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BIOANALYTICAL

TRANSLATING SCIENCE INTO MEDICINE

Celerion Recognized by Biopharmaceutical Clients as a Leader in Contract Research Quality Benchmarking Survey. Inside, a complete outline of our large and small molecule assays and instruments.

BIOSIMILAR DEVELOPMENT

Flow (Cytometry) to Clinic

BIOMARKERS

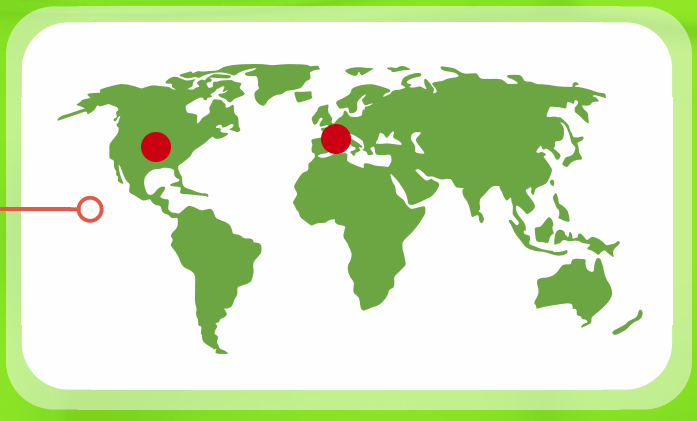
Earlier Focus, Better Results

ASSAYS/INSTRUMENTS

180
scientists

120
immunogenicity assays

35,000
samples/month



Our two strategically placed bioanalytical labs are located in Zurich, Switzerland, and Lincoln, Nebraska, USA.

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BIOANALYTICAL SERVICES

BIOSIMILAR ANALYTICAL METHOD DEVELOPMENT

Celerion supports all requirements for biosimilar drug candidates. Our expertise is in proven large molecule and immunogenicity bioanalytical assays.

WE UNDERSTAND THE COMPLEXITIES...

Biologics and their biosimilar counterparts are large, complex biomolecules produced from living cells; slight changes in the manufacturing processes may lead to subsequent changes in safety and efficacy as compared to the originator molecule. Therefore, special considerations must be given to the development of bioanalytical assays for use in biosimilar testing.

BIOSIMILAR ASSAY SUITES

Biosimilar products require a custom developed group of assays that are tailored to the biosimilar under development. These assays characterize the pharmacokinetics, anti-drug antibody reaction, and neutralizing antibody response to this unique entity. Celerion offers a tailored group of assays in close consultation with our clients.

Immunogenicity Assay Best Practices

Selection of one calibrated curve to be used for both the biosimilar and the reference product is required. Use of the overall data to evaluate the differences between the innovator and the biosimilar, and the impact on safety and efficacy is the goal.

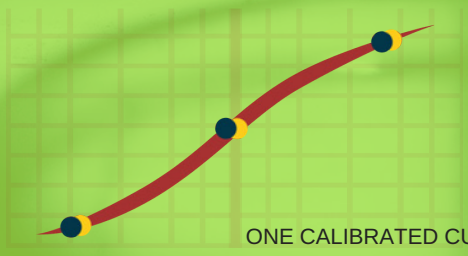
Get the Biosimilar Package

THE POWER OF ONE

- PK Assay
- Anti-Drug Antibody Determination
- Neutralizing Antibody Determination

PK Assay

Built to measure the biosimilar and innovator, this assay demonstrates bio-comparability between the two using calibrators (in either innovator or biosimilar) and quality control standards.



ONE CALIBRATED CURVE

Anti-Drug and Neutralizing Antibody Assays

Celerion offers a tailored group of assays in close consultation with our clients to characterize safety and efficacy.

Visit us at http://www.celerion.com to learn more

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BIOANALYTICAL SERVICES

ELECTRONIC LABORATORY NOTEBOOK (ELN)

One of the few labs currently using ELN and Watson Laboratory Management System (LIMS). Celerion utilizes a comprehensive tool that implements standardized bioanalytical processes and consistency in study documentation. This notebook system allows for automated data capture.

