



Immunogenicity Services

As an experienced leader in the field of immunogenicity testing, the Pharmaron US team understands the complexities related to immune responses which have the potential to affect a product's pharmacokinetics, pharmacodynamics, safety, and efficacy. Whether at a humoral level for antidrug antibodies (ADA) and neutralizing antibodies (NAb) or looking at cellular immune responses to specific antigens, we can help identify the optimal platform and methodologies to provide high quality reliable results.

Capabilities

Technology Platforms

- Ligand binding assays (ELISA)
- Fluorescence- and luminescence-based assays
- ELISpot and FluoroSpot
- Meso-scale discovery (MSD)
- Luminex
- Flow cytometry

Services

Humoral Immune Response

- Anti-drug antibodies – identification and titration of total binding antibodies
- Neutralizing antibodies - assessment of ADAs for neutralizing activity
 - Cell-based transduction inhibition
 - Plate-based ligand binding
 - *in vivo* transduction inhibition

Cellular Immune Response

- Peripheral blood mononuclear cell (PBMC) assays to detect cellular responses against the test agent, detection of secreted immune molecules or protein of interest (e.g., interleukins and cytokines)
- Quality PBMC preparations for analyzing antigen-specific cells
- Optimal concentration of each peptide pool

Multi-Tiered Approach per FDA Guidelines

- Screening assay for presence of any ADA
- Confirmatory assay to verify positive samples
- Titration to determine antibody titer
- Neutralizing assay, NAb titers
- ADA characterization for isotyping, epitope specificity, cross reactivity

