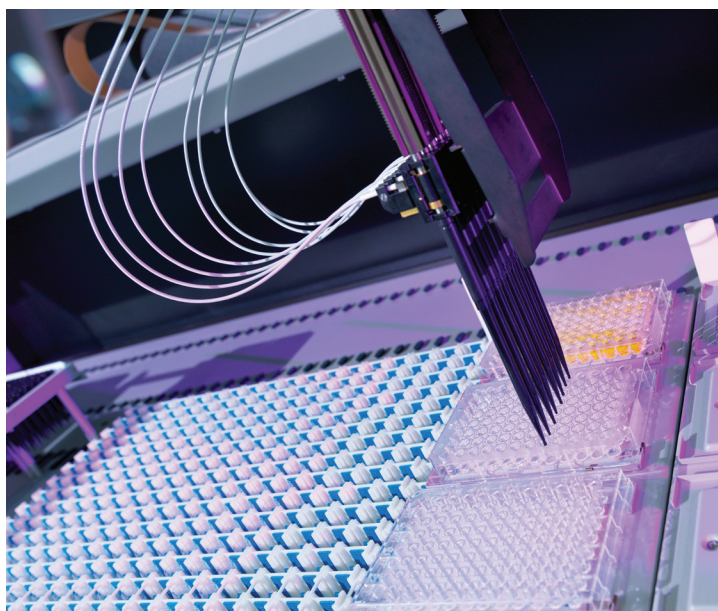


Bioanalytical Sciences

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. With more than a decade of expertise in utilizing electronic laboratory notebooks and fully automated workflow processes, Celerion ensures high throughput and provides faster access to accurate and high-quality data.

- Pharmacokinetics
- Immunogenicity assessment
- Cell-based assays
- Biosimilars
- Antibody-drug conjugates
- Cell and gene therapy
- Immuno-oncology
- Biomarker Analysis
- Metabolite Identification & Profiling
- Biotherapeutic Characterization
- Oligonucleotide Measurement
- Nanoparticle formulations
- Support of Pediatric trials (microsampling)
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

- Triple Quad™ 6500(+)
- SCIEX Triple Quad 7500+
- QTRAP 5500
- API 4000

LC-MS/MS Capabilities

- Small molecule, peptide, protein and oligonucleotide analysis
- Ultrasensitive assays
- 2D-LC-MS/MS methodology
- Microflow LC-MS/MS
- Immunocapture LC-MS/M

LC-HRMS (High Resolution Mass Spectrometry)

- SCIEX TripleTOF 6600+
- v.ARC3 Radioisotope Detector
- SCIEX ExionLC
- LCJet Fraction collector
- PerkinElmer TopCount scintillation counter
- HIDEX Beta Counter 300 SL

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)
- 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 Assays Instrumentation

- BD Fortessa (18 color)
- BD FACS Melody – Cell Sorter
- Muse Cell Analyzer
- ImmunoSpot® S6 MICRO
- Bio-Sys Bioreader 4000 Pro
- Applied Biosystems 7500 Real Time qPCR
- Quant Studio 5 qPCR
- Agilent Bioanalyzer 2100
- Maxwell RSC automated DNA/RNA extraction

CELLULAR/FUNCTIONAL ASSAYS 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- γ 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 when located at clinical site.



ADVANCED TECHNOLOGIES FOR SWIFT RESULTS

High Quality Information Technologies

- Electronic Laboratory Notebook (LabNotes)
- Watson LIMS with immune response module
- Barcode based processes ensures 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 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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