Global Bioanalytical Network

LabNotes' electronic laboratory notebook is now part of our global bioanalytical network. It allows for a paperless environment from standard and QC preparation, through sample preparation and analysis to data management and reporting.

ELN also eliminates manual calculations and sources of potential error.

ELN and LIMS standardizes most bioanalytical processes, improves documentation consistency for all studies, and supports the generation of data in a validated electronic environment across our global facilities.

FEATURES

- BUILT-IN CALCULATIONS FOR CRITICAL ASPECTS OF THE BIOANALYTICAL WORKFLOW
- STANDARDIZATION OF REFERENCE STANDARDS, TO INSTRUMENT AND PIPETTE CALIBRATION
- CONSISTENCY AND SIGNIFICANTLY REDUCES CHANCES OF MANUAL ERROR
- VALIDATED TO OECD, GLP, AND FDA 21 CFR PART 11 COMPUTERIZED SYSTEM REGULATORY REQUIREMENTS

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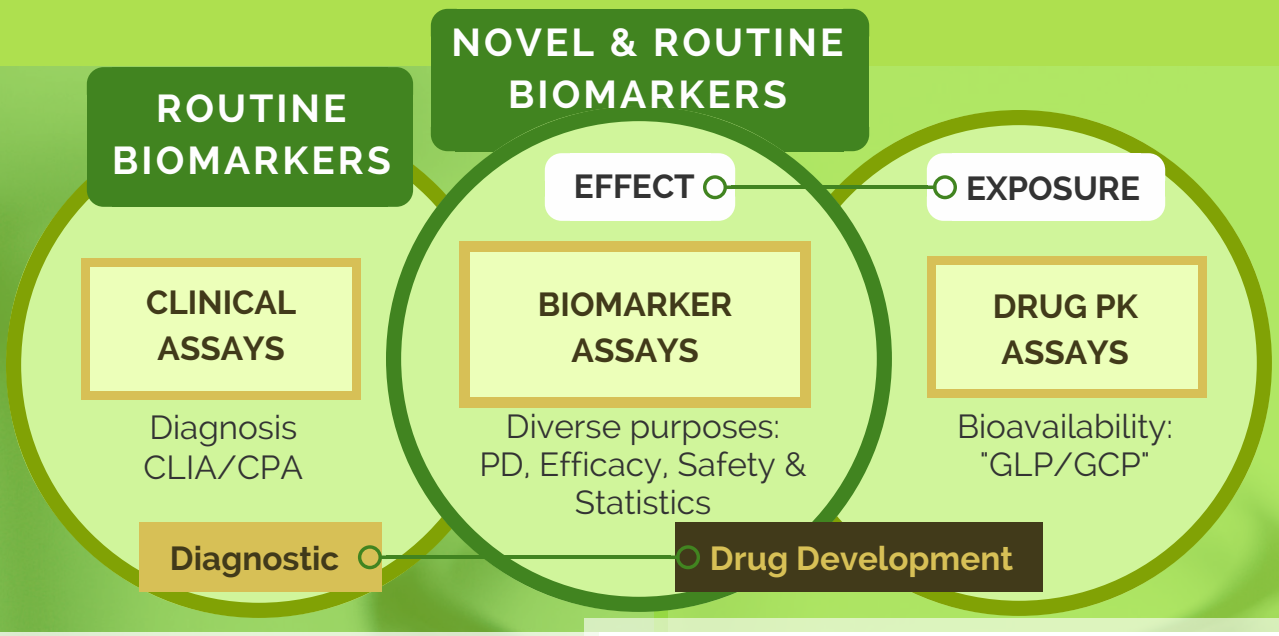
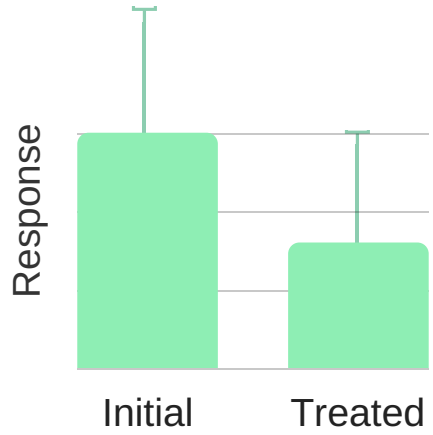
BIOANALYTICAL SERVICES

