







# **Quantitative Immunoassays**

Immunoassays are based on antibody specificity and are used to quantify an analyte (bio/pharmaceutical or biomarker) in a biological matrix. These ligand binding assays are an important tool to determine the safety and efficacy of bio/pharmaceuticals by assessing pharmakokinetics and pharmacodynamics. Each ligand binding assay must be developed using the most appropriate assay format and must be validated to ensure robust data. A reliable, validated assay is vital to support critical decision making during drug development and clinical trials.

The expertise of Eurofins BioPharma Product Testing Munich for quantitative immunoassays includes method development, assay transfer, optimization with respect to validation (including kit assays) and routine sample analysis.

### **Method Transfer**

Develop assays from scratch or adaptation of any commercially available assay kit

#### **Method Development**

Transfer and optimization of non-validated or validated assays to client specifications

# **Method 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, we offer a fully consultative and comprehensive assay validation or cross-validation service.

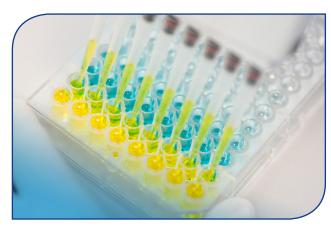
### **Sample Analysis**

From preclinical trials to Phase III clinical trial projects, we are equipped to handle variable sample numbers and large volumes. If desired, all our work can be performed in compliance with GLP/GCP to meet your specific needs.

Our ligand binding assay experts are experienced in selecting the most suitable assay format, including

- Enzyme-Linked Immunosorbent Assay
- Electrochemiluminescence
- Time Resolved Fluorescenz

We have extensive knowledge in establishing assays with various matrices including serum, urine, stool and tissue homogenates.



For the analysis of biomarkers our immunonalytics team has characterized a range of assays using the Enzyme-Linked Immunosorbent and Mesoscale Discovery (MSD) Electrochemiluminescence platform. These GLP/GCP compliant biomarker assays reliably detect either individual (singleplex) or multiple analytes (multiplex) simultaneously and have been set up for different species.

The following Biomarker are a representative part of our portfolio:

- IFN- $\gamma$ , IL-10, IL-12p70, IL-13, IL-1 $\beta$ , IL-2, IL-4, IL-6, IL-8, TNF- $\alpha$  (Serum, Human)
- IFN- $\gamma$ , IL-1 $\beta$ , IL-2, IL-4, IL-5, IL-6, KC/GRO, IL-10, IL-13, TNF- $\alpha$  (Serum, Rat)
- IFN- $\gamma$ , IL-1 $\beta$ , IL-2, IL-4, IL-5, IL-6, KC/GRO, IL-10, IL-12p70, TTNF- $\alpha$  (Serum, Mouse)
- Anti-KLH IgG, anti-KLH IgM (Serum, Mouse/Rat)
- Total-IgG, Total-IgM (Serum, Rat)

By selecting Eurofins BioPharma Product Testing Munich GmbH, you gain an outsourcing partner with extensive experience in ligand binding assay method development, validation and bioanalytical sample analysis. New projects are assigned to and managed by a study director with support from a team of experienced analysts and a project manager ensuring high quality of data.

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

## Services

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Cell Banking Services
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Microbiology

Molecular & Cell Biology Raw Materials Testing Release Testing Stability Testing & Storage Viral Clearance & Viral Safety Professional Scientific Services®

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.