**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

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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 lymphohematopoietic stem cells and primitive hematopoietic stem and progenitor cells.
• 7-Population Assays: Primitive lymphohematopoietic 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.