In Vitro Toxicity Testing Contract Services

HemoGenix® has been providing *in vitro* toxicity contract services since 2000. The company specializes in using fresh, primary stem and progenitor cells as targets, since these provide the most predictive information prior to pre-clinical animal studies and human clinical trials. HemoGenix® has developed its own proprietary high throughput *in vitro* assays for many definitive, continuously and partially proliferative cell systems.

Consider HemoGenix® as your Outsourcing Partner

Benefits of Outsourcing *In Vitro* Toxicity Testing to HemoGenix®

- HemoGenix® *in vitro* predictive assay platforms have been used by small, medium and half of the top 50 biopharmaceutical companies as well as government agencies.
- Incorporates advanced proprietary Bioluminomics™ (standardized ATP bioluminescence) technology developed by HemoGenix® that has been validated according to FDA Bioanalytical Method Guidelines.
- Where applicable, all toxicity results provided as IC values, area under the curve (AUC) and estimates of starting doses for animal or human studies from *in vitro* IC values.
- All contract studies are customized for specific client goals and to obtain the maximum amount of information.
- All studies are available as non-GLP or GLP contract services. Alternatively, perform routine *in vitro* toxicity assays in-house using our assay kits that usually include everything required to perform the assay, except cells.
- HemoGenix® works closely with other contract research organizations (CROs) to expand animal studies by including *in vitro* toxicity assays that cannot be performed by other organizations.
- All Bioluminomics™ assays exhibit high-throughput capability using 96- or 384-well plate formats allowing ADME-Tox drug or compound screening or testing at any stage during drug development.
- Studies using fresh, primary human cells can often be performed as paired samples (normal and diseased) to produce information of differential toxicity and therefore the therapeutic index.
- Studies often incorporate the ComparaTOX™ Platform allowing direct comparison of cells from different tissues and organs from multiple species to be directly compared to each other. These studies help reduces animal use and are consistent with the 3Rs Paradigm-Reduction, Refinement, Replacement.
- All Bioluminomics™ assay are calibrated and standardized, incorporate the most sensitive ATP bioluminescence readout available to measure proliferation, cytotoxicity, cell number and even apoptosis and demonstrate low CVs and high reliability and reproducibility.
- All cell culture techniques use the specialized high performance media to provide the maximum growth and sensitivity for the assays.
- Fast turnaround: Studies are usually completed in less than 14 days. Initial report sent within 5-7 business days.
- All HemoGenix ® assays have been designed for multiplexing providing you with the most information from the same sample.
- All contract services are confidential and include exceptional customer service.

HemoGenix®
Changing the Paradigm

Assays You Can Trust
Innovative Expertise You Can Count On

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HemoGenix® Proprietary Assay Platforms:

- **HALO®-Tox HT and CAMEO™-4 and CAMEO™-96** for the lympho-hematopoietic system.
- **ImmunoGlo™-Tox HT** for the primitive lymphopoietic and immune system.
- **MSCGlo™-Tox HT** for the mesenchymal stem/stromal cell (MSC) system.
- **STEMGlo™-Tox HT** for stem cells, cell lines and primary explanted cells.
- **NeuroGlo™-Tox HT** for neural stem and progenitor cells.
- **HepatoGlo™-Tox HT** for hepatotoxicity.

Specialized Assay Platforms

- **DDI**: Cellular drug-drug interaction assays.
- **PRT**: Predictive residual stem cell toxicity assays.
- **FloDiff™**: Flow cytometric assays.
- **OxyFLOW™**: Oxidative DNA damage assay.

Contract Services Available for the following Cell Systems:

- Lympho-hematopoiesis
- Immune system
- Mesenchymal stem/stromal cell system
- Primary stem and progenitor cells
- Hepatocytes
- Neural stem and progenitor cells
- Cancer stem cells
- ES cells
- iPS cells
- Breast
- Heart
- Lung
- Kidney
- Bladder
- Prostate
- Ovary
- Skin

Multiplexing Assay Panel

Includes, but not limited to, the following:

- Membrane integrity: LDH or PI dye exclusion.
- Cellular and mitochondrial integrity and viability: All Bioluminomics™ assays.
- FloDiff™: Flow cytometric membrane expression marker detection, cell cycle analysis, ploidy, apoptosis.
- Biochemical caspase detection.
- GFkine™: Growth factor/cytokine production/release using FloDiff™ analysis or ELISA.
- Mitochondrial dysfunction: Mitochondrial ToxGlo™: Mitochondrial dysfunction.
- Glutathione Assay (GSH): Oxidative stress.
- OxyFLOW™: Oxidative DNA damage.
- cAMP assays.
- Phosphodiesterase assays.
- Kinase assays.
- P-glycoprotein assays.
- Proteosome assays.
- Cytochrome P450 enzyme assays.

Species Available for Contract Services
(not all species available)

- Human
- Non-human primate (Cyno or Rhesus)
- Horse
- Pig
- Sheep
- Dog
- Rat
- Mouse

Our Contract Services Workflow

- Discuss prospective study to understand your goals.
- Prepare quote and revise if required by client.
- Prepare study plan and revise for client's acceptance.
- Shipment of test articles to HemoGenix®.
- Procurement of target tissue/cells for study.
- Arrival of tissues/cells and start of study.
- Completion of study usually within 2 weeks or less.
- Phase I Final Report provided between 5-7 days.
- QA audit.
- Phase II Final Report and study termination.

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