

Fraunhofer Institute for Cell Therapy and Immunology IZI

**Competence atlas** 

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# Diagnostics

# Interdisciplinary competences and partnership for future projects

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



#### Contact

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# Liquid biopsy

### **Tools for diagnostics and therapy**

#### **Research topics**

- Extracelluar 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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# 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 structrues
- 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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# 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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# Statistical consulting

#### 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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# Chromatography & mass spectrometry

#### 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



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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 cytometryrelated 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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# 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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Jasmin Fertey <sup>1</sup> , Lea Bayer <sup>1</sup> , Thomas Jasmin Fertey <sup>1</sup> , Lea Bayer <sup>1</sup> , Thomas Jasmin Colzmann <sup>2</sup> , Javier Portillo Casado <sup>2</sup> , Jessy J	3ailer <sup>4,3</sup> , EKREA
Gaby Gotal Wetzel 2, Mar Christiane Wetzel 2, Mar and Sebastian Ulbert 1,*	100

# 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



#### Contact

Dr. Jasmin Fertey Vaccine Technologies Unit Department of Vaccines and Infection Models Tel. +49 341 35536-2160 jasmin.fertey@izi.fraunhofer.de Expression ProteinSequence Diagnostics ProteinSequence Regulation Surface PosttranslationalModification ModeOfActionStructure

# roteomic Signalling Quantification Phosphorylation SurfaceProteome Drug Targets Interactome

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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



# Food allergy diagnostics

### Cross reactivitiy 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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# 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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# DNA Nanodevices group

#### 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 phagederived 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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