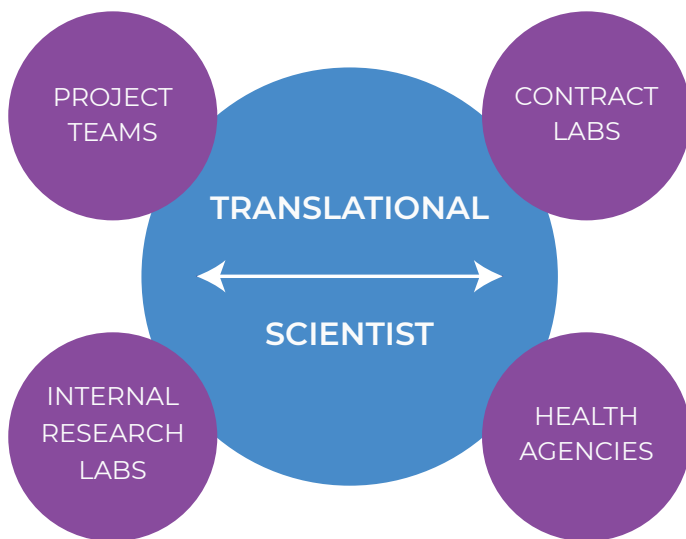


TRANSLATIONAL SCIENCES

Designed By Drug Developers, Run By Drug Developers

OUR EXPERTISE

- Biomarker, bioanalytical and clinical research strategies
- Regulatory interactions and document writing
- Scientific oversight of assays and life cycle management
- Study data analysis and interpretation



Translational Strategy

Project-specific bioanalytical and biomarker strategies for all stages of drug development

Scientific Execution

Hands-on guidance & oversight of bioanalytical and biomarker projects

Regulatory Engagement

Expertise in regulatory filings & effective regulator interactions

Translational Sciences Leadership

Lauren Stevenson, PhD - CSO & Co-Founder

Devangi Mehta, PhD - Executive Director & Co-Founder

Chris Stebbins, PhD - Scientific Director

John Allinson, FIBMS - VP of Biomarker Sciences



*Translational Sciences is based in
the Greater Boston Area*



BIOMARKER EXPERIENCE

Individual Analytes (updated regularly)*

anti-KLH IgG	IL-1 β / leukocytic pyrogen	MIP-1 β
anti-KLH IgM	IL-2/TCGF	Neurogranin
CCL-24/Eotaxin-2	IL-2Ra/CD25	NF-H
CXCL13	IL-4	sCD40
Eotaxin 1/CCL11	IL-5	sCD40-Ligand
Eotaxin-3/CCL26	IL-6	sCD73/5NT
GM-CSF/CSF2	IL-7	NF-L Ultrasensitive
IFN- γ	IL-8 (HA)	Placental Growth
IL-10/CSIF	IL-8	Factor (PIGF)/PGF
IL-12/IL-23p40	IP-10	TARC/CCL17
IL-12p70	MCP-1	TNF-b
IL-13	MCP-4/CCL13	TNF- α
IL-15	M-CSF/CSF1	Transthyretin (TTR)
IL-16/LCF	MDC/CCL22	VEGF
IL-17a	MIP-1 α	
IL-1a		

Multiplex Panels*

- V-Plex Chemokine Panel 1
- V-Plex Cytokine Panel 1
- V-Plex Pro-Inflammatory Panel 1
- V-Plex Th17 Panel
- V-Plex Abeta Peptide Panel 1
- V-Plex Neuroinflammation Panel 1
- V-Plex Angiogenesis Panel
- V-Plex Vascular Injury Panel
- V-Plex NHP Cytokine Panel
- Multiple Luminex Panels - please enquire
- Multiplex and Multianalyte ELLA Panels

** Experience with many additional biomarker assays*



EQUIPMENT PLATFORMS

Mesoscale Discovery Sector
Imager 600

Spectramax - L -
Luminescence

Luminex Flexmap 3D

Perkin Elmer Envision -
Fluorescence

ProteinSimple
ELLA

Hamilton Starlet

Spectramax 384 -
UV/VIS

CytoFLEX S
Flow Cytometer



Diseases/Therapeutic Areas

- Allergy
- Anemia
- Bone Metabolism
- Cardiovascular
- Diabetes
- Growth
- Inflammation
- Immunology
- Metabolic
- Endocrinology
- Apoptosis
- Neuroscience
- Oncology
- COPD

BIOMARKER SCIENCES



OUR EXPERTISE

- Globally recognized Key Opinion Leaders and authors
- Context of Use Strategies and Validations
- Emphasis on endogenous QCs and Parallelism
- Pre-analytical sample considerations
- Collaborations with platform developers



