



AIT Bioscience

Transforming the Process. Partnering for Results.

BIOANALYTICAL SOLUTIONS FOR BIOTHERAPEUTICS AND SMALL MOLECULE THERAPEUTICS

IMMUNOGENICITY/ANTI-DRUG
ANTIBODY ASSAY (ADA) CAPABILITIES

Advantages

- Statistically sound approach that exceeds FDA expectations
- Standalone statistical cut point report detailing the procedures and data to establish the cut point
- Anti-Drug Antibody experience on multiple assay platforms and designs (Direct binding, colorimetric, Radio-Immunoprecipitation assay, MSD (Direct and Bridging))
- Intelligent, forward-looking assay design that can readily be translated from preclinical to clinical phase of development
- Risk based approach to preclinical and early phase clinical ADA assay support
- Partnership with a statistically-focused third party industry leader

Types of molecules supported:

- Fusion proteins
- Recombinant proteins
- Antibody-Drug Conjugates (ADCs)
- Pro-bodies
- Peptides
- Multi-domain antibodies
- Various Insulin derivatives

Key equipment:

- MSD (Meso Scale Discovery) Electri-chemi luminescence
- Gamma Counter (for Radio Immuno-precipitation assay)
- Colorimetric plate reader
- ViCell Cell counter
- Temp and CO2 level monitored Incubators

Our Differentiators



- No “one-size-fits-all” approach to ADA:

- Each assay is designed to meet the needs of the study and therapeutic indication (disease state) of the drug candidate.
- Robust Cut-Point experiments across disease states and potential study subjects to identify statistical and biological outliers



- Statistics based approach to:

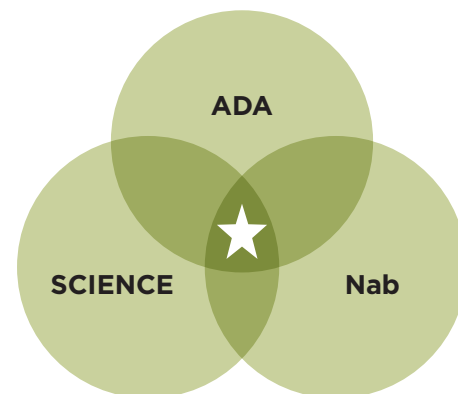
- Cut-point determination
- Assay design



- Capabilities to support Neutralizing Antibody assays:

- Cell based
- Plate based

Integrated Science & Technology



Learn more at www.aitbioscience.com or contact us at 317-715-8800 to see how we can provide you with bioanalytical solutions for biotherapeutics and small molecule therapeutics.