

BioPharma Product Testing







Cell Based Assays

In recent years cell based assays have become one of the most important tools in human drug development. The use of a cell based system allows for more accurate and biologically relevant modeling of different processes than ligand binding assays, while at the same time reducing cost and complexity when compared to *in vivo* systems.

The immunoanalytics group at Eurofins BioPharma Product Testing Munich has many years of experience in working with cell based systems. From setup and optimization to validation and eventually routine measurement we provide broad scientific and technical expertise to ensure high-quality results. We not only offer ready-to-use assays but also have the possibility to transfer customer developed assays to our facility or develop an assay de-novo according to your specifications and needs.

Our facility in Munich works under GLP/GCP regulation with regular internal and external audits to ensure the highest standards.

Whether performing cell proliferation, neutralization, cytokine release or phagocytosis assay we are capable of tailoring our cell-based assay services to meet your specific level of regulatory requirement.

Cell proliferation

Eurofins Munich has vast experience in the analysis of cell proliferation in many different cell lines and primary cell types (e.g. PBMC or splenocytes). To this end, we employ different techniques including colorimetric assays as well as flow cytometric assays. The latter can of course be combined with further functional or phenotypical read-outs.

Neutralization Assays

To support immunogenicity evaluations of biologicals a three tiered approach is employed with screening and confirmation assay usually being performed as ligand binding assay and a subsequent neutralization assay in a cell based assay format. Like this the neutralizing capacity of the anti-drug antibodies is tested in a more physiological way and thereby mirrors the *in vivo* situation more closely than conventional ligand binding assays would.

Eurofins Munich has a broad technical knowledge in setup and use of cell based neutralization assays. Our assays are validated according to EMA and FDA guidelines and can be used to support drug development from preclinical up into all clinical phases.



Our scientists are trained in performing assays using different cell lines, including reporter cell lines, and readout formats to accommodate for the specific needs of our customers.

Cytokine release Assay

In vitro assay tools to predict and evaluate a drug's potential to induce cytokine release of blood cells are essential to evaluate drug safety already at a preclinical stage. To this end, Eurofins Munich has setup a cytokine release assay using human PBMCs. In this assay the drug of interest can be applied to the assay in different ways (in solution, wet– and dry–coating) to mimic a wide range of possible in vivo interactions and thereby to maximize the significance of the assay.

We offer a wide variety of pro- and anti-inflammatory cyto-kines as read-outs to our customers in either a multiplex (up to 10 cytokines) or in a singleplex format using the Meso Scale Discovery (MSD) platform. These assays have been validated by MSD and further characterized in-house and can be selected by the customer, giving them a high degree of flexibility to get the solution needed.

Phagocytosis Assays

Eurofins Munich has setup a variety of phagocytosis assay systems using both cell lines and primary cells as phagocytes. These can be combined with different read outs (FACS-based) to help quantify the respective phagocytic activity and for example estimate vaccine efficacy. Our assays can easily be adapted to analyze different reagents or drug products for their capacity to induce or block phagocytosis.

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.