AnaKat Institut für Biotechnologie GmbH	
AnaKat Institut für Biotechnologie GmbH has specialized on analytical determination of pharmaceutical ingredients.	anakat.de
Analyticon Discovery GmbH	
AnalytiCon is a biotechnology company focusing on the development of compound libraries consisting of natural product (NP) and synthetic small molecules. As the global market leader in NP small molecule screening compounds, AnalytiCon is the only company which is able to provide vast collections with completely disclosed structural information. As a pure compound provider the company is offering its products and services to the pharmac., chemical, biotech, cosmetical and nutraceutical industry.	ac-discovery.com

AnaTox GmbH & Co. KG	
The AnaTox GmbH & Co. KG deals with the development and optimization of analytical methods and devices for HPLC and dissolution.	anatox.de
Aokin AG	
Aokin AG is a Berlin biotechnology company that is specialized in the development and commercialization of innovative analytical systems on the base of the rapid kinetic assay technology. The aokin systems are unique in their precision and operating speed. Areas of application are food and antibody analytics as well as clinical diagnostics. We also offer laboratory services in the area of food analytics, Pharmacoanalytics and chemical synthesis.	aokin.com
Aptarion biotech AG	
Aptarion biotech develops biostable L-aptamers for the treatment of life-threatening diseases and for biosensors. Spearhead for our therapeutic strategy is AON-D21 that binds and inhibits the complement protein C5a with a unique mechanism of action. Encouraging preclinical data in several disease models support the development of AON-D21 in indications such as severe pneumonia, sepsis or lung cancer. Based on a recently established proprietary and broadly applicable technology to immobilize L-aptamers on various sensor types, we plan the development of novel biosensors together with partners.	aptarion.com
Astra Biotech GmbH	
Astra Biotech GmbH offers high quality reagents, allergens, antibodies, recombinant proteins, and assays for the determination of hormones, allergies, tumour markers and infectious diseases. Quality is one of the key cornerstones on which Astra Biotech maintains its reputation and with which we strive to increase customer satisfaction and gain growing customer loyalty. We take great pride in our highest quality assays, which are all IVD compliant and therefore suitable for direct, accurate and reproducible diagnostic purposes, as well as for research.	astrabiotech.de
ATLAS Biolabs GmbH	
ATLAS Biolabs GmbH is a leading provider of microarray based genomic services such as genome-wide gene expression and SNP analysis, CGH analysis and diagnostic services for registered doctors and hospitals, as well as for pharmaceutical, biotechnological and diagnostic enterprises.	atlas-biolabs.com
Attomol GmbH Molekulare Diagnostika	
The company's aim is to develop, produce and distribute medical diagnostics for human medicine in the field of molecular genetics, infectious and autoimmune diseases.	attomol.de
BDW Berliner Diagnostik Werke GmbH	
BDW Berliner Diagnostik Werke GmbH was founded in 2017 to develop, manufacture and commercialize new diagnostic technologies that leverage the potential of carbohydrate-science for sensitive and specific multiplex assay solutions. First product developments focus on diagnostic assays for determining the general vaccination status as well as companion diagnostics for vaccination status related to specific vaccines. Other applications include the analysis of specific allergies, autoimmune and infectious diseases. Business areas include the development of own products and customized diagnostics for the healthcare industry.	
BG Berlin-Genetics GmbH	
BG Berlin-Genetics GmbH is a new provider for genetic diagnostics and consulting in genetic diagnostics. We are a team of experienced human geneticists and have worked for many years in the field of human genetic science and human genetic diagnostics. Our aim is the development of innovative cooperation concepts, to connect classical patient-based medical care centers with modern technology-based service centers. In future, these cooperation forms will enable efficient, high quality, and patient-based genetic diagnostics.	bg-berlin-genetics.de
Bioanalyt GmbH	
Bioanalyt develops and distributes the worldwide first easy-to-use and portable test kits for the analysis of vitamins and micro nutrients. The iCheck-iEx test kits enable food producers, food authorities and NGOs to monitor their ongoing food programs more efficiently and at low-cost. The company was founded in 2006 by Prof. Dr. F. J. Schweigert as a spin-off of the University of Potsdam. Read more on our website www.bioanalyt.com .	bioanalyt.com
BIOCYC Gesellschaft für Biotechnologie und Recycling mbH & Co.KG	
Production of bio-chemicals, peptides, in vitro diagnostics, test-kits. Development of consumer service for peptides and biochemicals.	quartett.com
BioGenes GmbH	
BioGenes is a full-service immunoassay and antibody (monoclonal and polyclonal) development company with outstanding problem solving capabilities specializing in challenging projects that are carried out by an exceptionally experienced and interdisciplinary team.	biogenes.de

Bioline GmbH	
