devTOX™ DISCOVERY

Prediction **Metabolomics** **Biochemical Insight**

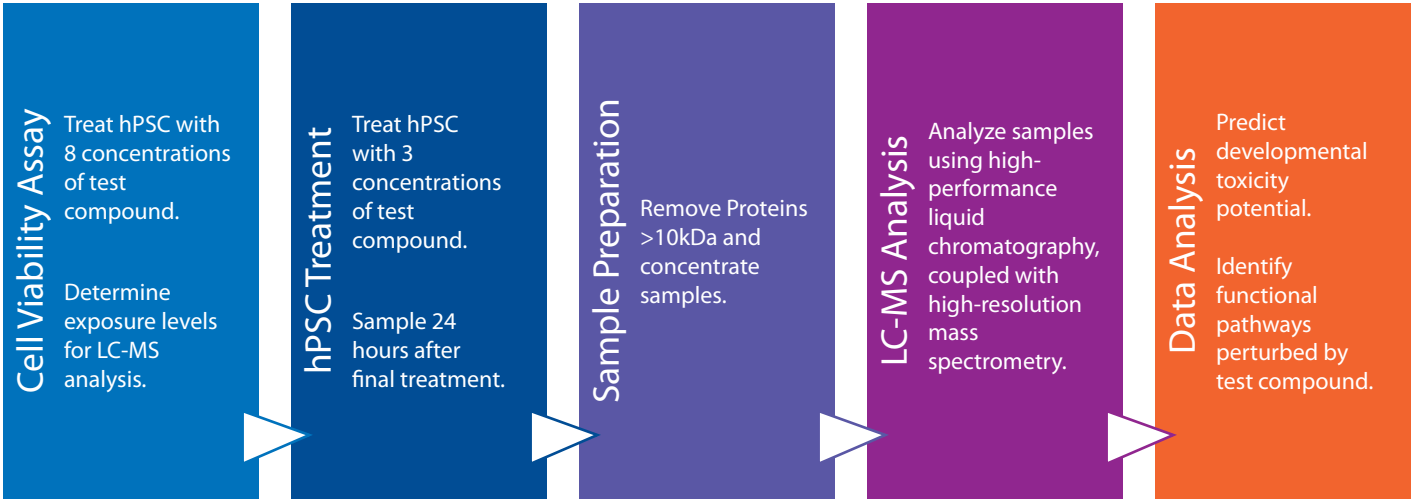
As part of our portfolio of screening services, Stemina Biomarker Discovery offers **devTOX** DISCOVERY, a **human**-based assay developed to predict the potential toxic impact of test compounds on human embryo/fetal development and offer insight into altered biochemical processes.

Our team of experienced professionals works with a variety of clients including pharmaceutical, chemical, agricultural, tobacco, and cosmetic companies, as well as government agencies, to employ **devTOX** in early-stage decision-making. Our predictive **devTOX** model was built based on a set of 23 pharmaceutical compounds with known human developmental toxicity outcomes.

When applied across a wide range of 80 chemicals, our model is 85% predictive. In addition to providing a prediction of the potential for developmental toxicity, Stemina's **devTOX** DISCOVERY assay provides information on the functional pathways altered by compound exposure.

Continued >

devTOX™ DISCOVERY PROCESS



Stemina
BIOMARKER DISCOVERY

PREDICTIVITY

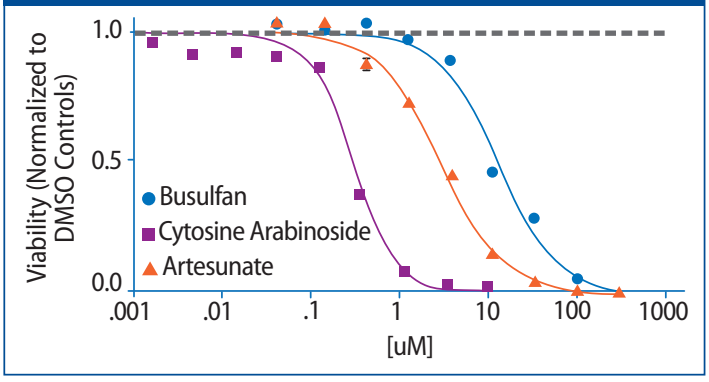
Stemina's devTOX assay is a proven model for assessing the potential for human developmental toxicity.

COMPARING *IN VITRO* MODELS*

Assay	N	Accuracy*
devTOX™	36	89%
Zebrafish	26	75%
Mouse EST	23	74%
Whole Embryo	24	73%

* Palmer JA, Smith AM, Egnash LA, Conard KR, West PR, Burrier RE, Donley EL, Kirchner FR. Establishment and assessment of a new human embryonic stem cell-based biomarker assay for developmental toxicity screening. Birth Defects Res B Dev Reprod Toxicol. 2013;98(4):343-363.

CELL VIABILITY



SCIENCE AND DELIVERABLES

Cell culture

devTOX can be conducted using human embryonic stem (hES) cells or induced pluripotent stem (iPS) cells.

High-Performance Liquid Chromatography-Mass Spectrometry

We utilize high-performance and high-resolution LC-MS instrumentation, including TOF and QTOF platforms, incorporating both positive and negative electrospray ionization.

Bioinformatics

Our platform uses LC-MS feature identification, alignment, and standardization protocols followed by both uni- and multivariate analysis and scoring against the significant metabolites in our database. Putative metabolites of interest are evaluated relative to biological pathways.

Biomarker Confirmation

Stemina has a comprehensive library of human small molecules established by MS/MS analysis. Metabolite confirmation with MS/MS fragmentation and comparison to reference standards can be performed (additional cost).

Quality

From start to finish, Stemina has a well-defined, quality program to ensure the integrity of our data.

Experience Counts

Our team has extensive experience in screening a wide variety of proprietary compounds including pharmaceuticals, agri-chemicals, tobacco products, consumer products, and cosmetic ingredients. Stemina was founded in 2006; its state-of-the-art facilities are located in the United States.

Extending Our Global Reach

CiToxLAB

Stemina has partnered with CiToxLAB, which has facilities in Canada, France, Denmark, and Hungary, to provide worldwide service.

EPA ToxCast™ Contractor

Stemina Biomarker Discovery | Cambridge Innovation Center | One Broadway | Cambridge, MA 02142
504 South Rosa Road, Suite 150 | Madison, WI 53719 | 608-204-0104 (office) | customerservice@stemina.com