Neurotoxicity Contract Services

Neurotoxicity Contract Services from HemoGenix®

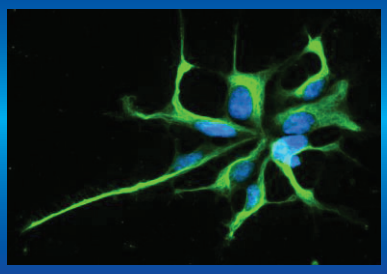
Neurotoxicity may be almost immediate or delayed, but occurs when a compound disrupts the normal activity of neurons. Neurotoxicity can occur by exposure to drugs, chemotherapy, radiation and other treatments and from numerous xenobiotic agents. Neurotoxicity represents one of the most important types of toxicity tested for new drugs and xenobiotic agents. To help predict potential neurotoxicity, HemoGenix® now offers *in vitro* neurotoxicity testing using ArunA Biomedical's hNP1™ and hN2™, human embryonic stem (ES) cell - derived neural cells. NeuroGlo™-Tox HT is an ATP bioluminescence 96- or 384-well high throughput assay platform used with hNP1 and hN2 target cells. NeuroGlo™-Tox HT provides a standardized and validated measurement of iATP using a luciferin/luciferase-based, bioluminescence readout. NeuroGlo™-Tox HT provides a rapid, reliable and reproducible assay to determine neurotoxicity This sheet provides information on the neural cells and the bioluminomics™ NeuroGlo™-HT assay system and associated multiplexing assays that can be provided to produce a wealth of information to help improve safety and efficacy of potential drug candidates and determine neurotoxicity by xenobiotic agents.

hNP1 Cells

- Human ES (H9, WA09)-derived Neural Progenitor Cells
- Feeder-free
- Serum-free growth
- Stable, diploid karyotype Adherent, proliferating cell line
- Proneural markers: >90% Nestin and Sox 2 positive
- Embryonic marker: <5% Oct-4
- Phenotypic differentiation potential:
  - Dopaminergic cells
  - Cholinergic cells
  - Glutametergic cells
  - GABA-ergic cells
  - Serotonergic cells
  - Astrocytic cells

NeuroGlo™-Tox HT

In Vitro Neurotoxicity Testing



HemoGenix®

ArunA BIOMEDICAL

hN2 Cells

- Human ES (H9, WA09)-derived Neuronal Cells
- Feeder cell-free
- Adherent, non-proliferative
- Serum-free growth
- Neuronal morphology: >90% β-III tubulin, >60% MAP2 positive
- Embryonic marker: <5% Oct-4
- Express high levels of:
  - Glutamatergic phenotypes
  - GABA-ergic phenotypes

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Changing the Paradigm

Assays You Can Trust
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Benefits of Using NeuroGlo™-Tox HT

- Incorporates an ATP-based luciferin/luciferase bioluminescence signal.
- Bioluminomics™ measures intracellular ATP (iATP) (the cell's energy source) to determine viability, cellular functionality, proliferation/cytotoxicity and cell number, all of which are proportional to the iATP concentration.
- Designed for all stages of drug development, from screening to pre-clinical animal studies.
- For hNP1™ and hN2™ neural and neuronal cells derived from the human ES cell line H9 (WA09).
- Adherent cell cultures.
- 96- or 384-well plate high throughput formats.
- Most sensitive non-radioactive signal detection readout available.
- Single-addition reagent with a 10 minute bioluminescence developing time.
- Non-subjective, instrument-based and quantitative assay system.
- All assays are calibrated and standardized with an external ATP standard and controls, providing additional validation, when required.
- Assay standardization allows for comparison of results over time.
- Always reliable and reproducible results with CVs equal to or less than 15%.

NeuroGlo™-Tox HT Multiplexing Capability

- Cellular functionality/viability assays (LIVEGlo™, MTT etc).
- Growth factor/cytokine assay production and release assays.
- Apoptosis assays: caspases.
- Oxidative DNA damage.
- High content imaging.
- Phenotypic markers for neural and neuronal cells.
- Gene expression analysis.

Parameters Used to Define the Study

- Number of test compounds.
- Number of reference, positive and/or negative compounds.
- Add-on or multiplex assays to be performed.
- Type of cells to be tested.
- Compound dose range.
- Number of compound doses (usually 6-12).
- Type of test compound addition.
  - Timed pre-culture addition.
  - Direct addition for culture duration.
  - Timed post-culture addition.
- Culture conditions.
- Curve fit analysis, number of EC/IC values (if relevant) and statistics (if applicable).
- GLP/non-GLP/QA audit.

Contract Services Workflow

- The CSO of HemoGenix® will advise and consult with our clients to achieve the goals of the study.
- Prepare quote and revise if required to suit budget.
- Prior to the start of the study, a detailed Study Plan will be prepared by the Study Director for the Study Monitor's approval.
- Sponsor shipment of test compounds.
- Initiate study on arrival of tissues.
- Completion of study will depend on the target cells being used.
- Phase I report provided between 4-7 business days after study completion.
- Audit of study data and Phase I report.
- Phase II Final Report and study termination.

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