Dedicated Biomarker Laboratory

- Designed and built for large molecule biomarker assays
- Commercial kit optimization
- Multiplexing expertise
- Dedicated Critical Reagent team



De novo Assay Strategies

Target Engagement

Mechanistic

Pharmacodynamic

Disease Specific

Ex-vivo Stimulation

FACILITIES

*Designed and built for large molecule
bioanalytical and biomarker sciences*



Dedicated Laboratory Spaces

- 19,000 square feet of laboratory
- Ligand binding assays
- Cell-based assays
- Flow Cytometry
- Quantitative PCR
- Critical Reagent Services
- Clinical and Preclinical Biomarker assays
- Sample handling and storage with 24 hour monitoring systems



Secure Building Facilities

- 14,000 square feet of office and meeting space
- Diesel generator backup system
- Restricted electronic card access to laboratory and sample storage space
- Validated specimen storage monitoring system
- Secure on-site Archival storage and data storage
- End-to-End Informatics Platform



Support Teams

- Critical Reagent characterization and qualification
- Quality Control
- Data Systems
- IT Systems
- Quality Assurance
- Document Control
- Sample receiving, handling, and operations
- Finance and Accounting

IMMUNOGENICITY



OUR EXPERTISE

- Critical Reagent characterization
- Consistent, thorough Method Development process
- Performance characteristics meet/exceed regulatory requirements
- Performance Evaluation to assure successful validation
- Assay Validation
- Sample Analysis for Pre-clinical and Clinical studies
- Cloud-based Project Management Informatics
- Customized communication processes



Ligand Binding Based Immunogenicity Assays

- Custom drug labeling
- PC characterization
- Optimal MRD and drug tolerance
- ACE and SPEAD adapted methods



Method Development

Focus on the most clinically relevant aspects of assay

Performance characteristics meet regulatory requirements

Dedicated Method Development expert team with systematic transfer to production

CELL BASED ASSAYS



Range of Cell Based Assays

- Neutralizing Antibody
- Mechanism of action studies
- Apoptosis and Cell Death
- Cell Signaling and Secretion
- Reporter Gene Assays
- ADCC & CDC Assays
- Ready to go cell assays



Dedicated Cell Laboratory & Team

- Cell Based Assay Experienced Scientists
- Master and Working Cell Banking and Monitoring
- Validated Instrumentation
- Class II Biosafety Cabinets
- GxP Compliant Practices
- Clinical and Pre-clinical assays



INSTRUMENTS USED

Zeiss Axiovert 25 Microscope

Beckman Coulter Vi-Cell
Blu Hemocytometer

Labconco Logic+
Biosafety Cabinets



CRITICAL REAGENT ANALYSIS



OUR EXPERTISE

- Critical Reagent Labeling, Characterization, and Qualification
- Lot-to-Lot Bridging and stability
- Biomarker Calibrator Material Characterization and Stability
- Recombinant Protein Characterization (eg. transgene proteins)
- Pre-Assay Binding assessment



Protein Analysis Expertise

- Protein Concentration
- FPLC analysis including:
 - Purity of Preparation
 - Degradation analysis
 - Aggregation Status
- Confirmation of successful incorporation for conjugated chromophores



Custom Antibody and Protein Labeling

- Biotin and Sulfo-tag protein labeling with multiple challenge ratios
- Small Quantity (≤ 5 mg) and Large Quantity (> 5 mg) capabilities
- 1-2 Days + QC Review of documentation
- Four Service Tiers to Meet Needs at Different Stages of Drug Development
- Reagent Services reports

CRITICAL REAGENT SERVICES – TIER MATRIX

Service	Pilot¹	Tier I	Tier II	Tier III
Scale (per label)	<0.5mg	up to 10mg	up to 10mg	up to 10mg
Buffer Exchange (if necessary)	x	x	x	x
Concentration/ %Recovery	x	x	x	x
Conjugation				
Biotin	x	x	x	x
Ruthenium	x	x	x	x
DIG	x	x	x	x
Post-Conjugation Cleanup	x	x	x	x
Concentration / %Recovery	x	x	x	x
Label Incorporation				
HABA Assay	x	x	x	x
MSD Cuvette Test	x	x	x	x
FPLC-SEC Analysis				
Pre-Conjugation	x	x	x	x
Post-Conjugation	x	x	x	x
Purification on FPLC ²				x
Kinetics Testing (Octet) ^{2,3}			x	x
Quantitation Testing (Octet) ^{2,3}				x
Dilution/Aliquot of Reagent(s)		x	x	x
Final Report		x	x	x

¹ Pilot reagent labeling includes basic characterization (nonGLP/exploratory) with no report. Limited to 3 conditions maximum.

