

Full-Service Biomarker Assay Development

Experience and the Application of Technology

The growing use of biomarker data to support and streamline the drug development process has become an integral part of the path to bringing new and effective therapeutics to market.

Eurofins Bioanalytical Services has extensive experience in performing large molecule bioanalysis, which includes routinely performing quantitative assessment of soluble biomarkers, using a variety of platforms including Gyrolab[™], Luminex[®], MSD[®], Ella[™]*, and QuantStudio[™] 7 Flex. We utilize the different platforms based on knowledge of the specific strengths and weaknesses of platform and the associated methods.

Eurofins Bioanalytical Services provides the technical expertise, quality assurance, and peace of mind essential when considering an outsourcing partner for pre-clinical through clinical sample analysis, and has unsurpassed experience and a deep understanding of regulatory guidance.



Partnering to Advance Therapeutic Innovation

Development of Biomarker Assays in Large Molecule Bioanalysis

"Fit-for-Purpose" Biomarker Analysis

- Consultation and services for biomarker assay validation
- Implements scientific and industry best practices including "fit-forpurpose" qualification and validation of all bioanalytical assays
- Full GxP compliance
- Breadth of experience contributing to industry guidelines.
- Single-plex and multiplex assays
- Validation of analytical methods in support of regulatory submissions
- Fully consultative and comprehensive assay validation or crossvalidation service
- Validate our bioanalytical assays following the "fit-for-purpose" strategy, guided by our in-house expertise and latest industry white paper recommendations

Exploratory Biomarker Services

- Expertise in complex assays across a wide range of technologies and matrices
- Commercially available kits offer:
 - Rapid implementation
 - Benefits of portability
 - Expedited analytical solutions and ease of operation

qPCR

- Gene expression analysis
- SNP genotyping analysis
- Biodistribution/persistence, vector shedding
- Assay development and validation

Flow Cytometry Services

- Over 20 years of experience in flow cytometry custom assay development, assay validation, and sample processing
- Design customized solutions to overcome logistics issues for multi-site trials
- Sophisticated consultation and service solution for a wide variety of applications
- Multi-color surface phenotyping and intracellular analysis, through target engagement and receptor occupancy assessments to the analysis functional endpoints such as antibody-dependent cellular cytotoxicity (ADCC)



Contact us today to discover how the Eurofins Clinical Trial Solutions team can make the difference in your projects.



About Eurofins Bioanalytical Services

Over 20 years of industry-leading global **Scientific Expertise** supporting the widest breadth of Biologics' clinical trials with PK/TK, ADA, NAb and Biomarker assays and sample analyses.

Versatile Performance and Project

Management Excellence to adapt to a client's specific needs. Clinical or preclinical, regulated or non-regulated, assay development, qualification or validation; we custom design our support to match the client's program.

State-of-the art laboratory facilities in St. Charles, MO, USA providing **Global Reach and Capacity** to address clients' needs while simultaneously offering regionallybased solutions.

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