eurofins | BioPharma Product Testing

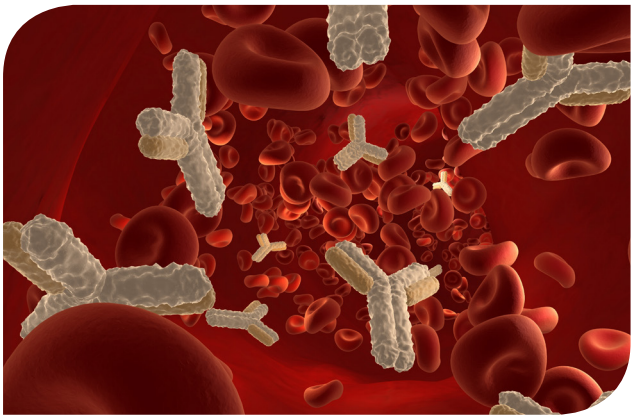


Immunogenicity Testing

Eurofins BioPharma Product Testing is an internationally active Contract Research Organization (CRO) offering comprehensive services in biological safety and activity testing.

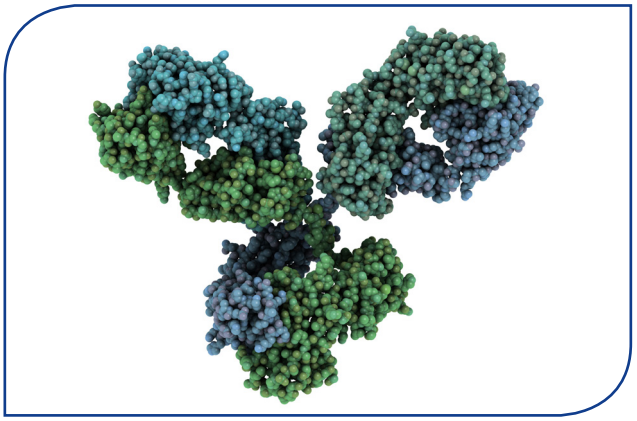
In support of pre-clinical and clinical trials the Immunoanalytics Department of Eurofins Munich contributes to biomarker analyses, pharmacokinetic studies, and the assessment of immunotoxicity and immunogenicity.

The measurement of unwanted immunogenicity of therapeutic proteins and peptides is a key scientific expertise of Eurofins Munich. The measurement of adverse immune reactions is complex as it depends on many drug- and disease-specific aspects. Therefore, the appropriate immunogenicity assays and assay strategies are selected according to client-specific requirements.



Immunogenicity is the property of a substance to elicit a humoral and/or cell-mediated immune response in an organism. Immune responses to clear true infections are wanted. This mechanism is utilized for vaccines, where robust responses against the pathogen are desired. In contrast, immune responses to therapeutic protein products may be undesired when the reaction can negatively influence the impact of the drug. These unwanted side effects of drug administration due to anti-drug antibody (ADA) formation are able to pose problems for both patient safety and product efficacy.

It is an issue relevant for medical, scientific as well as regulatory affairs that the induction of ADAs may lead to diverse clinical consequences. Altering pharmacokinetics, neutralizing the biological effect of the drug or cross-reaction with its endogenous counterpart are the main clinical effects of ADAs.



The ADA analysis is done in a tiered approach starting with the detection of binding antibodies in a screening assay. Screening for ADAs is usually done using ELISA-based formats. A bridging assay has been preferred since such method can be applied to immunogenicity testing in any host species. Thus, the same assay can be used for early animal studies and clinical studies in humans.

Positive screened samples have to be analyzed in a confirmation assay. The same screening assay is used for the confirmation 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, isotyping 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 are ADAs with neutralizing capacity and can be measured by cell-based assays or by competitive ligand binding (inhibitory) assays.

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

- Method Transfer
- Method Development
- Validation
- Sample Analysis

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Method Transfer

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

Method Development

To provide the best analytical solution for the broadest range of matrices and species, we develop assays that have analytical ranges appropriate for what is expected in the study samples and assess method feasibility in multiple technology platforms.

