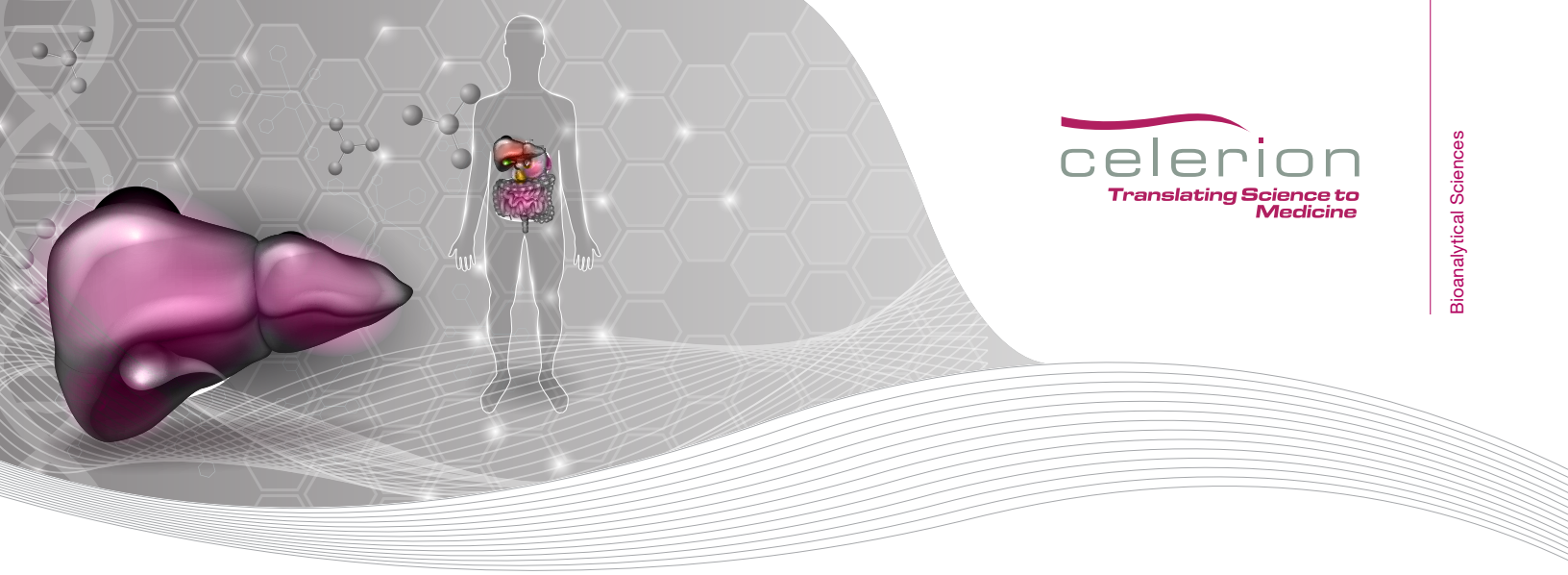


celerion
Translating Science to Medicine

Bioanalytical Sciences

Bioanalytical Roadmap:
Nonalcoholic Steatohepatitis (NASH)

Celerion has developed the ideal complement of soluble and functional biomarker assays to demonstrate the efficacy of candidate NASH drugs. This includes sample processing, RT-qPCR analysis, soluble biomarker measurement, and immune monitoring by flow cytometry and ELIspot. We offer a breadth of clinical services to determine drug efficacy including de novo lipogenesis clinical studies. Our metabolic and NASH scientists are industry leaders of guidance for biomarker assay validation, choice of biomarkers, technology platforms, and study design.

Additionally, Celerion's Bioanalytical Laboratories are fully equipped with staff skilled in performing a wide range of sample handling and assay techniques for clinical trials, including:

- Whole Blood Processing (PBMCs, Serum, Plasma) with demonstrated stability using novel stabilizing agents
- Automated RNA/DNA/miRNA Extraction, Purification, and Quantification

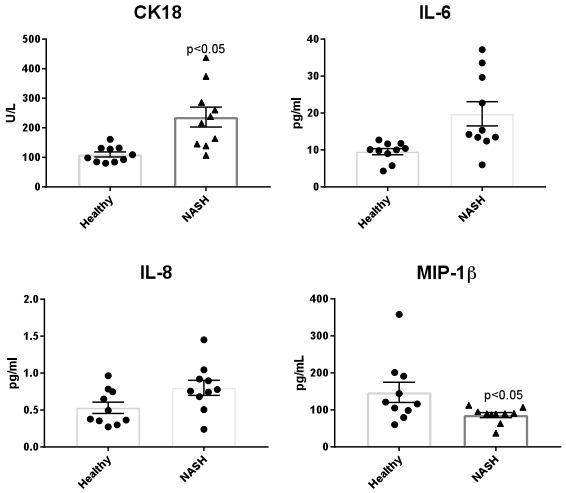
GLP Bioanalytical Method Validation for Biomarkers:

Celerion's fit-for-purpose GLP-based biomarker method validation optimizes cost and quality of your drug development. FDA guidelines indicate that biomarkers for drug development should be assayed in this environment. GLP assays are best suited for drug development since quality controls and sample analysis are configured for each individual study and patient.

Background:

Nonalcoholic fatty liver disease (NAFLD) is a spectrum of liver dysfunction associated with hepatic steatosis (fat accumulation), and nonalcoholic steatohepatitis (NASH) represents a more severe form of the disease. The incidence of NASH is expected to accelerate as the disease is strongly associated with diabetes and obesity, which have both reached epidemic proportions.

