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Immunogenicity Testing

What is immunogenicity?

Immunogenicity is the property of a substance to elicit a humoral and/or cell-mediated immune response in an organism. Immune responses to therapeutic protein products and anti-drug antibody (ADA) formation may impair product efficacy and compromise patient safety. Altering pharmacokinetics, neutralizing the biological effect of the drug or cross-reaction with its endogenous counterpart are the main adverse clinical effects of ADAs.

What is our approach?

The immunogenicity assessment for therapeutic proteins and peptides is a key scientific expertise of Eurofins Munich. Immunogenicity measurements are complex as they are dependent on drug- and disease-specific aspects. Therefore, we select the appropriate immunogenicity assay strategy according to client-specific requirements while adhering to current guidelines.

Eurofins Munich offers the complete immunogenicity assessment for protein therapeutics, including

- Method Development
- Method Transfer
- Validation (in compliance with GLP requirements)
- Sample Analysis (in compliance with GLP/GCP requirements)

Method Development

To provide the best analytical solution, we develop assays that have analytical ranges appropriate for the expected study samples and assess method feasibility using multiple technology platforms.

Method Transfer

Transfer and optimization of non-validated or validated client-developed assays.

Validation

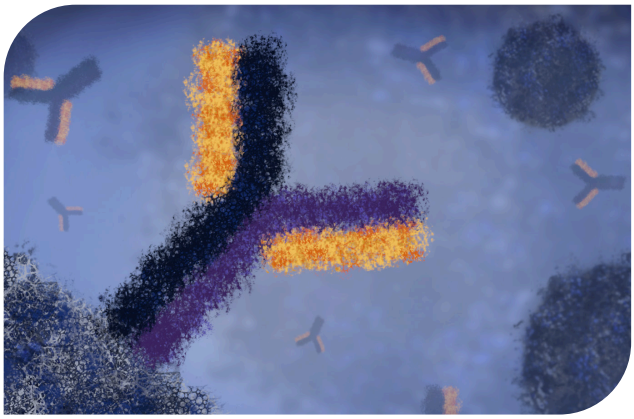
Validation of analytical methods is crucial in order to generate data to support regulatory submissions. In compliance with GLP requirements and current EMA/FDA guidelines, we offer a fully comprehensive assay validation or cross-validation service.

Sample Analysis

We support your clinical study by applying a tiered immunogenicity testing methodology accompanied with data analysis in compliance with GLP/GCP standards.

Assay formats we routinely use to measure ADAs are:

- Screening assay
- Confirmatory assay
- Titration assay
- Neutralization assay
- Characterization assays (e.g. Isotype)



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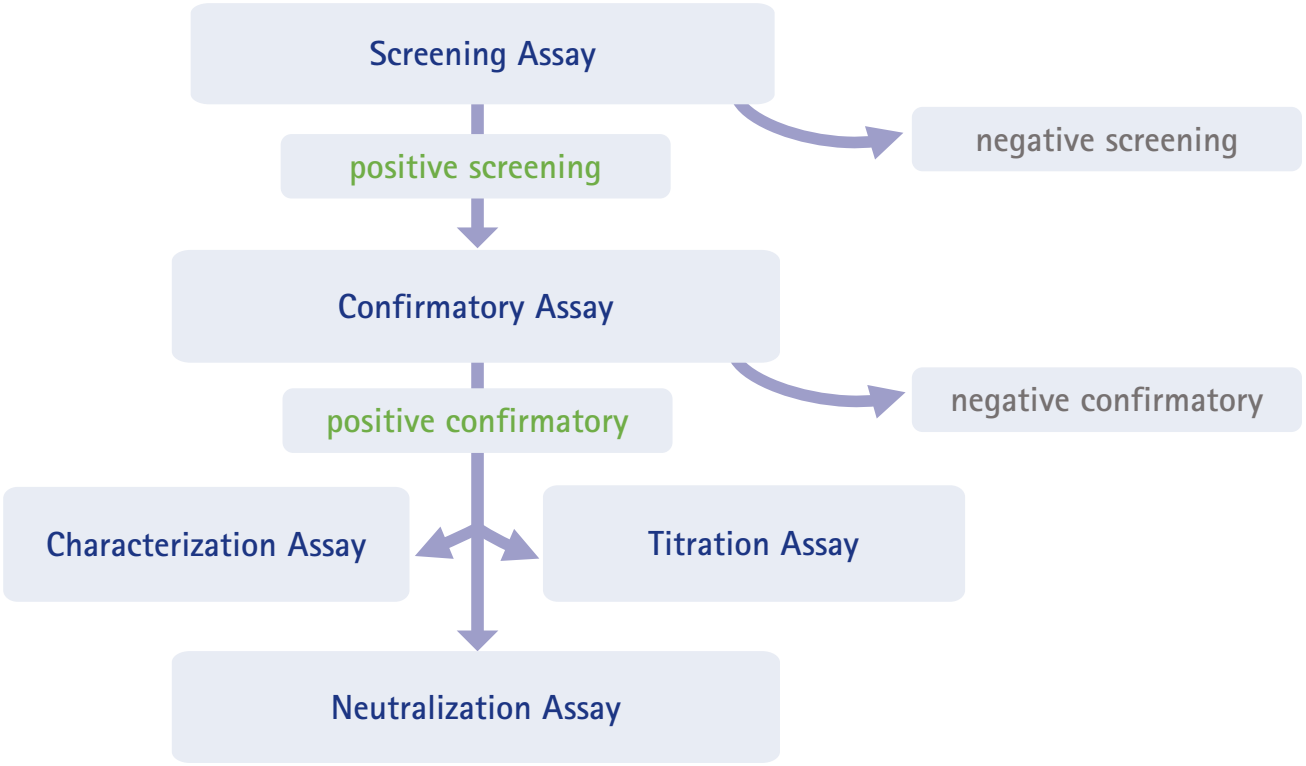
Tiered Immunogenicity Approach



The ADA analysis is usually performed in a tiered approach starting with the detection of binding antibodies in a screening assay. Screening for ADAs is typically conducted using ELISA-based formats. A bridging assay is preferred since such method can be applied to immunogenicity testing in any host species. Thus, the same approach can be used for early animal studies and human clinical studies. Positive screened samples have to be analyzed in a confirmatory assay. The same screening assay is used for the confirmatory step, e.g. by demonstrating inhibition of binding by excess of the drug. Confirmed positive ADA samples are further characterized for their neutralizing capacity, titer, isotype and other characteristics to understand the relevance of ADA formation. Neutralization assays are used to specifically detect the presence of ADAs that interfere with the activity of the therapeutic protein. These neutralizing antibodies can be measured by cell-based assays or by competitive ligand binding (inhibitory) assays.

Any questions? Please contact us at

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