Our mission is to provide customers with a range of products which are fast and easy to use, guaranteed to work and developed by scientists who understand what our customers are trying to achieve so they can focus on their scientific goals. Bioline reagents are used by molecular biologists and other research scientists to perform test-assays and research in many fields from medical, biotechnology and marine biology.	bioline.com
biotechrabbit GmbH	
biotechrabbit GmbH is determined to offer the newest and best life science products and innovative solutions to scientists leading the fight against disease and fueling our lives with innovations. We supply ultra pure enzymes and high-quality antibody services for diagnostics and a life science product portfolio (including reagents for PCR and nucleic acid purification) for molecular biology and proteomics. The biotechrabbit advantage is our combination of passion for excellent research with the agility of true entrepreneurship.	biotechrabbit.com
BIOTECON Diagnostics GmbH	
BIOTECON Diagnostics has been well known as a qualified partner in the field of molecular and microbiology for more than 15 years. We focus on development, production and marketing of PCR-based rapid detection systems. BIOTECON Diagnostics offers solutions for the food and beverage industry as well as for producers of pharmaceuticals and cosmetics.	bc-diagnostics.com
BioTeZ Berlin-Buch GmbH	
Services (custom DNA and RNA oligonucleotide synthesis, immuno affinity columns) – development of enzyme immunoassays, e.g. for therapeutic antibodies – bio conjugates – immobilization of bio molecules for better signalling-R&D (aptamer).	biotez.de
biotx.ai GmbH	
Clinical datasets are difficult to analyze by reported Machine Learning approaches due to their small samples and many features. Our approach is able to identify significant patterns, which can be used for novel diagnostics and therapies.	biotx.ai
BST Bio Sensor Technology GmbH	
BST develops and produces biosensors to provide high quality analysis at moderate prices. In 1982 BST brought on the market the first multi-way biosensor based blood glucose analyzer in Europe and is since then market leader in Europe. Today BST sells more than 60.000 sensors a year. Since 2008 BST is besides biosensors also manufacturer of POCT and laboratory instruments.	bst-biosensor.de
Caprotec bioanalytics GmbH	
Caprotecs Capture Compound Mass Spectrometry (CCMS) Technology allows separation and isolation of proteins based on functionality. For many applications, CCMS is clearly superior to conventional methods – thus addressing an unmet need in the proteomics research community. The company is commercializing the CCMS technology through ImproMed projects with pharmaceutical and biotechnology companies. The focus on these collaborations is on investigating mechanisms of drug action (MoA) and identification of on- and off-target proteins to understand potential adverse effects of drug candidates on a molecular level. This can be easily carried out in the lead optimization process, or even earlier to increase the probability of success later on in the clinic.	caprotec.com
CellTrend GmbH	
Celltrend is certified according to ISO 9001, ISO 13485 and GMP Cell culture systems for research on active substances (bioassays, preclinical research, for quality control), development and production of antibody-based detection systems (ELISA), chemosensitivity assay for optimization of chemotherapy (tumor patients).	celltrend.de
Chemicell GmbH	
Chemicell develops and produces magnetic, fluorescent and colored nano- and microparticles, reactive fluorescent dyes and special chromatography-materials for the separation or detection of cells, bacteria, viruses, proteins or DNA/RNA and new gene transfer systems.	chemicell.com
Chipron GmbH	
Chipron GmbH specializes in production and distribution of array based detection systems for DNA/pathogens.	chipron.com
CMZ-Assay GmbH	
Marketing of diagnostic reagents for measuring concentrations of proteins, hormones and their isoforms, exclusively for research purposes.	cmz-assay.com
CONGEN Biotechnologie GmbH	
CONGEN is specialized in food testing by molecular analytics based on DNA and RNA detection. CONGEN has been a pioneer for over a decade in the development and application of food and feed analytics by real-time PCR. The methods are available as complete analytic kit as well as a service. Our mission is to serve the food industry with an excellent service and with standardized and reliable test kits in order to realize highest possible food safety and food quality.	congen.de

cpo - cellular phenomics & oncology Berlin-Buch GmbH	
cpo is a state-of-the-art in vitro service provider aimed at offering high-quality, reasonable priced cell culture models complementing classical in vivo assays using patient-derived 3D cell cultures. We view ourselves as partners with our customers, our employees, our scientific community and our environment. Our mission is to help the biotech and pharma industries create innovative testings of novel anti-cancer drugs.	cpo.berlin
Diaglobal GmbH	
Development, production and distribution of in vitro diagnostics for analytical purposes and the distribution of medical products.	diaglobal.de
Dr. Götz Verfahrenstechnik Biotechnik Umwelttechnik	
Contract research and contract manufacturing using bacteria, yeasts and fungi.	drgoetz.de
Dr. Lerche KG	