A robust biomarker plan allows determination of pharmacokinetics, mechanism of action (MOA), and efficacy of a candidate metabolic or NASH therapeutic. Protein biomarkers of inflammation, cell death, and fibrosis are potential non-invasive secondary endpoints. Soluble miRNA biomarkers may also be causal to the disorder and influenced by treatments.



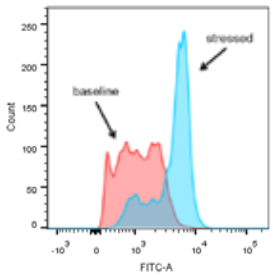
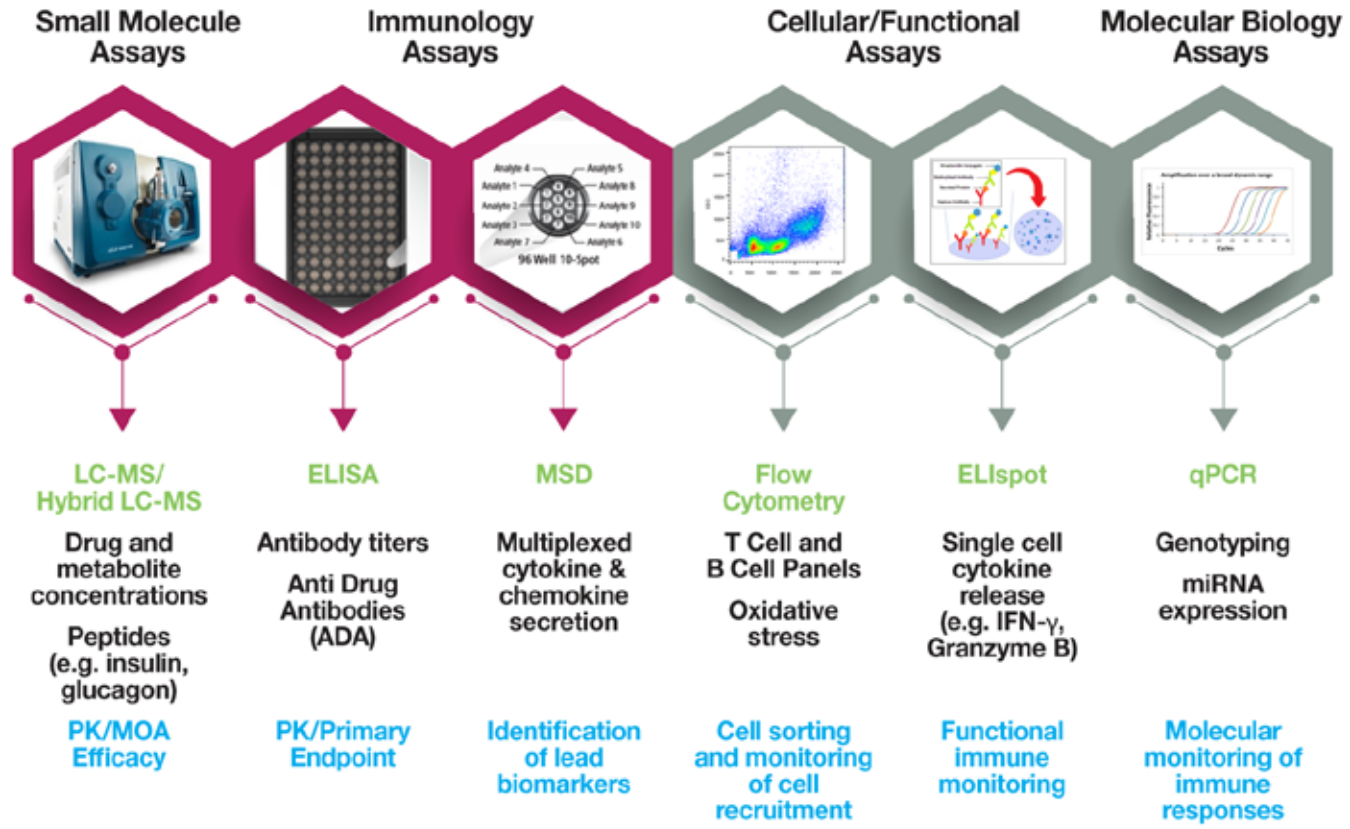


Figure 1. Serum cytokines and CK-18 measured by immunoassays and cellular oxidative stress measured by flow cytometry show increased inflammation and apoptosis in NASH and can be used as a secondary endpoint of efficacy in clinical studies

Bioanalytical Assays for Metabolic Diseases

Technology
Assay example
Context



Celerion Biomarker Assays for Metabolic Disease

Analyte(s)	Platform
Adiponectin	ELISA
CK-18	ELISA
Ghrelin	ELISA
GLP-1	ELISA
Glucagon	LC-MS
IL-1β, IL-6, IL-8, TNF-α, IFN-γ (multiplexed)	MSD ECL
Insulin	ELISA/LC-MS
Leptin	ELISA
MCP-1, Eotaxin, MIP-1β (multiplexed)	MSD ECL
VCAM-1, SAA, CRP (multiplexed)	MSD ECL

Read more about our expertise at: https://www.celerion.com/service/nafld-nash

Contact us at info@celerion.com