

Immunogenicity & Pharmacokinetic Assays

BioGenes has significant experience in the development of ELISAs for the detection of anti-drug antibodies and quantitative ELISAs used in PK studies. Our scientific team specializes in complex immunoassays and demanding antibody development.

Sandwich ELISA for Pharmacokinetic (PK) Testing

BioGenes develops highly sensitive sandwich immunoassays used to detect and quantify biologics and biosimilars in human serum samples. You can use these assays for your PK studies and routine drug monitoring.

Immunogenicity ELISA as Screening Test for Detection of Anti-Drug Antibodies (ADAs)

BioGenes offers the development of highly sensitive ELISAs for the detection of ADAs in human serum samples. Based on the special bridging format, these ELISAs provide superior detectability of immune-complexed ADAs.

Assay Services:

- In-house Ab Development
- Pair Search
- ELISA Method Development
- ELISA Optimization
- Testing of Matrix Effects
- Method Transfer to GLP Lab

→ *Discuss your project with us today!*

Tools for Testing of Biosimilars

Testing of biosimilars is a complex approach, which involves comparative PK immunoassays and immunogenicity assessment. BioGenes' anti-idiotypic antibodies are very useful tools for these purposes.

Pre-Qualified Assays for Testing of Biosimilars to Adalimumab and Infliximab

BioGenes has developed pre-qualified PK and immunogenicity ELISAs for Adalimumab and Infliximab. These assays can easily be adapted to individual biosimilars. Thereby, BioGenes provides biosimilar developers the opportunity to quickly and cost effectively investigate the PK and immunogenicity profile of their antibody-drug candidate compared to Adalimumab and Infliximab.

Antibody Development for Biosimilars

For all biosimilars to other therapeutic antibodies, BioGenes offers the generation of anti-idiotypic antibodies (Anti-IDs) for the development of ELISAs. BioGenes is an expert manufacturer of Anti-IDs and has successfully generated Anti-IDs against different types of antibodies, e.g. human, humanized and chimeric antibodies.

Pre-Qualified Immunoassays:

- Adalimumab (Humira®)
- Infliximab (Remicade®)

Services:

- Antibody Development (MAb, PAb)
- Anti-Idiotypic MAb
- Pair Search & Matrix Effects
- Drug Labeling

→ *Discuss your project with us today!*