Innovative company engaged in development, production and marketing of specialized microcapsules for bio- and medical technology - Development and production of novel DNA-Purification-Kits with proprietary technology - Production and marketing of microcapsules (LUMiTainer), microbeads and cell based sedimentation standards for blood analysis (Sedi-Val ESR standards) - Encapsulation of cells - Contract analysis for characterization of microcapsules, porous membranes and hollow fibres.	lerche-biotec.com
Dr. Rölleke Labor für Genetische Analytik GmbH	
Dr. Roelleke is specialized in the identification of microorganisms, particularly in the area of food safety. Furthermore, Dr. Roelleke is authorized expert on paternity tests for courts and the private sector.	dr-roelleke.de
E.R.D.E.-AAK-Diagnostik GmbH	
E.R.D.E.-AAK-Diagnostik GmbH is a laboratory that offers antibody testing for commercial purposes.	aak-diagnostik.de
EMP Biotech GmbH	
Production of fluorescent dyes and chemiluminescent reagents. Contract chemical synthesis of small molecules. Contract labeling and purification of proteins, antibodies and oligonucleotides. Production of size-exclusion gels, columns and filter plates. Production of high quality reagents for DNA synthesis.	empbiotech.com
Epigenomics AG	
Development and commercialization of innovative molecular diagnostic test products based on DNA methylation for cancer screening and for cancer specialty applications.	epigenomics.com
Epiontis GmbH	
Establishing methylation fingerprinting as Gold Standard for quality control in Regenerative Medicine and Immunomonitoring.	epiontis.com
Eurovir Hygiene-Institut/Dr. Thraenhart	
Laboratory service for testing the efficiency of products against viruses (virucides) and of processes for inactivating or eliminating viruses (virus safety).	eurovir.de
FILT Lungen- und Thoraxdiagnostik GmbH	
Development of innovative, non-invasive diagnostic methods in the area of respiratory diseases and allergies.	filt.de
GA Generic Assays GmbH	
Development, manufacturing and international distribution of in vitro tests including tissue and cell-based IFA, Dot and ELISA assays for the diagnosis of rheumatic and other autoimmune diseases with neurologic, vascular, hepatic, renal or gastrointestinal origin. Patent holder of CytoBead® assay, a one-step diagnostic tool combining cell/tissue-based immunofluorescence assay for the screening and microparticle-based multiplex assay for the differentiation and confirmation of autoimmune diseases.	genericassays
GenExpress Gesellschaft für Proteindesign GmbH	
GenExpress is a flexible company providing services in molecular biology. For over a decade we have successfully worked for customers in clinical laboratories, research institutions and the industry. We offer cloning of PCR targets, preparation of synthetic genes, expression of proteins, evaluation of LightCycle® assays, furthermore production of internal controls and standards for Real Time PCR systems, also cloning, expression and purification of proteins.	genexpress.de
GILUPI GmbH	
GILUPI is a medical diagnostics company with an initial focus on the prenatal and cancer market. The company is developing an innovative new diagnostic product based on nanotechnology. Our goal is to catch specific cells, which can be found only in very low concentration in the blood. The first application for our new nanosensor device will be prenatal diagnoses of chromosomal aberration out of maternal blood. The second application will focus on the early diagnosis of cancer.	gilupi.com

Glycon Biochemicals GmbH	
Glycon Biochemicals is a specialist in the field of carbohydrate chemistry, ionic and non ionic carbohydrate detergents, first of all anomeric pure n-Dodecyl β -maltoside and building units used for the synthesis of new pharmaceutical compounds and diagnostics.	glycon.de
HealthTwiSt GmbH	
HealthTwiSt is a service provider for "Genetic Contract Research" in the fields of Functional Genomics, Epigenetics, Proteomics or Functional Food / Nutraceuticals. In particular, HealthTwiSt is offering access to extensively characterized human subjects and samples as well as prospective studies in twins, together with know-how in the analysis of complex genetic traits. Furthermore, database development, data management and statistical analyses for clinical projects are provided.	healthtwist.de
Histalim	
For nearly 10 years HISTALIM provides services in the fields of histology, cytology and molecular biology for clients from a wide range of sectors including human and animal health, dermo-cosmetics, chemistry, environment, agronomics, agri-food industry	histalim.com
hospital Laborverbund Brandenburg-Berlin	
The hospital laboratory composite Brandenburg-Berlin, based in Berlin, employs approximately 100 employees at 5 locations. More than 4 million tests are carried out with a total of 2,000 different analytical procedures annually. The goal is an inexpensive, fast and high-quality laboratory diagnostics.	hospital-laborverbund.de
Hybrotec GmbH	
Hybrotec GmbH is specialized in the development of monoclonal antibodies and immunoassays (preferably homogenous assays) as customs service. Our main focus lies on antibodies binding low molecular weight substances (e.g. toxins, fluorophores, hormones) as well as antibodies against novel proteins.	hybrotec.com
ifp Institut für Produktqualität GmbH	
