

## Immunogenicity Testing

Biologics such as therapeutic antibodies, cytokines and growth factors may lead to unwanted immunogenicity when administered in humans. Development of anti-drug antibodies (ADA) can lead to allergy or induction of autoimmunity, and may result in a reduction in efficacy. Thymed's Visualizing Immunity™ platform provides assays for determination and characterization of both wanted and unwanted immunogenicity in the context of ADA as well as epitope-specific T-cell responses. Thymed's assays enable clinical evaluation of biologics and their generic versions, as well identification and validation of immunogenic epitopes in peptides and proteins.

The assays enable assessment of both antibody and cellular immune responses following therapy and encompass many standard tests as well as a diverse and powerful whole blood assay. The whole blood assay permits ex vivo analysis of immunogenicity in donor/patient whole blood in both clinical and preclinical settings.

Assays suitable for immunogenicity testing include, but are not limited to:

- Anti-drug antibody ELISAs
- Neutralising-antibody assays
- Whole blood assay
- Multiplex microbead arrays (TH1/TH2 cytokines, chemokines, cardiovascular markers)
- Cellular immunophenotyping
- Tetramer analysis
- ELISpot
- Cell-mediated immunology testing and functional assays
- iTOPIA™ MHC Class I epitope discovery & mapping
- MHC Class II epitope discovery & mapping (high density peptide microarray)
- Antibody epitope mapping & validation (high density peptide microarray)

### The Essentials

- **Material Requirements** - assay dependent - please enquire
- Suitable for **R&D, Preclinical and Clinical Phases I to IV**
- Detects unwanted **Immunogenicity**
- Confirms **Immunological Safety** of drug, therapeutic or vaccine
- Permits **Identification of Immunogenic Epitopes** prior to clinical development
- Enables detailed **Characterization** of immune response and potential identification of companion biomarkers/diagnostics

These help you define and visualize both wanted and unwanted immune responses to your novel vaccine, therapeutic or pharmaceutical, thereby empowering you in your decision-making process and providing crucial information for regulatory authorities, in all phases of clinical development.



Located 45mins from Frankfurt International Airport, in the heart of Europe, Thymed boasts excellent logistics. Thymed's well-equipped, state-of-the-art laboratories and specialty testing services are ISO 9001 certified and conform to GLP.