

Biomarker & Assay Development Services

Biomarkers are rapidly becoming the main drivers of innovation for medicine in the 21st century. Biomarkers are used as indicators of biological processes and pharmacological responses to a specific drug or therapy.

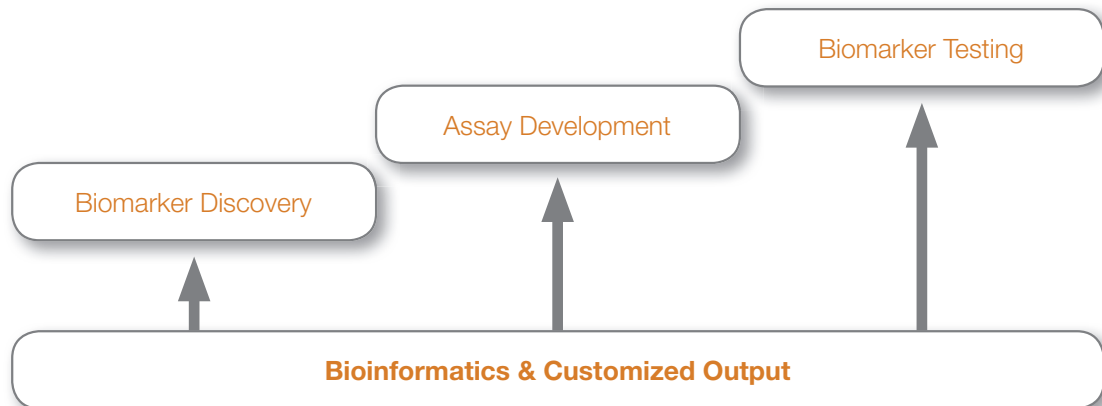
Since they improve the potential to tailor treatment to the specific needs of individual patients, they have become a critical prerequisite to personalized medicine, companion diagnostics and they are also an integral part of the drug discovery and development process.

Thanks to its many years of experience in contract research for biopharmaceutical, biotech, and nutritional companies, an increasing number of biopharmaceutical companies rely on Biocrates, conducting in-depth R&D on novel biomarkers.

What we offer

Incorporating an innovative, integrated mass spectrometry technology platform, Biocrates' quantitative approach enables immediate identification of more than **600 metabolites** and measurement of their **absolute concentrations**.

Biocrates combines a thorough understanding of customer needs with a unique expertise in interpreting the biological pathways behind specific biomarker patterns.



BIOCRATES Analytical Spectrum

- Amino acids (proteinogenic and non proteinogenic)
- Acylcarnitines and free carnitine
- Bile acids
- Biogenic amines and polyamines
- Eicosanoids and other oxidized polyunsaturated fatty acids
- Free and total fatty acids
- Glycerophospholipids
- Intermediates of central energy metabolism
- Monosaccharides
- Oxysterols
- Phospholipids and Ceramides
- Spingomyelins
- Vitamins
- Neurotransmitters
- Steroids
- Thiol redoxpairs (Oxidative Status Assay)

Biocrates Biomarker & Assay Development Services are available as package or single services:

Biomarker Discovery

Identification of new disease-specific metabolite panels in exploratory studies including experimental design, application of statistical models, biochemical interpretation and pathway mapping

Assay Development (development and application of biomarker assays)

Development of quantitative mass spectrometry-based biomarker assays, validation (fit-for-purpose) and documentation

Biomarker Testing

Verification of metabolomic biomarkers in independent sample cohorts

Bioinformatics & Customized Output

Statistical analysis, Biochemical data interpretation, customized data reports, decision support, study design

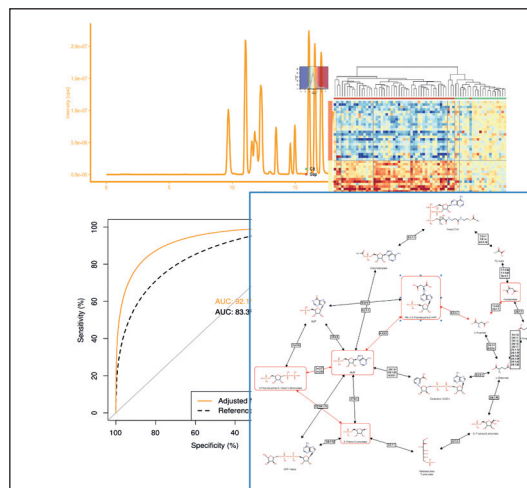
BIOCRATES' Special Expertise

- **Biomarker discovery in diabetic nephropathy/diabetes**

Successful identification of metabolomic biomarkers which can be used to elucidate the pathomechanisms, assessing progression of and diagnosing CKD (Chronic Kidney Disease), comprehensive safety profile for drug candidates

- **Expertise in development and validation of MS-based assays for the quantitation of endogenous analytes¹⁾**

Our team of scientists has many years of experience in the development of FIA/LC-MS-based methods for the analysis of endogenous analytes resulting in our kit products. Examples for methods that we have recently developed for our customers are thiol redoxpairs and neurotransmitters.



- **Statistical analysis**

Modern statistical methodologies are applied to identify differentially regulated metabolites and to build prognostic and predictive disease models: Empirical Bayes methods for batch normalisation and moderated t-statistics, supervised learning techniques and feature selection (e.g. multivariate lasso and elastic-net regularized linear models, support vector machines), robust validation techniques (cross-validation, bootstrap resampling), hierarchical clustering, principal component analysis

¹⁾ **Related Literature:**

K. Suhre et al. *PLoS One* [Online] 2010, 5(11).

U. Lundin et al. *Advances in the Study of Genetic Disorders*, pp 81-98.

Technology platforms

At Biocrates we use state-of-the-art technologies in the field of metabolomics and we are equipped with the latest technical devices for high-throughput analysis.

Contact Details

For further information on our services, please feel free to contact Dr. Guido Dallmann at

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 IN BIOMARKER AND ASSAY
 DEVELOPMENT