ifp Institut für Produktqualität is a laboratory and competence centre for state-of-the-art food, drinking water and pharmaceutical analysis. The accredited and GMP-certified company focuses on comprehensive services for the food and pharma industry. An additional core competence of ifp is the development and production of innovative diagnostics comprising the real-time PCR kits of the brand "mericon" (QIAGEN), vitamin tests in microtiter plate format, enzymatic microtiter plate kits for sugars/acids, and allergen tests in lateral flow and ELISA formats.	produktqualitaet.com
IKDT Institut Kardiale Diagnostik und Therapie GmbH	
IKDT was founded in August 2002 in Berlin-Steglitz and is one of the leading laboratories on Viral Infections of Heart Muscle Tissue and Dilated Cardiomyopathy (DCM) in Germany. IKDT lab is performing a comprehensive molecular diagnostic examination of endomyocardial biopsies as one of a limited number of specialized cardiological labs worldwide. Its service enables physicians firstly to start an efficient, pathophysiologically based causal therapy.	ikdt.de
ILBC GmbH	
Research, consulting, production, trade & services in the areas biology, molecular biology and protein chemistry - Expression and production of antimicrobial peptides.	mobiclup.de
In.vent DIAGNOSTICA GmbH	
in.vent DIAGNOSTICA GMBH is a biomedical company. We are focused on the project-oriented provision, processing and distribution of biological raw material for development and production of diagnostics and control material. We are your reliable partner for the customised development of assays for medical in vitro diagnostics.	inventdiagnostica.de
Innovative Optische Meßtechnik GmbH	
Fluorescence Assay Solutions and Instrumentation (Microplate Readers).	iom-berlin.de
Institut für Medizinische Molekulardiagnostik (IMMD) GmbH	
Gene tests for prenatal, predictive and tumor-diagnostics.	immd.de
InVivo Biotech Services GmbH	
InVivo is a contract manufacturing organization (CMO) dedicated to the development and production of monoclonal antibodies and expression of recombinant proteins for research, diagnostic and pre-clinical use. In the last 19 years more than 3000 monoclonal antibodies were produced on demand for customers of the IVD or pharma industry in any scale. Regarding immunoassay development InVivo covers every aspect of the whole value chain. From antigen production via transient gene transfection in HEK cells to CE approval of the final test InVivo manufactures on demand and provides advice and support.	invivo.de

JPT Peptide Technologies GmbH	
JPT Peptide Technologies GmbH is the leading provider of innovative peptide-based services and products, as well as a partner for R&D projects in immunotherapy, proteomics and drug discovery.	jpt.com
Kairos GmbH - Berlin	
Kairos is a renowned IT-specialist, which looks back on more than 10 years of experience in the development of IT-system solutions for the health care. In addition to technological special knowledge in the implementation of medical middleware platforms, we have extensive know-how in the IT-supported orchestration of work processes via workflow engine.	kairos.us
KNAUER - Wissenschaftliche Gerätebau Dr. Ing. Herbert Knauer GmbH	
KNAUER UHPLC and HPLC systems as well as columns are used in research and development, quality control and production plant laboratories around the world. Customers are typically governmental and industrial organizations as well as universities. Fields of application are wide-ranging and include pharmaceutical and medical research, analysis of foodstuffs and cosmetics, as well as environmental analysis. With our biochromatography solutions we focus on high resolution separations.	knauer.net
L.U.M. Gesellschaft für Labor-, Umweltdiagnostik & Medizintechnik mbH	
Analysis, diagnosis and sensor technology as well as stability, rheology and segregation behavior of dispersions.	lum-gmbh.de
Labor Berlin – Charité Vivantes Services GmbH Labor Berlin – Charité Vivantes GmbH	
Labor Berlin – Charité Vivantes GmbH Labor Berlin Services is the service subsidiary of Europe's largest hospital laboratory for clinical pathology. It offers complete solutions for any kind of testing in the IVD and pharmaceutical industries, CROS, life science companies, and other research facilities. Labor Berlin itself is the exclusive laboratory partner of Charité - Universitätsmedizin Berlin and the Vivantes Network for Health. Labor Berlin and Labor Berlin Services combined perform over 40 million analyses in clinical pathology each year and provide diagnostic services for over 400,000 in-house patients every day as well as more than one million out-patients each year.	laborberlin.com
LGC Genomics GmbH	
LGC Genomics is the division of LGC with specific expertise in high quality, cutting-edge genomic and related services and products. LGC Genomics delivers: Next generation sequencing services. DNA sequencing. Genomics services. Nucleic acid extraction services DNA extraction products. LGC is an international science-based company and market leader in analytical, forensic and diagnostic services and reference standards (www.lgc.co.uk).	lgcgenomics.com
LGC GmbH	
Production of calibration substances for purity testing of drugs.	mikromol.de
Limetec Biotechnologies GmbH	
The core competence lies in the development of high-speed and high-quality proof systems for the detection of pathogens, as well as in the allelic discrimination of hereditary diseases. All products are marked with the CE-Certificate. The second area of expertise is the creation of communication networks which connect out-patient and hospital patient treatments, intensify data exchange and provide information to all health institutions, thus establishing partner relationships between them.	limetec-biotechnologies.de
