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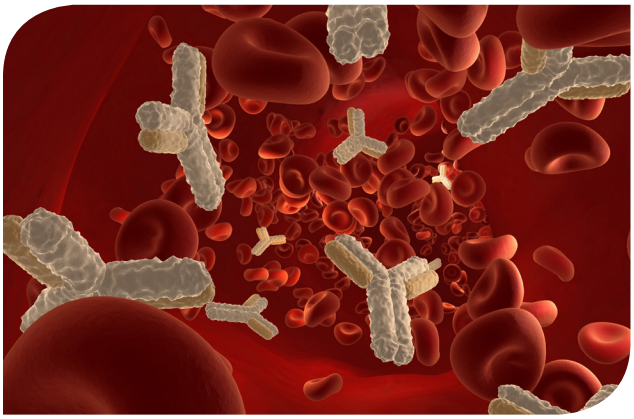
Immunogenicity Testing

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

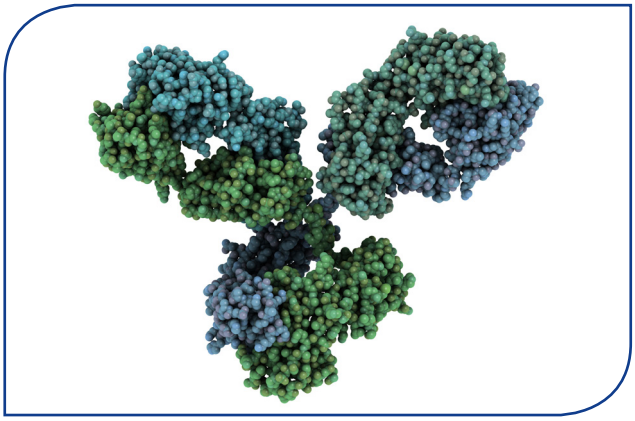
In support of pre-clinical and clinical trials the Immunoanalytics Department of **Eurofins BioPharma Product Testing Munich GmbH** contributes to biomarker analyses, pharmacokinetic studies, and the assessment of immunotoxicity and immunogenicity.

The measurement of unwanted immunogenicity of therapeutic proteins and peptides is a key scientific expertise of **Eurofins BioPharma Product Testing Munich GmbH.** 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 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 can 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-based approach starting with the detection of binding antibodies in a screening assay resulting in a 5 % false positive rate for clinical use. 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 BioPharma Product Testing Munich GmbH offers the complete immunogenicity assessment for protein therapeutics covering immunoassays as well as cell-based neutralization assays in a GLP-certified laboratory. For customized analyses, an approach consisting of method development, optimization and validation, followed by sample analysis under GLP can be applied.

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Our immunogenicity testing strategy comprises a broad range of assay types and is continuously updated according to regulatory guidelines and white papers.

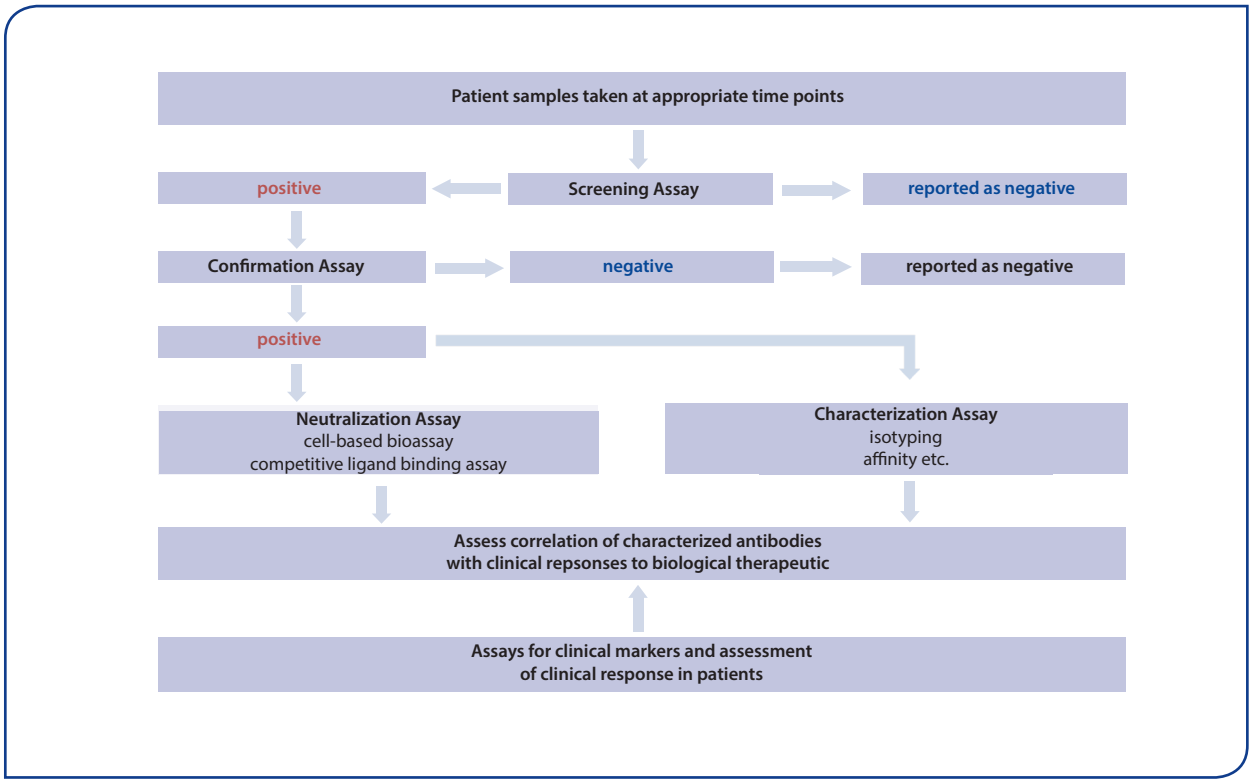
Assay Types

Screening Assay
- ELISA-based format (e.g. direct ELISA or bridging ELISA)

Confirmatory Assay
- Drug competition assay

Neutralization Assay
- Custom assay development of bioassays proving neutralizing capacity of detected anti-drug antibodies

Characterization Assay
- Isotyping
- Titers



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