



**AIT Bioscience**

*Transforming the Process. Partnering for Results.*

## BIOANALYTICAL SOLUTIONS FOR BIOTHERAPEUTICS AND SMALL MOLECULE THERAPEUTICS

### NEUTRALIZING ANTIBODY (NAB) DETECTION 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

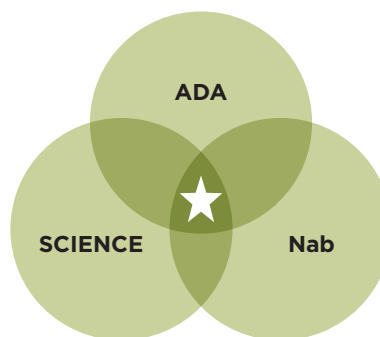


- **Cell-Based Nab Assay Design**
- Coordinated, client-centric approach to the development of cell-based Nab assays that is cost-efficient:
  - Selects a suitable, stable cell line that produces a measurable response to the Therapeutic; system used produces the appropriate sensitivity level and dynamic range needed to measure the response
  - Determines if the Cell-Based assay is reflective of the Therapeutics mechanism of action in the in-vivo system
  - Identify the positive control antibody for the Nab, which will neutralize the therapeutics' cellular effect
  - Negative control
  - Therapeutic control
- Each control is used to help validate a different aspect of the assay and provides information to confirm results



- **Nab assay Cellular responses monitored here at AIT Bioscience**
- Receptor binding
- Receptor phosphorylation
- Detection of cAMP or ATP
- Signal transduction-specific protein phosphorylation
- Cellular proliferation or apoptosis
- Cytokine production

#### Integrated Science & Technology



Learn more at [www.aitbioscience.com](http://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.