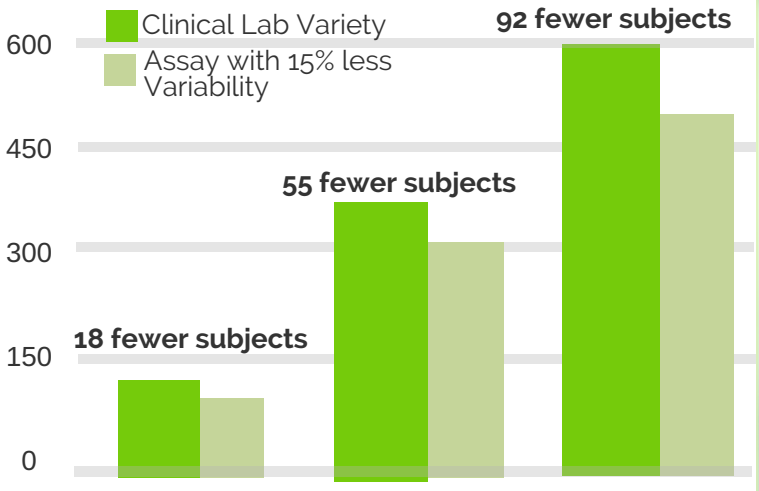
BIOMARKERS

Biomarkers are a critical element in achieving better decisions faster in early drug development. When used for statistical comparisons the quality of the bioanalytical assay for a biomarker has a direct impact on the number of subjects needed for the study. Celerion develops and validates the right assay for the biomarker, thereby decreasing the timelines and cost of the clinical program.





Method Validation - Precision
COST SAVINGS: Able to dose fewer patients



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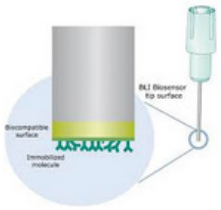
BIOANALYTICAL SERVICES

BIOMARKERS AND LARGE MOLECULE PLATFORM

Celerion uses state-of-the-art LC-MS/MS, immunoanalytical and immune-based large molecule technology, validated Watson LIMS, and LabNotes Electronic Laboratory Notebook (ELN) to quickly speed data to our clients.

Luminex

Magnetic bead-based immunoassay platform allows for **measurement of up to 100 proteins simultaneously** in robust and reproducible manner.



Octet

Monitors the binding of proteins and other biomolecules directly in real time using label-free Bio-Layer Interferometry (BLI) technology.

Microplate Readers

Microplate readers capable of reading **absorbance, fluorescence, luminescence, time resolved fluorescence (TRF) and fluorescence polarization signal.**

MESO QuickPlex SQ 120

Electrochemiluminescence (ECL) detection technology that offers a unique combination of **sensitivity, dynamic range, and convenient workflow.**

ABI7500

The 7500 Real-Time PCR System features an innovative optical **system that enhances sensitivity and allows access to a broader range of fluorophores.**

ImmunoSpot Analyzer

Designed for scanning and evaluating a wide range of microtiter plate-based bioassays - in particular, **ELISPOT assays. Precise, fast, user-friendly scanning and analysis of all plate types.**

Radioimmunoassay (RIA)

Radioimmunoassay (RIA) is a **very sensitive in vitro assay technique used to measure concentrations of antigens** (for example, hormone levels in blood) by use of antibodies. As such, it can be seen as the inverse of a radio binding assay, which quantifies an antibody by use of corresponding antigens.

