



Your Partner for Customised Bioanalytical Solutions

Our mission is to provide bioanalytical data at the highest standards to support preclinical and clinical drug development.

www.kremes-bioanalytics.com

Bioanalytical services

We are specialised in innovative bioanalytical services for large molecules. With our comprehensive scientific expertise in immunology, hematology and cancer research, we are your competent provider in routine and advanced bioanalytics.

Your partner in immunology, hematology, and oncology

Krems Bioanalytics is an internationally operating contract research institute providing cutting-edge bioanalytical services in the fields of immunology, hematology, and oncology. We have a long-standing expertise in the development and validation of customised GxP and IVDR compliant analytical assays for large molecules and vaccines. We offer sample analytics for early and late preclinical studies (R&D or GLP) and for clinical trials (GCP).

Experience the best of both worlds

As a university-based contract research organisation (CRO), we are uniquely positioned to bridge the gap between cutting-edge research and quality assured pharmaceutical drug development. Partnering with us accelerates drug development, ensuring quality and innovation from bench to bedside.



Immunogenicity testing and predictions

- Anti-drug antibody (ADA) detection and characterisation:
 - multi-tiered approach: screening – confirmation – neutralisation
 - additional characterisation: isotype and subclass differentiation
- Innovative platform: affinity characterisation of ADA directly in sample matrix
- Neutralising capacities of ADAs:
 - Bethesda assay
 - Pseudovirus neutralisation assays
- In vitro models for immunogenicity prediction of therapeutic proteins:
 - Cytokine release assay (CRA)
 - Complement activation assay
 - T cell activation assay
 - T cell proliferation assay
 - DC activation assay



Cellular immune monitoring

- Immunophenotyping: monitoring the frequency of different immune cell populations and the differentiation and activation status of specific subsets
- Cytokine profiling
- Characterisation of antigen-specific responses:
 - Th1 and Th2 polarisation assay
 - T-cell polyfunctionality
 - T-cell memory phenotype



Cell based assays

- Cell proliferation
- Apoptosis and cell death
- Reporter gene assays
- Cell signaling assays
- ADCC and CDC assays
- Receptor Occupancy (RO) testing
- Motility
- Toxicity



Biomedical mass spectrometry

- Protein interactions in macromolecular complexes
- Antigen-antibody epitope mapping
- Antibody sequencing
- Molecular characterisation of major histocompatibility complex (MHC) peptides
- Cytokine profiling
- Pharmacokinetics (PK) testing for large molecules
- Plasma proteomics



Coagulation assays

- aPPT assay (PathromtinSL)
- PT-INR assay (ThromborelS)
- FII activity testing (ThromborelS)
- FVII activity testing (PathromtinSL)
- FIX activity testing (PathromtinSL)
- FX activity testing (ThromborelS)
- Anti-FXa antibody assay
- Protein C
- Protein C neutralising antibody assay
- Derived fibrinogen
- D-Dimer
- Free protein S



Process-related impurity testing

- Host cell proteins (HCP)
- Protein A and culture impurities
- Detection and characterisation of subvisible particles and protein aggregates in protein therapeutics using flow cytometry



Biopotency assays

- In-depth evaluation of mode of action
- Identification of suitable in vitro models
- Feasibility testing applying different technologies



Pharmacokinetic testing services

- Drug level quantification
- Drug activity testing
- Drug efficacy testing



Enzyme activity assays

- Evaluation of enzyme activity
- Determination of enzyme inhibitors
- Investigation of enzyme selectivity

Your Partner for Customised Bioanalytical Solutions.



University of
Applied Sciences
Austria

Institute Krems Bioanalytics
Part of IMC Krems University of Applied Sciences

Office & Laboratories: Technology & Research Center
Magnesitstraße 1
3500 Krems an der Donau, Austria
T: +43 (0)2732 / 802 – 179
E: office@krems-bioanalytics.com
www.krems-bioanalytics.com