Lipidomix GmbH	
LC/MS/MS based high throughput analytic of lipid mediators and metabolites. Analytical method development, analytical support for LC/MS/MS in life science, food safety, forensic science.	lipidomix.de
MedInnovation GmbH	
MedInnovation GmbH has developed a new method and a special ESR-analyser, which for the first time allows a simple routine laboratory test for evaluation of functional characteristics of plasma proteins and further opens a reliable possibility for cancer diagnostic, named MMS-technology (mobility of molecular structure).	medinnovation.de
Medipan GmbH	
Development, manufacturing and international distribution of radioactive (RIA) and non-radioactive (ELISA) in-vitro diagnostic tests, covering the field of autoimmunity, mainly thyroid autoimmunity and type 1 diabetes. Invention and worldwide distribution of the AKLIDES® system, a platform technology for the automated interpretation of cell and bead-based immunofluorescence assays. A new application is the detection of DNA damage caused by radiation, oxidative stress or drugs.	medipan.de
Metabolomic Discoveries GmbH	
Metabolomic Discoveries is an analytical service and research company. We provide mass spectrometry based metabolite profiling and fingerprinting of biological material, as well as single compound measurements.	metabolomicdiscoveries.com

Metanomics GmbH	
Metabolite Profiling for identification of gene function relationship in plants, metabolite biomarkers and metabolic networks.	metanomics.de
Metanomics Health GmbH	
Metanomics Health GmbH is a company specializing in the scientific area of metabolomics. Its research targets the identification of metabolic biomarkers for pharmacology, nutrition and diagnostics. The company runs its own clinical biomarker program aiming at disease use cases with high unmet medical need, e.g. the early detection of pancreatic cancer and heart failure. With its MxP [®] Quality Control Plasma product the company is enabling preanalytical quality control of biospecimen.	metanomics-health.de
Mfd Diagnostics GmbH	
The mfd Diagnostics GmbH (BT Luckenwalde) is a life science research and development company for diagnostic and therapeutic application of innovative laser technologies. The main advantages of the developed technologies are the non-/minimally-invasive measurement methods, the non-artificial approach and the possibility of real-time measurement. Therefore, those are promising tools for the diagnosis and therapy monitoring in the neurological practice and in the perinatal surveillance.	mfd-diagnostics.com
MicroDiscovery GmbH	
MicroDiscovery GmbH is a leading provider of high quality software for biomolecular research, innovative diagnostics and personalised medicine. The company is ISO 9001 certified and has a strong track record in creating software systems in accordance with relevant regulatory directives for the life science and IVD industry. Customised services ranging from biostatistical data analysis to bioinformatical design and support of complex research projects complete the product line of MicroDiscovery.	microdiscovery.de
Minerva Analytix GmbH	
Minerva Analytix GmbH is a leading analytical service lab for the control of microbial contamination. Our core competence lies in the control of mycoplasma, bacteria and viruses in cell cultures and biopharmaceuticals	minerva-analytix.com
Minerva Biolabs GmbH	
Minerva Biolabs is developing and manufacturing molecular diagnostic reagents for contamination control in academic research labs and biopharmaceutical industry. We employ kits and reagents for basic PCR work, mycoplasma assays and cell culture contamination prevention reagents, microbial detection assays in food and water, meat identification assays, halal- and vegan-confirmation assays for professional quality control testing labs. In addition, we are busy as contract manufacturer (CMO) specialized in the design and production of molecular biological reagents, PCR assays and sample preparation kits according to DIN EN ISO 13485.	minerva-biolabs.com
MLB Mikrobiologisches Labor GmbH	
Accredited test laboratory for drinking water, clean rooms, sterility, bioburdens, D-PL-13398-01-00, EN 17025. Accreditation according to VDI 6022.	mikroberlin.de
Molnar-Institut für angewandte Chromatographie	
Molnar-Institute, established in 1981, offers you a complete scientific and technical service for all problems concerning Quality by Design (QbD) for HPLC-methods. We develop for you the Design Space for your HPLC-separation and establish Critical Quality Attributes (CQA's). We offer detailed DryLab-courses and show you, how to develop robust methods in the Design Space and how to save time. We supply and implement the DryLab-software and train your coworkers. We assist you in automated method development processes and support you in the selection of proper instruments, their installation and use.	molnar-institute.com
moloX GmbH	
moloX GmbH is a company focusing on custom protein production in bacterial and insect cell expression systems and subsequent protein purification to ultra-high purity. On customer demand a team of experts can perform protein crystallization experiments and determine the 3D structure of target proteins by X-ray crystallography.	moloX.de
Nano Access Technologies Ltd.	
