

# TARGETED METABOLITE ASSAYS

## CUSTOM OR PRE-DEVELOPED LC-MS/MS<sup>1</sup> ASSAYS

### Targeted Metabolite Biomarker Assays for Research and Clinical Trials

Targeted assays 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, signaling pathways (e.g. kinase inhibitors), 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 of metabolites offer unique advantages over legacy assay platforms such as ELISA or IHC.

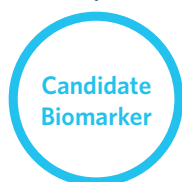
### The Core of a Biomarker Development Program

Targeted assays are an ideal follow-up to the screening of hundreds to thousands of metabolites with our revolutionary Discovery Metabolomics Technology. Following the identification of candidate biomarkers with this approach, or established by other means, sponsors can select from an ever-expanding set of >250 pre-developed assays or initiate the development of a custom assay. Assays can be run in a research or clinical trial setting.

### UNPARALLELED LC-MS/MS EXPERIENCE WITH ENDOGENOUS METABOLITE ASSAYS

- >15 yrs of metabolite MS experience & innovation
- >4,000 different metabolites across 400 matrices
- Exceptional at multiplexing
- Quality systems tailored to sponsor needs:
  - Rapid quantitative screening
  - RUO
  - GCP
  - CLIA

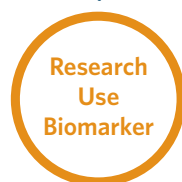
#### DISCOVERY



#### Discovery Metabolomics

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

#### DEVELOPMENT



#### Targeted Metabolite Assays

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

#### COMMERCIALIZATION



#### Clinical Diagnostics

Advance your biomarkers to commercial diagnostic testing

<sup>1</sup>The majority of assays are developed with state-of-the-art LC-MS/MS. Some legacy panels or assays may use other mass spectrometry methods.

# YOUR BIOMARKERS, OUR PROCESS.

Each project begins with a scientist-to-scientist consultation to determine your assay needs, including regulatory requirements, and to establish the project timeline. In doing so, we will explore how to best meet those needs through existing assays, custom-developed assays, or a combination of both.

In-depth institutional knowledge of metabolic pathways along with our deep-expertise in metabolite-based mass spectrometry guides the selection of candidate biomarkers.

This ensures that the key aspects of the subsequent study or trial are clearly assessed and that the assays and multiplexing scheme most effectively meet your needs.

Assays can be customized based on the sponsors needs and developed and validated for research use only (RUO) or run under Good Clinical Practice (GCP). Our expertise throughout the continuum of biomarker development makes Metabolon an exceptional partner for validated assay development and analysis.



## SPONSOR-LED CONSULT

- Identify client needs/ constraints, list of candidates, redundancy
- Assess technical feasibility, analyte evaluation
- Evaluate prospective reference material and extraction and instrument methods
- Draft, review, approve work order and deliverables
- Collaborate on regulatory needs of the assay



## DEFINE A PATH (GCP OR RUO)

### Custom Assay

- Affirm reference standards
- Assess multiplexing feasibility
- Develop analytical methods
- Validate analytical performance
- Perform recovery, stability, linearity, AMR testing
- Sponsor-directed development of classes such as:
  - Catecholamines
  - Oxidative stress markers
  - Inflammatory markers

### Pre-developed Assay

- Select from an ever expanding menu not limited to:
  - Fatty Acids
  - Acylcarnitines
  - Bile Acids
  - Cholesterol Metabolism
  - Amino Acids
  - Stratum Corneum Lipids



## SAMPLE TESTING & REPORTING

- Manage samples through accessioning and chain of custody tracking
- Create project-specific worksheet for data management in a validated LIMS environment
- Report study results as defined in work order

## An Expanding Menu of Panels

Metabolon currently offers a number of panels and assays useful for many areas of research, and we continue to expand to meet the needs of our clients. For details about specific metabolites, assays or panels, contact your local Metabolon representative.

## 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 (FDA/EMA)
- ✓ 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](http://WWW.METABOLON.COM)



**METABOLON®**

Where **knowing** comes to **life™**

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