PRECISION for medicine

Immunogenicity Testing Services

Precision for Medicine provides one of the most comprehensive and advanced capabilities for executing agency requirements throughout preclinical and clinical development.

The Precision team includes globally renowned experts in immunogencity who have led industry and agency working groups to formulate risk-based strategies for addressing these critical safety concerns. Our team has been centrally involved in the creation of seminal white papers that are widely considered to be the basis of agency guidance documents.

Today, Precision continues to push the forefront of immunogenicity assessments. We have worked with dozens of clients addressing some of their most difficult challenges, and have facilitated communication with agencies to respond to evolving concerns. This includes the evaluation of complement activation and IgE response in the case of hypersensitivity, and evaluation of immunogenicity for "newer" biological products such as gene therapies.

Product types

- Small peptide
- Recombinant protein
- Monoclonal antibody
- Bispecific antibody
- Antibody-drug conjugate
- Biosimilar
- PEGylated protein
- Gene therapy (multiple AAV serotypes)

Assay types

- Screening Anti-Drug Antibody (ADA) assay
- Confirmatory ADA assay
- Neutralizing ADA assay (functional cell-based and non–cell-based)
- Specialty assays (IgE, complement)
- Specialty techniques (acid dissociation, SPEAD)
- Custom PK assays to support a comprehensive bioanalytical strategy
- Fully compliant (CLIA) cell-based NAb assays for AAV for companion diagnostic and commercial use

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Precision's Comprehensive Immunogenicity Monitoring Solution

While our offering includes method development or transfer, validation, and sample testing, our approach begins with a thorough strategic assessment of the need and any gaps in terms of critical reagents and ability to validate.

Assay Development Strategy	1 Recommendation for production of positive control antibodies (critical PK/ADA assay reagent) 2 Selection of optimal assay formats/platforms for binding antibodies 3 Selection of optimal assay formats for neutralizing antibodies 4 Design of appropriate monitoring strategies
Routine Implementation	5 Assay development/validation plans and reports (PK, ADA, NAb) 6 Characterization of anti-drug antibody responses, including NAb assays under CLIA for patient screening 7 Sample collection time points, frequency, and duration of ADA testing
Unique Specialty Immunogenicity Offerings	8 Specialty assays (eg, functional IgE assay, anti-PEG IgE, and IgM) 9 Detection of circulating B-lymphocytes producing ADA 10 Detection of drug-specific immune complexes and complement activation 11 Binding of ADA to aggregated drug 12 Clearance of immune complexes

End-to-End Support

Precision can address your immunogenicity needs from concept through phase 3.

- Unparalleled scientific leadership
- Fit for purpose – design, qualify, validate (GLP, GCLP, CLIA) the right assays at the right time
- Global scale – logistics to support global sample collection and storage in a 65,000-square-foot state-of-the-art CAP-accredited and ISO-certified facility

For more information on our immunogenicity testing services, please contact us at info@precisionformedicine.com, or visit precisionformedicine.com.

PRECISION for medicine
shift the curve

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