The company addresses the combined access to key technologies such as life science and nanotechnology. As a first product, a low cost AFM for operation with so-called active cantilevers has been developed. Besides this, functionalized cantilevers for future biosensors are another focus of the company.	nano-access.com
Nanalytics Gesellschaft für Kolloidanalytik mbH	
We are a contract laboratory specializing in the physico-chemical characterization of pharmaceutical proteins, biopolymers, nanoparticles and colloidal systems. Our core-competences are Analytical Ultracentrifugation, in combination with Static and Dynamic Light Scattering as well as spectroscopic (CD, fluorescence) and thermodynamic techniques (ITC, DSC).	nanalytics.de

neweramabs	
new/era/mabs GmbH provides all-round solutions for the generation and characterization of murine, camelid and human antibodies. The company offers a highly effective immunization and selection platform in order to combine antibody generation with a very early validation directly after fusion. Founded in 2014 by Katja Hanack and Pamela Holzlöhner, the company-owners have over ten years of experience in antibody development, validation and assay development. With a world-wide patent-pending system we are now looking for reliable and competent business partners to market our platform.	neweramabs.com
OakLabs GmbH	
OakLabs provides the most flexible products and services for large scale custom SNP genotyping on the market. OakLabs offers several formats for analysing a variable number of SNPs in any sequenced organism.	oak-labs.com
OpTricon Entwicklungsgesellschaft für optische Technologien mbH	
OpTricon develops and produces mobile readers for quantitative analyzes of immunoassays for Point-of-Care-diagnostics, especially Lateral Flow Assays (LFA). Additional business segments are components and systems for signal transmission and sensors for bioanalytics. opTricon develops the devices in partnership with the customers and works as OEM-supplier and is certified by TÜV Rheinland according EN ISO 13485:2003+AC: 2007 and EN ISO 9001:2008.	optricon.de
ovalehn GmbH	
Production and application of specific recipes containing IgY for diagnostics and oral, passive immune therapy.	ovalehn.de
Peptides&elephants GmbH	
Custom synthesis of peptides and peptide libraries, development of parallel synthesis technologies, distributor of peptide synthesis automation.	peptides.de
PolyAn, Gesellschaft zur Herstellung von Polymeren für spezielle Anwendungen und Analytik mbH	
PolyAn is specialised in Molecular Surface Engineering (MSE). Using our surface modification expertise PolyAn optimises the performance of analytical systems by improving the signal-to-noise ratio as well as the reproducibility of consumables for multiplex diagnostics, LifeScience research and screening applications. PolyAn's product portfolio includes functionalised microarray slides, microparticles for multiplex bead arrays and functionalised membranes for medical diagnostic applications.	poly-an.de
Preclinics Gesellschaft für präklinische Forschung mbH	
Preclinics is a commercial cooperation partner for preclinical research and development. As a competent, creative and experienced partner preclinics investigates pharmaceutical substances, therapeutic methods and proceedings as well as medical products during the preclinical phase. Additional we provide custom antibody production in lama, goat, sheep, rabbit and other species.	preclinics.com
Predemtec GmbH	
Predemtec GmbH is a company focused on the research, development and manufacture of innovative diagnostic tests for use in the detection of dementia-related risk factors. The goal has been to make the early and reliable diagnosis of various dementia-related illnesses a reality through the use of our innovative diagnostics tests.	predemtecDX.com
PROTEKUM - Umweltinstitut GmbH, Oranienburg	
We plan to eliminate fluid and solid waste products in a manner which is compatible with environment protection. Our methodology is largely based on painstaking analysis. We use modern equipment and scientific methods. Protekum offers high-quality products and services in environmental analysis redevelopment.	protekum.de
Proteome Factory AG	
Biomarker & target discovery, validation, analysis of food and ingredients, absolute quantification of proteins and peptides, sequencing and characterization of proteins and antibodies (CDR), 2DE and LC-MS based proteomics studies, pharmacokinetics, pharmaco, immuno and membrane proteomics, protein identification, characterization of proteins and peptides (PTMs, e.g. phosphorylation, glycosilation), quality control, mass determination, N-terminal amino acid sequencing, silver staining kit etc.	proteomefactory.com
Provitro GmbH	
