

CORPORATE OVERVIEW

Alera Labs is a contract research organization offering high quality analytical and pre-formulation support to pharmaceutical, biotech and medical device industries.

"Our company specializes in providing high quality analytical services at a low cost with the fastest turnaround time in the industry."

- Dmitri Moundous, PhD, Founder and President

Partner with Alera Labs

Alera Labs provides custom analytical chemistry services in a state-of-the-art analytical laboratory. Alera Lab's team of experienced staff is committed to providing expert and timely analytical chemistry support. Our expertise spans a wide range of compounds and techniques from analysis of pharmaceutical compounds, drug metabolites, impurities, degradants, environmental contaminants and various biological materials. The laboratory is equipped with a wide range of fully qualified analytical instruments. All data undergo multiple levels of review and Quality Assurance audit prior to release to the client.

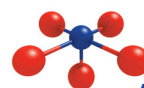
Our philosophy is to provide top quality science and customer service no matter how "small" your project is. Your needs and timelines are our highest priorities.



We invite you to visit us, audit our facilities, discover our insights and learn more about our commitment to excellence. Visit www.aleralabs.com or call 919-228-8209

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ALERA LABS



ANALYTICAL SERVICES

Alera Labs operates a modern analytical laboratory providing custom services to its clients, including but not limited to characterization and certification of client materials, material stability studies, method development and validation, impurity studies, structure elucidation, and method transfer.

“Alera was very flexible in helping to meet the unique product's needs. They had the speed and ability to run complex analyses without any OOS's. We look forward to working with them again in future endeavors.”

- Carrie S., Project manager from Lyophilization Technology, Inc.

Expansive services

- Analytical method remediation
- Analytical method development, validation and transfer
- Stability studies
- Biomarker analysis and assay development services
- Large molecule analysis (composition, MW, Assays)
- Identification and structure elucidation
- Preformulation studies
- Filter compatibility screening
- Solution product development
- Determination of residual solvents
- Determination of organic volatile impurities
- Impurities profile
- Moisture determination
- ADME/Tox Assays

Instrumentation

- HPLC: Agilent, Shimadzu (UV-Vis, RI, FLD, ELSD, GPC, IC)
- LC-MS: Agilent
- GC-MS
- ICP-MS
- Brookfield cone/plate rheometer
- FTIR
- UV-Vis Spectrophotometer
- Karl Fischer
- Plate reader
- Capillary Electrophoresis
- 1D/2D NMR

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ANALYTICAL DEVELOPMENT

With hundreds of methods developed, validated and/or transferred, Alera Labs' team consists of highly skilled analytical chemists talented in developing and validating phase appropriate methods. Once we develop a method, we can assist with method validation and transfer to a third party or to the client's laboratory. We will provide necessary guidance on the validation experiments required in compliance with cGMP.

CAPABLE SUPPORT OF VARIOUS PRODUCT FORMS

- Injectables
- Solids, semi-solids and liquids
- Inhalation/Nasal
- Transdermal
- Biological materials
- Polymers

Method development and validation services

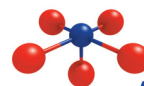
- Assay and related substances
- Forced degradation studies
- Characterization and identification of contaminants
- Stability indicating assays
- Residual solvent identification
- Solubility curves
- Stabilizer screening
- Filter compatibility screening
- Agglomeration or micelle determination and size
- Method transfer
- Process validation support
- Reference standard qualification

Instrumentation

- HPLC: UV-Vis, RI, FLD, ELSD, GPC, IC
- LC-MS: Quadrupole with APCI and ESI
- GC-MS
- ICP-MS
- GC: direct injection and head space capability
- FTIR
- UV-Vis Spectrophotometer
- Karl Fischer
- Plate reader
- Capillary Electrophoresis

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EXTRACTABLES & LEACHABLES

Extractables and leachables studies can help you investigate harmful effects of your container closure systems, drug delivery systems such as pre-filled syringes and vials, single use, and disposable medical equipment, pharmaceutical packaging and others on your drug product. Our team of chemists have an average of 20 years experience with polymers, metals, and an array of pharmaceutical products. We will assist in identifying the components that can potentially contaminate your drug product.