² Services reflect those which may be specifically requested if client preference or assay performance dictates necessity.

³ Additional pass-through costs are applicable as needed (columns, sensors, etc.).

BIOANALYTICAL SCIENCES



OUR EXPERTISE

- Critical Reagent characterization
- Consistent, thorough Method Development process
- Performance characteristics meet/exceed regulatory requirements
- Performance Evaluation to assure successful validation
- Assay Validation
- Sample Analysis for Pre-clinical and Clinical studies
- Cloud-based Project Management Informatics
- Customized communication processes



Ligand Binding Based Quantitation Assay Formats

- Drug target capture
- Anti-drug idiotype capture
- Double antibody sandwich assay



Method Development

Focus on the most
clinically relevant aspects
of assay

Performance
characteristics meet
regulatory requirements

Dedicated Method
Development expert team
with systematic transfer to
production

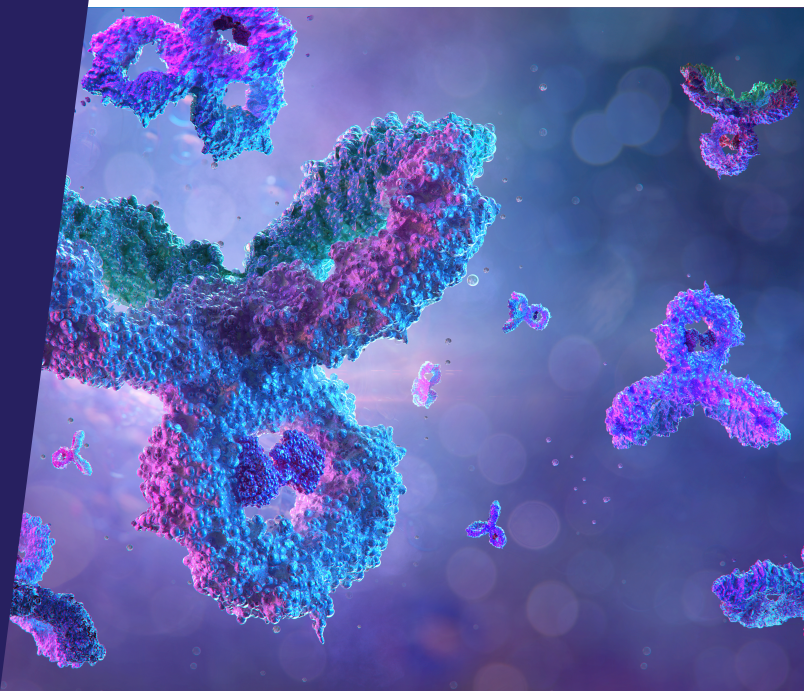
LEADERSHIP TEAM



GLOBAL IMPACT ON INDUSTRY

Authorship on Key Industry White Papers:

- GBC Bioanalysis
- Biomarker validation
- Application of Parallelism
- Commercial kit validation
- Multiplexing biomarkers
- Reference standards for biomarkers



THE TEAM

Michael Anderson, Ph.D.

President & Chief Executive Officer
manderson@immunologixlabs.com

Lauren F. Stevenson, Ph.D.

Chief Scientific Officer & Head -
Translational Sciences
lstevenson@immunologixlabs.com

Jason Ambrosius

Vice President - Bioanalytical Sciences
jambrosius@immunologixlabs.com

John Allinson, FIBMS

Vice President - Biomarker Sciences
jallinson@immunologixlabs.com

Corinna Fiorotti, Ph.D.

Executive Director - Translational Sciences
cfiorotti@immunologixlabs.com

Linda A. Terry, Ph.D.

Executive Director - Biomarker Sciences
lterry@immunologixlabs.com

Lydia Shaffer, RQAP-GLP/GCP

Director - Quality Assurance
lshaffer@immunologixlabs.com

John Ryan

Executive Director - Business Development
jryan@immunologixlabs.com

GENE & CELL THERAPY



OUR EXPERTISE

- Pharmaco/Cellular Kinetics for *In Vivo* and *Ex Vivo* Therapies
- Toxicity Assessments
- Immunogenicity
- Biodistribution



MODALITY EXPERIENCE

CAR-T

NKs

TCR

AAV

TILs



INSTRUMENTS USED

QuantStudio™ 7 Pro
Real-Time PCR

CytoFLEX S
Flow Cytometer

KingFisher™ Flex
Purification System