Provitro combines more than ten years of experiences in commercialisation of cell culture technologies, Tissue Microarrays and immunohistochemical analyses with the scientific expertise of the Pathological Institute of the Charité, Berlin. Based on a quality management system according to ISO 9001:2008, we provide our customers not only with high-quality products, CE marked in vitro diagnostics and state-of-the-art services but also with individual solutions for their specific requests.	provitro.de
RENSA UG	
Manufacturing and distribution of rapid tests, mainly for medical purposes (Point of Care Testing).	renesa.de

RIPAC-LABOR GmbH	
RIPAC-LABOR offers high-quality diagnoses of bacterial infections, particularly in poultry, pigs and cattle, but also in other farm and domestic animals. The company uses pathogen differentiation to provide quick and effective methods for fighting pathogens. It performs resistance tests and epidemiological analyses and also focuses on producing herd-specific vaccines.	ripac-labor.de
Roboklon GmbH	
Distribution, marketing and development of products for molecular biological research and genetic engineering.	roboklon.de
Scienion AG	
Scienion is a leading solution provider in the markets of precision dispensing and diagnostics solutions. The product portfolio comprises hardware, consumables and services. Scienion's leading product is the sciFLEXARRAYER non-contact dispensing system, available in different versions for R&D and manufacturing purposes. It represents the perfect tool for automated ultra-low volume liquid handling of various types of samples. The company has a wide-ranged experience in developing microarrays for numerous applications, including glycan-based assays, e.g. for the detection of Heparin-induced thrombocytopenia, a life-threatening prothrombotic condition.	scienion.de
selekt-ID BIOLABS GmbH	
The selekt ID Biolabs is a molecular biology service laboratory. The portfolio includes several PCR-based techniques detection methods: The core product is the identification of microorganisms (bacteria, yeasts, fungi) by sequence comparison of 16S respectively. Will also offer the detection of animal species in meat products and, as GMO analysis and detection of allergens.	selekt-id.de
Sepiatec GmbH	
Production, development and sales of automated HPLC machines for high-throughput purification and fractionation of complex substance compounds.	sepiatec.com
Seramun Diagnostica GmbH	
Seramun offers peptide synthesis, purification and conjugation of proteins, production of antibodies, customer research, in vitro diagnostics. We focus on the development and production of enzyme immunoassays for diagnosis of viral and bacterial infections and autoimmune diseases of the gastrointestinal tract, the development of multi-parameter assays as microtitre plate assays and as membrane immunoassays, as well as development of ready-to-use substrate solutions and for protein stabilizers.	seramun.com
sifin diagnostics gmbh	
Our company is manufacturing and distributing worldwide a broad range of microbiological and immunological products: bacteriological test reagents, blood grouping serological products, dehydrated and ready-to-use culture media. We do also offer a large variety of monoclonal antibodies and are open to develop and produce to customers' specifications in ready-to-use, concentrate or bulk format. MICRONAUT is the trademark of MERLIN's product line for automated microbial identification and antimicrobial susceptibility testing (AST) of clinically relevant bacteria and yeasts. It is exclusively available at sifin diagnostics gmbh.	sifin.de
Signature Diagnostics AG	
Signature Diagnostics is dedicated to the discovery, validation and commercial development of novel diagnostic products that predict outcome and drug response in patients with colorectal cancer (CRC), non-small cell lung cancer (NSCLC) and ovarian cancer. Signature believes that patient selection and stratification based on molecular gene signatures will soon become an important component of routine cancer treatment.	signature-diagnostics.de
SLM- Speziallabor für angewandte Mikrobiologie GmbH	
Microbiological quality control for medical devices, pharmaceuticals, cosmetics, drinking water, foodstuff, monitoring in clean rooms.	speziallabor.com
STRATEC Molecular GmbH	
STRATEC Molecular GmbH is a globally active provider of innovative system solutions for nucleic acid sample collection, stabilization, and both manual and automated purification from any sample type. Since 1992 the company is internationally respected for its outstanding and high performance technology platforms and offers a broad spectrum of superior products for molecular diagnostics, drug discovery and Life Science research.	invitek.de
Surflay Nanotec GmbH	
Surflay Nanotec GmbH, is specialized on coating colloidal and planar materials with functional films of nanometer thickness. Key technology is the Layer-by-Layer-Technology with functionalized polymers. Applications are in the fields of bio-sensing by Whispering Gallery Modes, separation materials, pigment encapsulation, and diagnostic particles. In addition to customer tailored projects Surflay offers an unique range of products of functional monodisperse microparticles, microsensors and dye-labeled polymers.	surflay.com

