HALO®-Tox HT

Predictive *In Vitro* Stem and Progenitor Cell Hemotoxicity Assay Kits

From the Leader in Predictive In Vitro Hemotoxicity Testing

Benefits of using HALO®-Tox HT for Predictive *In Vitro* Hemotoxicity Testing

- Fully validated *in vitro* assay platform used by small, medium and the largest biopharmaceutical companies and government agencies.
- Highly predictive; greater than 80% concordance between *in vitro* and *in vivo* results.
- High-throughput capability using 96- or 384-well plate formats allows ADME-Tox drug or compound screening, thereby significantly reducing unexpected results during pre-clinical testing.
- Can be used at all stages of drug development, even during clinical trial patient monitoring.
- 3Rs Alternative Assay Platform-Reduction, Refinement, Replacement for animal testing.
- Available for multiple species comparisons.
- Incorporates the most sensitive ATP bioluminescence readout available to measure proliferation, cytotoxicity, cell number and even apoptosis.
- Uses proprietary Suspension Expansion Culture™ (SEC™) and Bioluminomics™ Technology.
- Available for up to 7 different individual stem cell populations and 7 individual progenitor cell populations.
- Also available for "global" testing to predict potential toxicity to the whole lympho-hematopoietic system. Incorporate 4, 5 or 7 cell populations simultaneously.
- Results usually in 4 to 5 days depending on species.
- Validated according to FDA Bioanalytical Method Guidelines and against the Registry of Cytotoxicity Prediction Model as a cytotoxicity assay and allows estimates of starting doses for animal and human studies from *in vitro* IC values.
- Designed for multiplexing with other assay using the same sample.
- Available as contract services or assay kits that include everything required to perform the assay, except cells.

Assay Kits are Available for the Following Species

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

Cells and Tissues Used for Hemotoxicity Testing:

- Bone marrow (all species)
- Peripheral blood (human and large animal species)
- Umbilical cord blood (human).
- Purified human stem cell populations (e.g. $CD34^+$)
- Other hematopoietic organs from animals (e.g. spleen, fetal liver, yolk sac)

HemoGenix® also provides *in vitro* hemotoxicity contract services for any stage of drug development

HemoGenix®
Changing the Paradigm

Assays You Can Trust
Innovative Expertise You Can Count On

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HALO®-Tox HT

Assays are Available for the Following Individual Cell Populations or "Global" Testing Cell Populations

Stem Cell Populations

- Primitive lymph-hematopoietic stem cells.
- Primitive hematopoietic stem cells.
- Mature hematopoietic stem cells.

Progenitor Cells:

- Erythropoietic progenitor cells.
- Granulocyte-macrophage progenitor cells.
- Megakaryopoietic progenitor cells.
- T-lymphopoietic progenitor cells.
- B-lymphopoietic progenitor cells.

"Global" Hemotoxicity Assays:

- 4-Population Assays: Primitive hematopoietic stem and progenitor cells.
- 5-Population Assays: Primitive lympho-hematopoietic stem cells and primitive hematopoietic stem and progenitor cells.
- 7-Population Assays: Primitive lympho-hematopoietic stem cells, primitive hematopoietic stem and progenitor cells and lymphopoietic progenitor cells.

HALO®-Tox HT Assay Multiplexing:
To obtain maximum information from a single sample

For contract services, HemoGenix® offers a large number of additional multiplex assays to determine specific cell population response and mechanism of action to provide the maximum amount of information from a single cell sample. These include:

- 'HALO®-96 PRT: Predictive stem cell residual toxicity assay.
- CAMEO™-96: Detection of toxicity to both proliferation and differentiation processes under clonal conditions.
- CAMEO-4™. Traditional colony-forming cell (CFC) assay.
- Growth factor production/release assays.
- Flow cytometric assays: cell cycle analysis, membrane expression, apoptosis.
- Oxidative DNA damage assays (OxyFLOW™).
- Biochemical apoptosis assays (e.g. Caspase assays).
- Mitochondrial dysfunction assays.
- Protease, LDH, GSH, PGP, MOA, UGT assays.
- Cytochrome P450 assays.
- Gene expression analysis (not performed by HemoGenix™).

Hemotoxicity Assay Panel

HemoGenix® has developed a specialized panel of assays specifically designed for hemotoxicity testing.

- FloDiff™: Membrane expression marker detection, cell cycle, ploidy, apoptosis.
- Membrane integrity: LDH and/or PI.
- Chemotaxis/ migration assays.
- GFkine™: Growth factor/cytokine production/release.
- Mitochondrial ToxGlo™: Mitochondrial dysfunction.
- Glutathione Assay: Oxidative stress.
- OxyFLOW™: Oxidative DNA damage.
- Biochemical apoptosis assays: CaspaseGlo™.

Other Assays for *In Vitro* High Throughput Toxicity Testing

- **CAMEO™-4 and CAMEO™-96:** Hemotoxicity assays to determine the effect on hematopoietic differentiation.
- **ImmunoGlo™-Tox HT**: Lymphocyte proliferation/cytotoxicity assays.
- **MSCGlo™-Tox HT**: Mesenchymal stem / stromal cell toxicity assays.
- **STEMGlo™-Tox HT**: Cytotoxicity assays for primary stem cells, stem cell line (e.g. ES and iPS) and explanted cells from different organs and tissues.
- **NeuroGlo™-Tox HT**: Neural stem and progenitor cell toxicity assays.
- **HepatoGlo™-Tox HT**: Hepatotoxicity assays.
- **ComparaTOX™**: Contract service only assays to compare and rank toxicity based on cell type and species.
- **Drug-Drug Interaction (DDI) Assays**: Contract service only cellular drug interaction assays.
- **Residual Stem Cell Toxicity Assays**: To determine the presence of residual stem cells after *in vitro* drug administration.

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