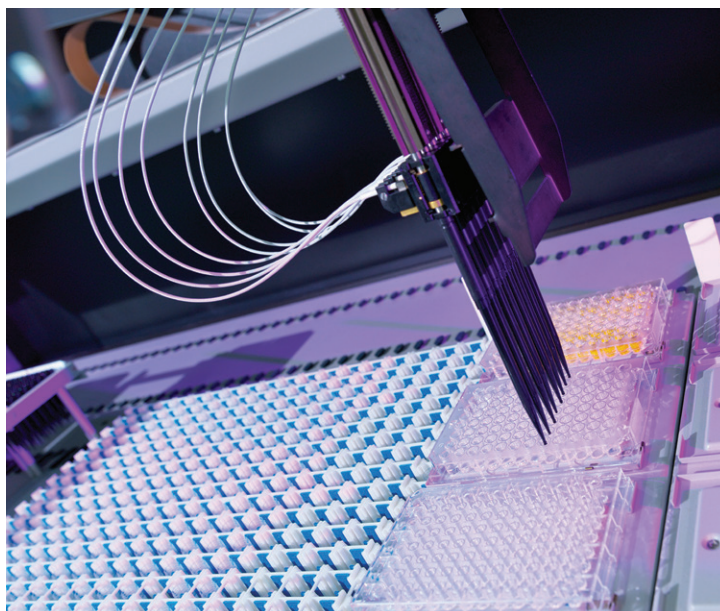


# Bioanalytical Sciences

Celerion's facilities in Zürich, Switzerland and Lincoln, Nebraska, USA are among the most established laboratories in the industry with over 40 years' experience supporting discovery through late stage clinical studies. Celerion applies more than 10 years' experience utilizing electronic laboratory notebook and fully automated workflow processes to provide faster access to accurate and high-quality data.

- Pharmacokinetics
- Anti-drug antibodies assays
- Neutralizing antibody assays
- Biosimilars and biobetters
- Antibody-drug conjugates
- Gene therapy and cell therapy
- Immuno-oncology
- Biomarker analysis
- Metabolite identification and profiling
- Biotherapeutic characterization
- Oligonucleotide measurement
- Nanoparticle formulations
- Pediatric trials including patient centric sampling



## CPU & Laboratory Alignment for Rapid Bioanalysis

Celerion's research laboratories in Lincoln, NE and Zurich, Switzerland pair the latest technologies for PK, immunogenicity and biomarker assays. Clinics and labs in the US and Europe ensure quick transport and turnaround time between locations.

- Phoenix, AZ, USA
- Lincoln, NE, USA
- Belfast, Ireland, UK
- Zurich, Switzerland

## LC-MS CAPABILITIES & PLATFORMS

### LC-MS/MS (Tandem Mass Spectrometry)

Total number of instruments: 40

- SCIEX Triple Quad™ 6500(+)
- SCIEX QTRAP 5500®
- SCIEX API 4000™

### LC-MS/MS Capabilities

- Chemical, peptide, protein and oligonucleotide therapeutic analysis
- Ultrasensitive assays
- 2D-LC-MS/MS methodology
- Nano, capillary and microflow LC-MS/MS
- Immunocapture LC-MS/MS

### LC-HRMS (High Resolution Mass Spectrometry)

- TripleTOF® 6600+
- v.ARC3 Radioisotope Detector
- SCIEX ExionLC™

### LC-HRMS Capabilities

- In-vitro and in-vivo metabolite identification
- Metabolite identification and profiling of radiolabelled ADME studies
- Biotherapeutic characterization
- Biomarker discovery

### ICP-MS (Metal Analysis)

- Agilent 7900
- PerkinElmer SCIEX DRC-e



## LARGE MOLECULE CAPABILITIES & PLATFORMS

### Immunoassay Instrumentation

- Plate readers (absorbance, fluorescence, luminescence)
- Gamma counters
- Meso Scale Discovery (MSD ECLIA)
- AlphaLisa/Tecan Infinity M1000
- SIMOA ultrasensitive

### Immunoassay Capabilities

- PK/PD primary endpoint
- Anti-drug antibodies (ADA)
- Antibody titers
- Seroconversion
- Multiplexed immune biomarker secretion (cytokines & chemokines)
- Multiple detection of vaccine antigens

### Cellular/Functional Assay Instrumentation

- BD Fortessa (18 color)
- BD FACSMelody™ – Cell Sorter
- Muse® Cell Analyzer
- ImmunoSpot® S6 MICRO
- BioSys Bioreader® 4000 Pro
- Applied Biosystems™ 7500 Real Time qPCR
- Applied Biosystems™ QuantStudio® 5 qPCR
- Agilent 2100 Bioanalyzer
- Maxwell® RSC automated DNA/RNA extraction

## CELLULAR/FUNCTIONAL ASSAY CAPABILITIES

### Flow Cytometry

- Specific cell population isolations
- Enumeration of vaccine-induced T cell
- Proximity to clinic for quick transport and rapid turnaround

### qPCR

- Viral load
- Genotyping
- Viral products
- Molecular monitoring of host immune response

### Cell-based Assays

- Neutralizing antibody assays
- Viral titers estimate by cell culture
- Proliferation and apoptosis assays

### Elispot

- Cell-mediated immune response
- Quantification of Ab-producing cells (PBMC, via ex-vivo stimulation)
- Monitoring T-cell response (IFN- $\gamma$  activation)

### Peripheral Blood Mononuclear Cells (PBMCS) Isolation

- Performed using Standard Operating Procedure (SOP) and highly trained personnel
- Methods extensively tested for high yields, viability and recovery
- Processing of PBMCS – available 24/7





## ADVANCED TECHNOLOGIES FOR SWIFT RESULTS

### High-Quality Information Technologies

- Electronic Laboratory Notebook (LabNotes)
- Watson LIMS with immune response module
- Barcode based processes ensure sample identity security
- Continuous climate monitoring with Vaisala viewLinc

### Celexus®

- Access to operational progress
- Real-time bioanalytical results
- Centralized repository for all study documents
- Data analysis tools

### Automated Liquid Handling Platforms Supporting All Areas of Analysis

- Hamilton StarLine
- Tecan Evo/Genesis
- Caliper Sciclone
- Worklist-driven processes ensure full traceability throughout the sample analysis

## Tiered Approach to Biomarker Validation

A purpose-driven approach based on regulatory requirements for discovery, exploratory, and endpoint analysis in preclinical and clinical tissue matrices.

### Exploratory

MOA, Discovery,  
& Nonclinical

### Partial Validation

Patient ID, PD,  
& MOA

### Full Validation

Primary, Endpoint,  
Label Claim, & Clinical  
Decision

## Celerion Science™

Personal scientific attention with a customized bioanalytical approach to rapidly deliver high-quality data.



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