Targenomix GmbH	
Targenomix GmbH is a startup company with core competences in computational and systems biology, quantitative and molecular genetics, cell biology and biochemistry. One of the main research fields is the identification of interactions between molecular targets and small molecules.	targenomix.com
Thanares GmbH	
Development, use and marketing of analytical process for diagnostic and therapeutic purposes. Future business activities: detection process for bioactive substances in bodily fluids, isolation, characterization and investigation of bioactive compounds from plants, in particular insoluble proteins or low concentrations of proteins, development of low cost genetic systems for over-expression and/or production of such proteins.	thanares.com
Thermo Fisher Scientific – B·R·A·H·M·S GmbH	
Thermo Scientific Biomarkers (B·R·A·H·M·S GmbH) explores, develops and produces new diagnostic test procedures to improve the diagnosis, and thereby the treatment, of life-threatening illnesses. This takes place with over 470 employees, in the disease areas infectiology, cardiology and pneumology as well as thyroid, autoimmunity and cardiology on the basis of our own patented biomarkers. Since October 2009 B·R·A·H·M·S GmbH is part of Thermo Fisher Scientific Inc. (NYSE: TMO), the world leader in serving science.	thermoscientific.com/brahms
TIB MOLBIOL Syntheselabor GmbH	
In 1990, TIB MOLBIOL became the first German manufacturer of oligonucleotides. In addition to designing and synthesizing primers and probes for Real-Time PCR assays, we develop and produce LightMix® Kits for Roche Diagnostics LightCycler® Instruments, covering applications in clinical chemistry, pharmacogenetics, pathogen detection, as well as cancer research. TIB MOLBIOL is ISO 13485 and ISO 9001 certified.	tib-molbiol.com
UGA Biopharma GmbH	
UGA Biopharma a private research and development company, focuses on research, development and commercialization of biopharmaceutical products under contract with other biopharmaceutical companies. UGA Biopharma conducts power of biosciences to develop high-tech, last generation of biomedicine, diagnostic kits, molecular biology items and also offers world class services in biotechnology area.	ugabiopharma.com
Yashraj Biotechnology GmbH	
Yashraj Biotechnology Limited (YBL) is a part of the “YASHRAJ GROUP” having diversified interests in finance, construction, agriculture, chemicals and biotechnology. YBL was established in 1999 with a mission to achieve excellence in biotechnology and utilize its power for the good of humanity.	yashraj.com
Zentrum für molekulare Onkologie GmbH	
Innovative methods for diagnostic and therapy of tumor diseases – Molecular genetics (K-RAS, PCA3, Septin9, ...) – Chemoresistance assay for prediction of chemotherapy – Pathology development of new biomarkers and analytical services for studies.	molekulare-onkologie.eu
Zytemed Systems GmbH	
Zytemed Systems' focus is the development, production and distribution of antibodies and detection systems for immunohistochemical cancer diagnostics as well as reagents and kits for in-situ hybridisation.	zytemed-systems.de

Universities and Research Institutions	
BAM Federal Institute for Materials Research and Testing	bam.de
Berlin Institute of Health	bihealth.org
BfR Federal Institute for Risk Assessment	bfr.bund.de
Brandenburg University of Technology	tu-cottbus.de
Charité - Universitätsmedizin Berlin	charite.de
German Rheumatism Research Center Berlin	drfz.de
Fraunhofer Institute for Applied Polymer Research IAP	iap.fraunhofer.de
Fraunhofer Institute for Cell Therapy and Immunology - Bioanalytics and Bioprocesses IZI-BB	izi.fraunhofer.de
Fraunhofer Institute for Reliability and Microintegration IZM	izm.fraunhofer.de
Freie Universität Berlin	fu-berlin.de
German Heart Institute Berlin	dhzb.de
German Institute of Human Nutrition (DIfE)	dife.de
Hasso Plattner Institute for Software Systems Engineering	hpi.de
Humboldt-Universität zu Berlin	hu-berlin.de
Institute for Thin Film and Microsensoric Technologies (IDM)	idm-teltow.de
Leibniz-Forschungsinstitut für Molekulare Pharmakologie (FMP)	leibniz-fmp.de
Leibniz-Institut für Analytische Wissenschaften - ISAS - e.V.	isas.de
Leibniz-Institut für innovative Mikroelektronik	ihp-microelectronics.com
Max Delbrück Center for Molecular Medicine (MDC) Berlin-Buch	mdc-berlin.de
Max Planck Institute for Colloids and Interfaces	mpikg.mpg.de
Max Planck Institute for Infection Biology	mpiib-berlin.mpg.de
Max Planck Institute for Molecular Genetics	molgen.mpg.de
Brandenburg Medical School Theodor Fontane	mhb-fontane.de
Physikalisch-Technische Bundesanstalt (PTB); Germany's national metrology institute	ptb.de
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