

# Celerion Bioanalytical Sciences

---

# Translating Science to **Medicine**

# 50+ Years of Bioanalytical Expertise

## Small Molecule, Peptide and Protein Analysis

- Biomarker Analysis
- Pharmacokinetics
- Immunocapture LC-MS/MS
- Metabolite Identification & Profiling
- Protein Characterization
- Oligonucleotide Measurement
- Antidrug Antibodies Assays
- Neutralizing Antibody Assays

## Cell-Based & Potency Assays/Therapeutic Areas

- Gene Therapy & Cell Therapy
- Biosimilars
- Antibody-Drug Conjugates
- Immuno-oncology

## LC-MS Capabilities & Platforms

### ■ LC-MS/MS

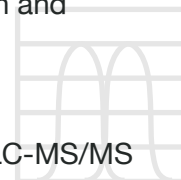
#### Mass Spectrometry

- Triple Quad™ 6500
- QTRAP 5500
- API 4000
- Waters ACQUITY UPLC®



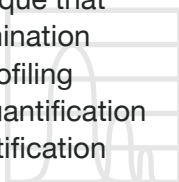
### LC-MS/MS Capabilities

- Small Molecule, Peptide, Protein and Oligonucleotide Measurement
- Ultrasensitive Assays
- 2D-LC-MS/MS Methodology
- Nano, Capillary and Microflow LC-MS/MS



### LC-HRMS Capabilities

- (HRMS) is a very selective technique that measures the exact mass determination
- In-vitro and in-vivo metabolite profiling
- Radiometabolite identification/quantification
- Cold metabolite profiling by identification



### ■ LC-HRMS

#### High Resolution Mass Spectrometry

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

### ■ ICP-MS Metal Analysis

- Agilent 7900
- PerkinElmer SCIEX DRC-e

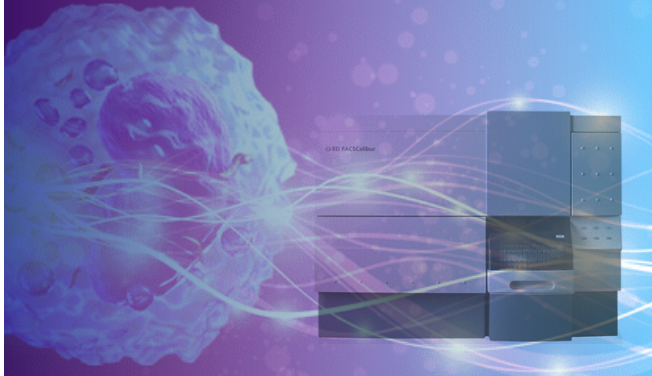


# Biomarker/Large Molecule Capabilities & Platforms

## Cellular/Functional Assays

### Flow Cytometry

- T cell, B cell, & NK cell panels
- Specific cell population isolations
- Enumeration of vaccine-induced T cell
- Proximity to clinic for quick transport and rapid turnaround



## Cell-Based Assays

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



## Elispot

- Cell-mediated immune response via ImmunoSpot® S6 MICRO
- Quantification of Ab-producing cells (PBMC, via ex-vivo stimulation)
- Monitoring T-cell response (IFN- $\gamma$  activation)



## Equipment

- FACSCalibur DXP6 (six color)
- BD Fortress (18 color)
- BD FACS Melody – Cell Sorter
- Muse Cell Analyzer



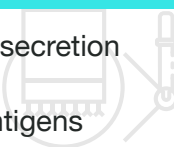
## RIA/ELISA

- Antibody titers
- Anti drug antibodies (ADA)
- Seroconversion
- PK/primary endpoint



## ECLIA

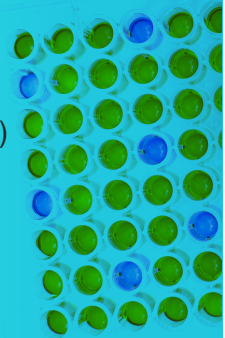
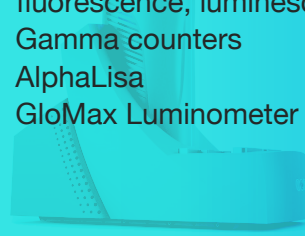
- Multiplexed immune biomarker secretion (cytokines & chemokines)
- Multiple detection of vaccine antigens



