Competence atlas

Diagnostics
Medical therapy is difficult to imagine without excellent diagnostics. The SARS-CoV-2 pandemic alone has shown us how diagnostic tests can save lives and make it easier for society to return to normality. But also in the case of oncological, cardiometabolic, rare or neurological diseases, treating physicians need a well-founded diagnosis.

The Fraunhofer Institute for Cell Therapy and Immunology offers these diagnostic solutions that go far beyond a traditional assay development. With this brochure, we want to show you innovative technologies and diagnostic procedures that address future trends in this important area of research and development.

We would like to offer you our interdisciplinary competences and partnership for future projects – from biomarker research to complete diagnostic devices. Our team is passionate about science and diagnostics, so please feel invited to get in touch with the experts at the institute and to discuss new projects. We look forward to you and your challenges, because we are convinced that solutions like application-oriented, innovative and sophisticated diagnostics have a major benefit on human health. After all, it is through diagnostics that therapy becomes effective and life-saving.
Cell and gene therapy development

Analytics and quality controls

Research topics

- Generation and functionality testing of cell and gene therapeutics (in vitro & in vivo models)
- GMP process & quality control development for cell and gene therapeutics, proteins and viral vector production

Competences

- Molecular phenotyping (e.g. qPCR, ddPCR, Western blot)
- Cellular phenotyping (fluorescence microscopy, flow cytometry, histology)
- Development of cytotoxicity and potency assays
- Automated analytics and quality controls
- Under GMP compliance

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Bioassays und lyophilization

Tools for diagnostics and therapy

Research topics

- Lyophilization
- Bioluminescence / luminescent bioassays
- Sample preparation
- Sustainability of POCT

Competences

- Developing adapted lyophilization processes and verify lyophilized product regarding certain parameters
- Validating and experimenting with assays based on bioluminescence
- Developing sample preparation technologies and handling e.g. whole blood filtration via membranes
- Finding more sustainable materials for POCT and verifying them with practical assays

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Liquid biopsy

Tools for diagnostics and therapy

Research topics

- Extracellular vesicles and their use in diagnostics and therapy
- Detection of cytokine release syndrome

Competences

- Total and specific isolation of extracellular vesicles from cell culture supernatant, blood plasma and urine
- Characterization of extracellular vesicles
- Antibody-microarray
- Homogeneous immunoassays
- Assay integration in microfluidic devices

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Liquid biopsy
Sample preparation

Solutions for preanalytical phase in diagnostics

Research topics

- Integrated diagnostics & Point-of-care tests
- Medical diagnostics
- Environmental, food & beverage analytics

Competences

- Target isolation & enrichment
- Lysis techniques for cells and viruses
- Inactivation of inhibitors
- Strategies for rare targets
- Technical integration of sample preparation into test systems

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Microfluidics

Tools for diagnostics and research

Research topics

- Integrated diagnostics & Point-of-care devices
- Organs-on-chip
- Microfluidic design

Competences

- Design, development and testing of microfluidic structures
- Hot-embossing for rapid prototyping of microfluidics and optical structures
- Process development and optimization in manufacturing technology

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MicroArray and lateral flow test

Tools for diagnostics and therapy

Research topics

- MicroArrays and lateral flow tests are multi-purpose tools in diagnostics
- Antibody-, peptide-, oligonucleotide- or artificial molecule-based assays for the detection of pathogens and biomarkers
- Visible- or fluorescence-based read-out

 Competences

- Design, development and testing of MicroArrays and innovative lateral flow assays
- Interdisciplinary exchange for assay development
- Integration into microfluidic structures

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Next-generation diagnostics

Genomics & transcriptomics for diagnostics and research

Research topics

- Genomics & Transcriptomics for clinical and non-clinical research e.g. in oncology and immuno-oncology
- Biomarker discovery and validation using next-generation sequencing and PCR-based methods
- Pathogen testing (e.g. SARS-CoV2 detection)

Competences

Classical NGS methods
- Whole transcriptome sequencing (mRNA and total RNA)
- Whole genome and exome sequencing
- Small genome and 16S sequencing

Advanced NGS methods
- Single-cell multi-omics
- Spatial transcriptomics

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Next-generation diagnostics
Medical bioinformatics for precision medicine

Research topics

- Medical bioinformatics in oncology and immuno-oncology
- Software development for precision medicine
- Biomarker discovery and validation
- Computational RNA biology & functional genomics