Delivery systems supported

- Nasal products
- LDPE ampoules
- pMDI
- PVC blister packs
- Injectables
- Medical devices
- IV bags
- Ophthalmics
- And many more container/closure systems

Comprehensive services

- Development of a tailored study design for extractables and leachables
- Extractables profiling (both organic and inorganic)
- Characterization of extractables by chromatographic and spectroscopic techniques
- Leachables studies
- Routine container/closure testing
- Formulation compatibility and stability
- Determination of AET and of the qualification threshold based on SCT

Instrumentation

- GC-MS
- LC-MS/MS
- ICP-MS
- LC-MS
- FTIR
- Soxhlet

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FORMULATION

Alera Labs offers complete services for drug development. We help our clients turn their innovative ideas into a finished product. A dedicated team of skilled formulation chemists will go to work developing multiple prototypes to identify a winning formulation. Our formulation experts take clients from proof of concept to characterization. The formulation team's in-depth knowledge covers a diverse range of products, as well as a wide variety of dosage forms and routes of delivery.

In addition to our formulation capabilities, Alera Labs also conducts the necessary analyses and container/closure compatibility studies required to move your product through the regulatory process.

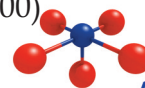
Pre-formulation and formulation services

- Solution stability studies (define sensitivities to pH, heat, oxidation, buffer, buffer strength, and salt concentration)
- Solubility curves (determine ionization constant (pKa), define solvent and complexing solubility)
- Drug-drug compatibility
- Excipient-drug compatibility
- Agglomeration or micelle determination and size
- Forced degradation and compound/protein stabilization studies
- Identification and quantification of impurities and degradation products
- Stabilizer screening (using pharmaceutical, veterinary or agricultural approved additives)
- Admixture and container/closure compatibility studies
- Photo-stability studies
- Water content determination

Instrumentation

- HPLC: UV-Vis, RI, FLD, ELSD, GPC, IC
- LC-MS: Quadrupole with APCI and ESI
- ICP-MS
- GC-MS
- Mettler Toledo Karl Fisher Coulometer
- Brookfield HBDV-II + cone/plate rheometer
- NMR
- LC-MS/MS (AB Sciex API 4000)

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BIOASSAY

Alera Labs offers a wide variety of bioassay services that cover a vast range of pharmacological relevance. Our experts will work directly with you to design and perform bioassay studies that are customized to your specific needs. Ask us about validated, reliable biomarkers that can be used in your project. We can provide free analysis of markers appropriate for your pathway or set up quantitative assays for your marker of interest.

Alera Labs provides customized biomarker assay development services to meet your needs for pre-clinical and clinical trials. We further validate the assay for its sensitivity, specificity, accuracy, reproducibility, and stability.

Bioassay services

- Bioassay transfer
- Bioassay optimization
- Bioassay development
- Proof-of-concept to verify the feasibility of reagents
- Quantification to test the validity of biomarkers
- Gel electrophoresis
- Capillary electrophoresis
- Western blot analysis
- Amino acid analysis
- Sugar analysis
- Glycan analysis
- Residual host cell protein detection
- Peptide mapping
- Protein content determination
- Cell-based bioassays
- ELISA

Instrumentation

- HPLC: UV-Vis, RI, FLD, ELSD, GPC, IC
- LC-MS/MS (AB Sciex API 4000)
- GC-MS
- ICP-MS
- Ultra-centrifuge
- Automated capillary electrophoresis
- Plate reader (Tecan Safire)
- UV-Vis spectrophotometer
- Post column amino acid derivatization system

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FACILITY

We have a dedicated team of scientists and technicians working in specialized state-of-the-art facilities to meet your program's specific requirements and timelines. We deliver results quickly, accurately, and cost-effectively. Your samples will be handled with the utmost care, expertise, and confidentiality.

Complete Package of Services

- Formulation Development
- Analytical Development
- Bioassay Services
- Specialty Analytical Services
- Extractables and Leachables
- Stability Studies
- Impurity Identification
- Structure Elucidation
- Drug Delivery Technologies