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inflammation & immunity

BIOANALYTICAL SERVICES

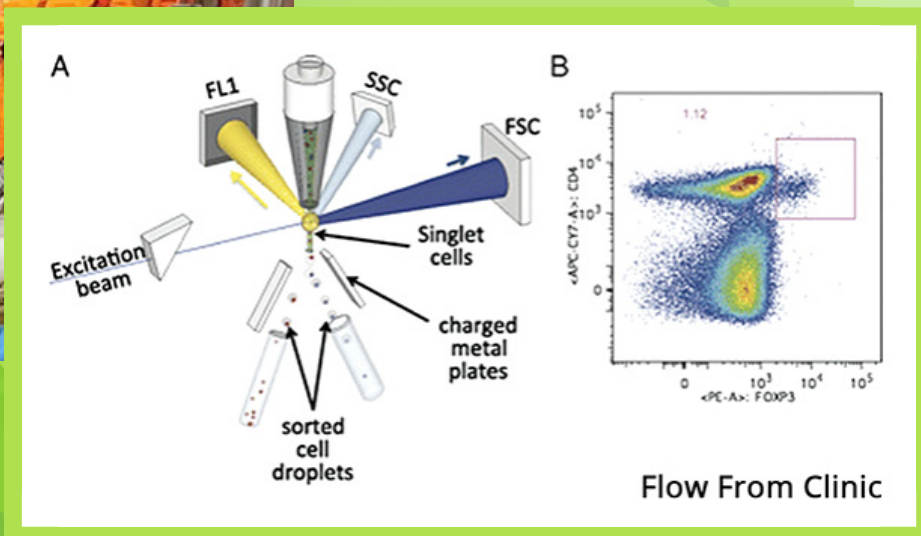
FLOW-TO-CLINIC

Flow Cytometry

Our primary flow cytometry location is Lincoln, Nebraska where our patient clinic is co-located with our lab. The technology is recognized for its powerful and versatile features for investigating many aspects of cell biology during drug discovery and development. Flow cytometry capabilities are most valuable when performed in immediate proximity to where clinical conduct studies are performed.

immuno-oncology

pulmonary



Whether you need access to a menu of off-the-shelf routine assays, want a fit-for-purpose custom assay to solve complex clinical challenges, or to support translational biomarker development, Celerion scientists can help you unlock the power of flow cytometry.

metabolic disease

CLICK HERE TO REVIEW OUR QUALIFIED AND VALIDATED ASSAYS

Visit us at http://www.celerion.com to learn more

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BIOANALYTICAL SERVICES

MASS SPECTROMETRY
SMALL AND LARGE MOLECULE ANALYSES

Mass Spectrometry (MS) has become the most widely used methodology for the quantification of analytes from small molecules to large proteins and for studying proteins and peptides over the last decade. Celerion provides the instrumentation and experienced researchers for your requirements.

LC-MS/MS

LC-MS/MS offers analytical specificity superior to that of immunoassays or conventional high performance/pressure liquid chromatography (HPLC) for small and large molecular weight analytes.

UPLC

The most robust, reliable, and highest quality nano-to-microscale UPLC separations.

SCIEX 6500

Revolutionary, new, multi-component IonDrive Technology merges highly evolved sensitivity with renowned performance.

BIOANALYTICAL IND PACKAGE

Preclinical (2 Species) and human parallel validation with a dedicated Senior Bioanalytical Specialist.

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THE POWER OF ONE

CONTACT CELERION NOW!

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BIOANALYTICAL SERVICES

CELERION SOLUTION

Over 40 years of experience conducting First-in-Human, clinical Proof-of-Concept and patient dose response studies, cardiovascular safety services (TQT, robust QT), ADME and NDA-enabling clinical pharmacology studies.

Highly qualified scientists assist in designing robust, efficient clinical studies as well as analyzing and interpreting data both during and post clinical conduct.

Global presence with 600 beds
at three global Celerion clinical facilities, in addition to a network of audited specialty sites in North America, Europe, South Korea and Singapore. Celerion scans the globe to find solutions to clients' early clinical research needs.

Extensive expertise on modeling and simulation, study design, medical writing (protocols and reports), clinical data sciences, biostatistics, and PK/PD analysis.

Bioanalytical services
at two global locations for method development and validation for small and large molecule assays for the analysis of drugs, metabolites, and biomarkers in a broad range of biological fluids.

Drug Development Services team
provides regulatory, drug development and program management support to complement Celerion's service offering.

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