## Immunoassays

### MSD/SIMOA

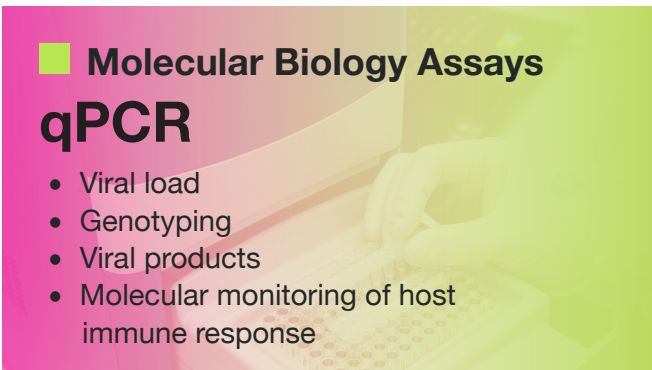
- Plate Readers (absorbance, fluorescence, luminescence)
- Gamma counters
- AlphaLisa
- GloMax Luminometer



## Molecular Biology Assays

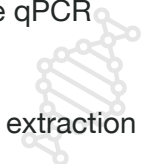
### qPCR

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



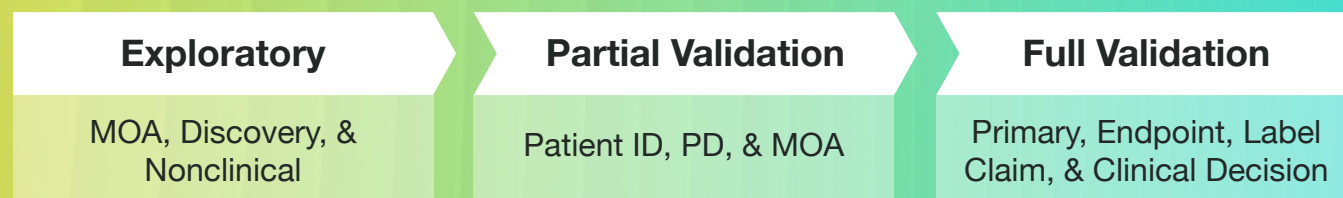
## Gene Expression

- Applied Biosystems 7500 Real Time qPCR
- Quant Studio 5 qPCR
- Agilent Bioanalyzer 2100
- Maxwell RSC automated DNA/RNA extraction
- Thermo Scientific Nanodrop 2000



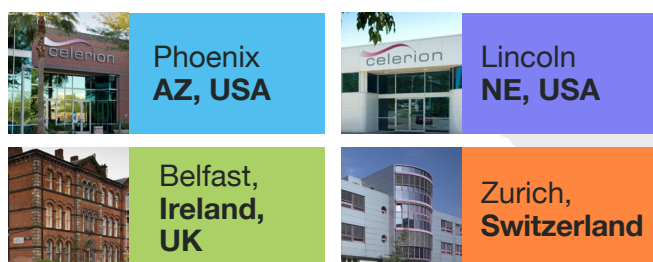
# Tiered Approach to Biomarker Validation

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



## 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.



### COVID-19

Clinics ensure safety of patients with Ab and Viral Titer screening tests for COVID-19



### Flow Cytometry

Rapid turnaround from clinic to lab for expedited functional profiling



### 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
- Near real-time processing of PBMCs – available 24/7



# Advanced Technologies for Swift Results

## High Quality Information Technologies

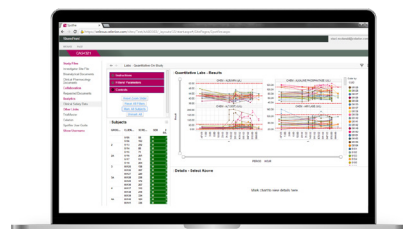
- Electronic LabNotes system
- Watson LIMS system with immune response module
- Complete barcode systems ensure sample identity security
- Continuous climate monitoring with Vaisala viewLinc

## Celexus®

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

## Automated Sample Handling Platforms

- Caliper Sciclone
- Hamilton StarLine
- Tecan Evo/Genesis
- Integra Assist Plus



## Celerion 2019 Year in Review



## Celerion Science<sup>SM</sup>

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

## Resources

- [Bioanalytical Assay List](#)
- [Bioanalytical Services](#)
- [Bioanalytical Capabilities for Vaccines](#)
- [Biomarker and Bioanalytical Assays for Immuno-oncology Drug Development](#)
- [Keys to Success in Biosimilar Bioanalytical Assay Development and Sample Analysis](#)
- [Challenges in Biomarker Analysis: SiMoA \(Single Molecule Array\)](#)
- [Unlocking Value of Flow Cytometry During Drug Development](#)
- [Interferon-Gamma Elispot Assay](#)

Contact Us

**celerion**  
Translating Science to  
Medicine