Validation

Validation of analytical methods is crucial in generating data to be used in support of regulatory submissions. Following GLP and the most up-to-date industry guidelines and white paper, we offer a fully consultative and comprehensive assay validation or cross-validation service.

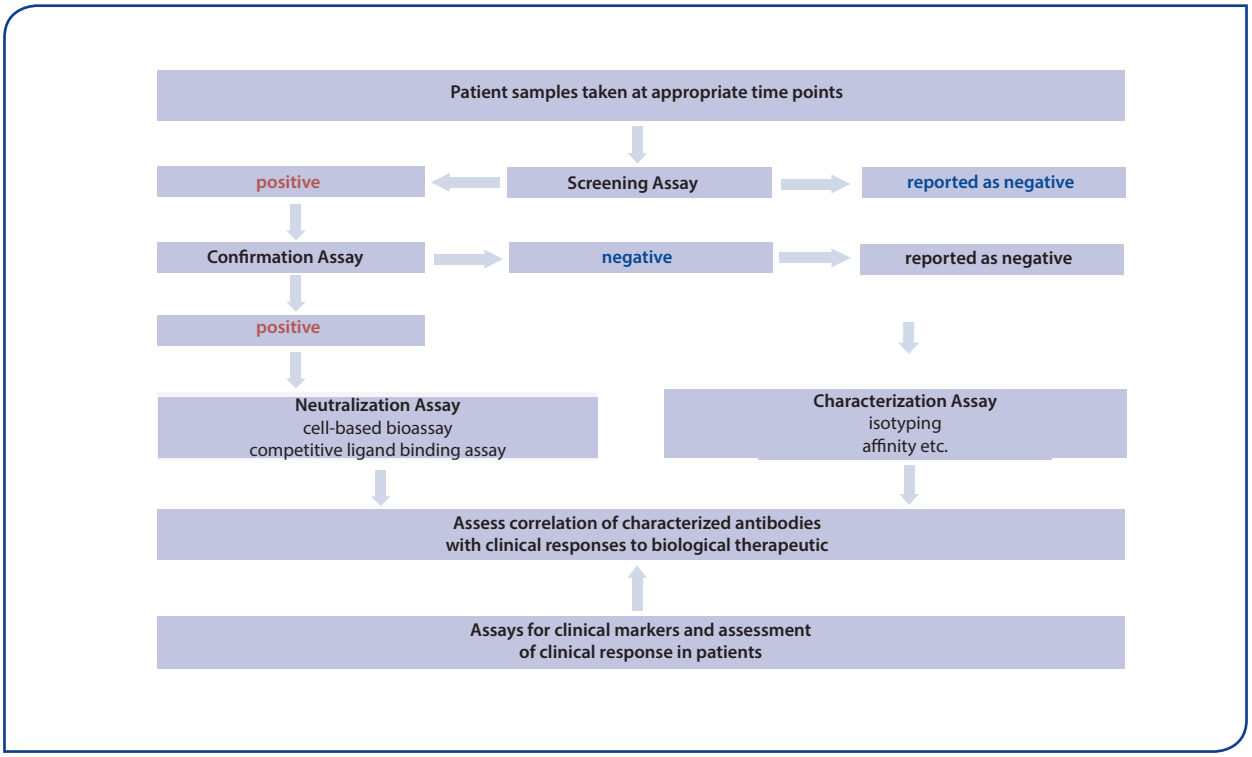
Samples Analysis

We apply a tiered immunogenicity testing methodology accompanied with statistical data analysis and support following GLP/GCP standards. The steps we use to measure ADA are:

- Screening assay
- Confirmatory assay
- Neutralization assay
- Characterization assays (Isotype etc.)

Biosimilar Assay Development & Testing

Additionally, Eurofins Munich offers customized immunogenicity assays for both the comparability testing of the biosimilar drug and the testing of its clinical performance.



Any questions? Please contact us at info-munich@eurofins.com.

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With more than 25 Laboratories in 13 countries, Eurofins BioPharma Product Testing is the largest network of harmonized bio/pharmaceutical GMP product testing labs worldwide.

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