Competences

- Machine learning & multi-omics: Machine learning & AI for deep molecular data; multi-modal data science; statistical learning; integrative bioinformatics; pipeline development
- Software components for IVDs: Development of algorithms and software components for medical devices in particular in-vitro diagnostic devices (IVDs) and lab developed tests

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Medical bioinformatics for precision medicine
Competences

- Support of applications for animal experiments (TVV/TVA) including case number planning and joint preparation of the biometrics section for the application text, advice in experimental design for the trial, determination of strategy and appropriate statistical methods for the subsequent evaluation
- Support for the biometric planning of other experiments, e.g. case number planning in the context of third-party funding applications
- Support in statistical planning for students and PhD students

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Competences

- Preparative chromatographic separations (RP, SEC, IC)
- Identity determination of isolated proteins by peptide mass fingerprinting (PMF) and MS/MS analyses
- MS-based elucidation and detection of protein modifications and protein interactions
- Consulting, sample preparation, performance and evaluation of proteomics studies
- Determination of toxins and metabolites in biofluids by Multiple Reaction Monitoring (MRM)
- Analysis of active substances and their degradation products by MRM
- Characterization of ssDNA and ssDNA conjugates

Contact

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Flow cytometry and FACS

Competences

- Cell-based assays (immunophenotyping, apoptosis, internalization, proliferation / cell cycle, migration, degranulation)
- Cell sorting
- Advice on set-up of experiments, evaluation and other flow cytometry-related topics

Equipment

- Beckman Coulter: Navios Ex TM 10/3, CytoFlex
- Merck/Luminex: ImageStream-X MarkII, FLEXMAP 3D
- BD: Influx Cell Sorter
- Sartorius: IntelliCyt ique Gen 2
- Miltenyi: MACSQuant X

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Flow cytometry and FACS
Microscopy and image analysis

Core Unit Imaging

Competences

- Acquisition and evaluation of various (also correlative) image data
- Brightfield, live cell, fluorescence and confocal laser scanning microscopy
- Slide scanning services
- In vivo imaging via magnetic resonance imaging (MRI), computed tomography (CT) and optical imaging (BLI/FLI) for small animals
- Microscopy training of users and technical support

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Specific detection of dengue and Zika virus antibodies using envelope proteins with mutations in the conserved fusion loop

Alexandra Rockstroh¹, Beyene Moges¹, Luisa Barzon², Alessandro Sinigaglia², Giorgio Palù³, Widuranga Kumbukgolla³, Jonas Schmidt-Chanasit⁴,⁵, Manoel Sarno⁶,⁷, Carlos Brites⁶, Andres Moreira-Soto⁸,⁹, Jan Felix Drexler⁸,⁹, Orlando C Ferreira¹⁰ and Sebastian Ulbert¹

Correlation of humoral immune responses to different SARS-CoV-2 antigens with virus neutralizing antibodies and symptomatic severity in a German COVID-19 cohort

Alexandra Rockstroh¹, Johannes Wolf¹,⁵, Jasmin Fertey¹,², Sven Kalbitz¹, Stefanie Schroth¹, Christoph Lübbert¹,²,⁵, Sebastian Ulbert¹,² and Stephan Borte¹,²

Pathogens Inactivated by Low-Energy-Electron Irradiation Maintain Antigenic Properties and Induce Protective Immune Responses

Jasmin Fertey¹, Lea Bayer¹, Thomas Grunwald¹, Alexandra Pohl², Jana Beckmann², Gaby Gotzmann², Javier Portillo Casado², Jessy Schönfelder², Frank-Holm Rögner², Christiane Wetzel², Martin Thoma³, Susanne M. Bailer⁴,⁸, Ekkehard Hiller⁴, Steffen Rupp⁴ and Sebastian Ulbert¹,*
Native and recombinant antigens

Tools for serological diagnosis of infections

Research topics

- Antibody detection with high specificity and sensitivity
- Viral and bacterial pathogens
- Zoonoses and (re-)emerging infections

Competences

- Inactivation of pathogens by low-energy irradiation to yield intact native antigens (patent)
- Mutant recombinant proteins to increase specificity by reduction of cross-reactive antibody binding (patent)
- Serum neutralisation assays up to BSL-3 to test for protective antibodies

