

TARGETED METABOLITE ASSAYS

RESEARCH & CLINICAL TRIALS

Targeted Assays at Metabolon

Targeted assays and panels zoom in on a specific metabolite or metabolites and can be used to track biomarkers and improve biological understanding in both clinical and preclinical research. They are an excellent tool for rapidly and accurately establishing pharmacodynamics, translational studies, gauging efficacy and safety in clinical trials and for post-market surveillance studies. The role of biomarkers is also expanding to inform new indications and targets, patient segmentation and novel mechanisms of action.

Metabolon's targeted metabolite assays provide precise measurements of metabolites in a wide variety of sample matrices. Metabolites can be valuable biomarkers because they are sensitive to specific enzyme inhibitors and signaling pathways (e.g. kinase inhibitors) and are associated with many diseases such as metabolic disorders and cancer. Successful, new treatments may bring about normalization of these metabolite levels.

LC-MS/MS-based assays offer unique advantages over legacy assay platforms such as ELISA or IHC. Assays can be customized based on your needs and developed and validated for research use only (RUO) or under Good Clinical Practice (GCP) and Clinical Laboratory Improvement Amendments (CLIA).

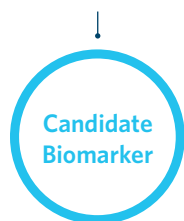
Pre-developed Assays for Research and Clinical Trials

Select from an ever-expanding, diverse menu of pre-developed assays (qualified and/or validated) involving more than 250 metabolites for research or clinical trial use, including fatty acids, bile acids and amino acids, such as:

- **Fatty Acid Metabolism Panel:** measures the major fatty acids of importance to human and animal metabolism, including saturated, mono-unsaturated omega-3, omega-6, trans and plasmalogen-derived fatty acids.
- **Short-Chain Fatty Acid Panel:** measures short-chain fatty acids in a variety of biological matrices. Quantitative measurements of SCFA can help understand the importance of the gut microbiome on human health.
- **Bile Acid Panel:** measures the major primary and secondary bile acids, as well as their glycine and taurine derivatives.
- **Cholesterol Metabolism Panel:** measures cholesterol, as well as intermediates in cholesterol synthesis and oxidation, phytosterols, and metabolic products of cholesterol to provide a comprehensive snapshot of sterol synthesis, absorption and excretion.
- **Stratum Corneum Panel:** measures more than 350 individual lipid metabolites found in stratum corneum, including free fatty acids, cholesterol sulfate, ceramides, dihydroceramides and phytoceramides.
- **Sebum Lipid Panel:** measures over 900 individual lipid species from multiple lipid classes, including wax esters and squalene. The fatty acids comprising the complex lipid classes are largely unique to skin metabolism and include odd and branched-chain fatty acids and a high concentration of the unusual sapienic acid (16:1n10) and its metabolites.
- **accuGFR™:** provides an estimate of the Glomerular Filtration Rate (GFR) that is more precise than current standard-of-care eGFR methods based on creatinine or cystatin C (MDRD or CKD-EPI), and it is independent of creatinine or cystatin C.
- **7 alpha-hydroxy-4-cholesten-3-one (C4):** measurement in peripheral blood provides an assessment of the rate of bile acid synthesis in the liver.
- **Metal ION:** provides precise measurements of biologically important macro and micro-nutrient metals, such as zinc, chromium, magnesium and iron, in plasma, serum or urine.
- **Amino Acid Panel:** Measures the major free amino acids in biofluids. Quantitative profiling of amino acids can be used to study a wide variety of genetic disorders and acquired conditions that influence the amino acid metabolism. Monitoring the amino acid profile is also a useful tool in bioprocessing applications.
- **Custom Assays:** provides precise measurement of metabolites in a wide variety of matrices. Metabolites can be valuable biomarkers because they are sensitive to specific enzyme inhibitors and signaling pathways and are associated with many diseases.

THE CORE OF BIOMARKER DEVELOPMENT

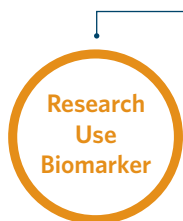
DISCOVERY



Discovery Metabolomics

Cast a wide research net with our global metabolomics and lipidomics platforms. (Up to 2,000 metabolites/sample)

DEVELOPMENT



Targeted Assays

Narrow your focus to specific pathways, themes or metabolites with custom or pre-developed assays. (1-dozens metabolites/assay)

COMMERCIALIZATION



Clinical Diagnostics

Advance your biomarkers to commercial diagnostic testing

Assay	NASH	Microbiome	Drug Development	MOA	Skin Care	Dermatology	Kidney Disease	Nutrition	Bioprocessing	Biomarker Discovery	Multiple Disease States
Fatty Acid Metabolism Panel	✓		✓					✓			
Short-Chain Fatty Acid Panel		✓	✓	✓				✓			
Bile Acid Panel	✓	✓	✓				✓				
Cholesterol Metabolism Panel			✓					✓			
Stratum Corneum Panel					✓	✓					
Sebum Lipid Panel	✓		✓	✓	✓	✓		✓			
accuGFR Panel	✓		✓	✓			✓				
C4	✓	✓	✓				✓				
Metal Ion Panel				✓				✓	✓	✓	
Amino Acids	✓	✓	✓	✓				✓	✓	✓	✓
Custom Panels	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓

Unparalleled LC-MS/MS Experience with Endogenous Metabolite Assays

- >15 years of metabolite MS experience & innovation
- Exceptional multiplexing capabilities
- Quality systems tailored to sponsor needs:
 - Rapid quantitative screening
 - Research Use Only (RUO)
 - Good Clinical Practice (GCP)
 - Clinical Laboratory Improvement Amendments (CLIA)

Support Capabilities

- Consultative approach; routine scientist-to-scientist communication
- Dedicated team of scientists supporting all aspects of biomarker testing
- GCP/ICH standards — SOP-driven processes, operations and data management
- Assays meet the most stringent regulatory standards
- Oversight by experienced program manager throughout the process
- Independent quality assurance review of processes, data and reports

FOR A COMPLETE LIST OF OUR METABOLOMICS SERVICES, VISIT WWW.METABOLON.COM



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