BIOANALYTICAL SERVICES

Discovery • Preclinical and Nonclinical • Clinical Study

Well-developed, validated bioanalytical methods that maintain continuity from preclinical through clinical development are of paramount importance for the success of any drug development program. We offer high-quality bioanalytical services from GLP-compliant, IND- and NDA-enabling toxicology studies through clinical trial sample analysis. All work conducted at a single location ensures secure sample handling and efficient coordination of activities.

IITRI's highly experienced analytical scientists are routinely tasked with providing robust and reliable analytical method development and support for even the most difficult projects. Drawing on our 40 years of expertise in working with regulatory agencies, we provide FDA-compliant, customized analytical chemistry, molecular biology, and immunology laboratory support across a wide range of test article types and tissue matrices.

BIOANALYTICAL SERVICES

- Method development and validation
- Method transfer and verification
- Dose formulation analysis
- Bioavailability studies
- Biodistribution and bioequivalence
- Clinical trial sample analysis

SMALL MOLECULES

- Preformulation analysis
- Radiolabeled compound analysis
- *In vivo* ADME studies
- Pharmacokinetics
- Pharmacodynamics
- Toxicokinetics

INSTRUMENTATION

- TomTec Quadra 3® Automated 96-well SPE System
- AB SCIEX 6500 LC-MS/MS
- AB SCIEX 4000 LC QTRAP
- Waters and Agilent HPLC Systems
- Capillary Electrophoresis
- Bruker Fourier Transform Infrared Analysis
- Bio-Rad CFX384 Touch Real-Time qPCR Detection System
- BD FACSCelesta™ Flow Cytometer, 14-parameter multi-color

BIOLOGICS AND VIRAL VECTORS

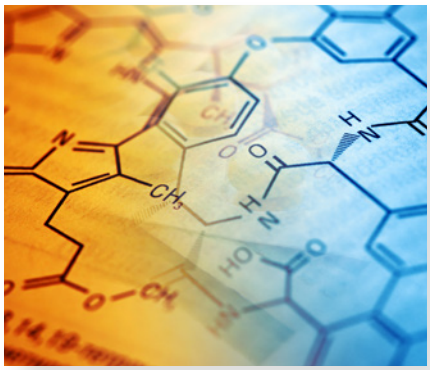
- Vector quantitation
- Transgene quantitation
- Anti-drug antibody (ADA) assays
- Neutralizing antibody (NAb) assays
- Immunophenotyping
- Viral vector infectivity assays

THE IITRI ADVANTAGE

- Highly experienced analytical chemistry team with BS-degreed technicians
- Expert molecular biology and immunology scientific team for the design and execution of molecular assays
- Demonstrated success in analysis of small molecule method development for even the most difficult drug candidates and complex tissue matrices
- All methods conform to regulatory guidelines and sponsor requirements
- Personalized attention and flexible communication that imparts the culture of a true partnership

IITRI

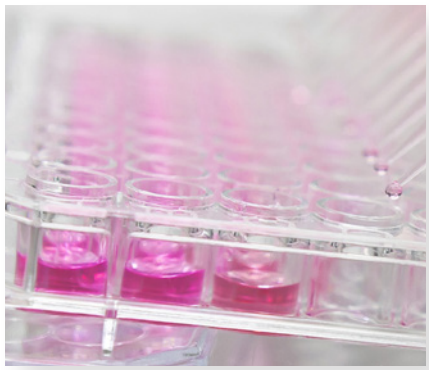
CORE SERVICES



DISCOVERY & DEVELOPMENT

Our team of analytical scientists has extensive experience in the development, transfer and optimization of bioanalytical methods for validation and reliable use throughout the study.

- Pre-formulation studies
- Method development, validation and cross-validation for different species
- PK screening
- Immunogenicity testing
- Assessment of biomarkers



BIODISTRIBUTION

Biodistribution studies determine the fate of the small molecule, biologic, or gene therapy treatment after administration.

- Quantitation of drug in tissues and fluids
- Radiolabeled drug analysis
  - Mass balance
  - Metabolite identification
- Viral vector quantitation
  - qPCR
  - RT-qPCR

TOXICOLOGY/IMMUNOGENICITY

Bioanalysis of tissue and fluid samples correlate toxicities to drug levels during toxicology studies. Immunogenicity assays detect immune responses to biologics.

- Dose formulation analysis
- Quantitation of drug in tissues and fluids
- Immunogenicity
  - ADA ELISA
  - Cytokine panels
  - NAb analysis

CLINICAL TRIAL SUPPORT

Analysis of human clinical trial samples maintains continuity in bioanalytical support.

- Bioanalytical method cross-validation
- Clinical sample analysis
- Pharmacokinetics
- Analysis of cytokine expression
- Assessment of biomarkers

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