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Proteomics

Biomarkers and understanding disease

Research topics

- Identification and validation of proteins to be used as diagnostic biomarkers or representing therapeutic targets
- Mode of Action of drugs and biomaterials
- Role of exosomes in diseases

Competences

- Quantitative Proteomics
- Protein/Protein/Ligand-Interaction
- Signaling analysis

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Antibody epitopes

Understanding antibody characteristics

Research topics

- Antibody epitope mapping
- Specificity of polyclonal sera
- Validation for diagnostic and therapeutic applications

Competences

- Antibody epitope fingerprinting from µg amounts of antibody
- Epitopes at amino acid resolution
- Mapping multiple antibodies in parallel

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Epitope mapping of the immunome

Immune reactions to disease and vaccination

Research topics

- Mapping the individual immune response
- Identifying and comparing epitopes on (auto-)antigens
- Applications: Allergies, auto-immune disease, vaccines, etc.

Competences

- Immune disease related peptide epitopes for diagnostics
- Comparing immunomes from a larger number of patients
- Anti-drug antibodies
- Ressource saving: 100 µl serum are sufficient
- In silico analyses of data allows for follow-up studies

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Clinical relevance of peptides recognition at EoT

**GL15 (epitope)**
- IgE: Decrease of LOAEL$_{15}$ at EoT
- IgG: Increase of LOAEL$_{15}$ at EoT

**GL14 (mimotope)**
- IgG: Decrease Cor a 1-spec. IgE conc. at EoT
- IgG: Increase intensity lip swelling at EoT

**HU4 (mimotope)**
- IgG: Decrease of number of subj. symp. at EoT
- IgG: Decrease of LOAEL$_{15}$ at EoT

**GL12 (mimotope)**
- IgE: Increase of Bet v 1, Gly m 4-spec. IgE at EoT
- IgE: Decrease of LOAEL$_{15}$ at EoT
- IgG: Increase of LOAEL$_{15}$ at EoT

**GL2 (epitope)**
- IgG: Decrease Cor a 1-spec. IgE conc. at EoT
- IgG: Decrease intensity oral itching
Food allergy diagnostics

Cross reactivity and relevance of food allergens

Research topics

- Improving diagnosis of food allergies
- Cross reactivity between food allergens
- Identification of allergy related peptide epitopes
- Immune response to allergy treatments

Competences

- Allergy related peptide epitopes for diagnostics
- Large biobank and data sets from hundreds of patients ready to use
- Peptide epitope arrays
- In silico analyses of data allows for follow-up studies

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Food allergy diagnostics
Tissue and cell targeting peptides

Tools for diagnostics and therapy

Research topics

- Specific binding to (cancer-)tissue or cell types
- Drug delivery
- Imaging
- Diagnostics

Competences

- Successful selection of short peptides binding to cells and/or tumor tissues
- Differential selection methods
- Databases for different tumor tissues

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Gaseous analyte detection

Tools for diagnostics and therapy

Research topics

- Analysis of volatile organic compounds (VOCs)
- Detection of infections and other diseases as well as antibiotic resistance
- Breath analysis

Competences

- Ion mobility spectrometry of gaseous samples, headspace above cultures and other samples, exhaled breath
- Method development
- Data analysis of IMS spectra

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Competences

- Synthesis, characterization & application of DNA-based nanostructures for diagnostic approaches
- Functionalization of DNA strands & nanostructures with (bio)molecules such as fluorophores, biotin, peptides, sugars, small molecules, etc.
- Antibody functionalization with fluorophores, small molecules, nucleotides, etc.
- Cell culture assays (e.g. proliferation, apoptosis, migration/invasion) and flow cytometry analyses
- Virus culture assays (e.g. infection inhibition assays, ELISA, dynamic light scattering (DLS) of viruses) and virus production
- Large-scale production of phage-derived scaffold DNA for DNA origami fabrication

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CardiOMICs Unit

Research topics

- Clinical studies on infectious diseases relevant to cardio- and prosthetic-surgery
- Identification of microorganisms and their virulence profiles in clinical samples
- Analysis of digitization in ambulant and clinical healthcare structures based on real patient pathways

Competences

- Processing of clinical and experimental studies
- Molecular and immune biological diagnostics based on proteomics, NGS and targeted PCR
- Histological and ultrastructural analysis of tissue
- Translation of diagnostic procedures into clinical routine

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