

Mesenchymal Stem Cell System Contract Services

Mesenchymal Stem Cell System Contract Services from HemoGenix®

Mesenchymal stem or stromal cells (MSC) are fibroblastoid-like cells that can be derived from many tissues and organs and even produced via induced pluripotent stem (iPS) cells. They are an adherent cell population that express multiple surface membrane markers and can differentiate into osteoblasts, chondrocytes and adipocytes and other cell types and therefore plays an important role regenerative medicine. The MSC system is, in part, responsible for the stem cell niche microenvironment, without which, stem cells would not be able to function. The MSCs are also immunomodulators and appear to play an important role during stem cell transplantation and repopulation. Damage to the MSC system can be expected to have profound effects. The use of MSCs in regenerative medicine applications also requires determination of their "quality" and potency. HemoGenix™ has developed (from its HALO® Platform for hematopoietic cells) proprietary assays for both MSC "quality" and potency for regenerative medicine applications.

Mesenchymal Stem Cell Cytotoxicity Testing

All *in vitro* toxicity testing is dependent upon standardized and validated assays and MSC toxicity testing is no exception. MSCGLO™-Tox HT is one of a family of proprietary assays developed by HemoGenix® to predict potential toxicity to the MSC system.

Benefits of Using MSCGlo™-Tox HT

- Predictive *in vitro* MSC screening and testing platform for drugs, xenobiotics and other damaging agents.
- MSCGlo™-384 DDI: a cell-based drug-drug interaction assay.
- MSCGlo™-96 PRT: a predictive residual toxicity assay to detect sensitivity change to multiple drug doses.
- All assays incorporate proven ATP bioluminescence technology.
- Fully standardized and validated assay readout.
- Can be used for both 2D and 3D MSC culture models.
- 96- or 384-well plate high throughput formats.
- Incorporates high-performance MSCGro™ low serum, serum-free or humanized media.
- Turnaround time: Usually 3-5 days.
- MSCGro™ differentiation media available for adipogenesis, chondrogenesis or osteogenesis.
- Available for multiple MSC sources from different species.

Mesenchymal Stem Cell "Quality" and Potency Testing

For regenerative medicine applications, the "quality" and potency of the MSCs are of paramount importance. MSC "quality" is measured by proliferation ability, while potency is measured by proliferation potential, two properties that help define and characterize stem cells.

MSCGlo™-96 HuQC: a MSC "quality" assay used to measure MSC proliferation ability before and after a specific procedure. It determines whether a method is optimal.

MSCGlo™-96 PQR: the only FDA compliant potency assay that compares the proliferation potential of MSCs against a reference standard of the same MSC source .

Benefits of MSCGlo™ "Quality" and Potency assays.

- Provides validated methodology and data for Biologics License Application (BLA) and IND.
- Incorporate a fully standardized and validated ATP bioluminescence readout platform.
- Incorporate high performance MSCGro™ medium.
- For virtually any MSC source.
- Results usually in 3-5 days.



Assays You Can Trust
Innovative Expertise You Can Count On

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Multiplexing Assays

- Studies using green fluorescence-labeled human MSCs.
- Studies using red fluorescence-labeled human MSCs.
- Studies using GFP-labeled human MSCs.
- MSC identification membrane antigen expression by flow cytometry using: CD29, CD49, CD90, CD166, Sca-1, Stro-1 as positive markers and CD45 and CD34 as negative markers (depending on species being tested).
- Markers used to identify MSC-derived differentiated cells. Please see next panel.
- Cellular functionality/viability assays (LIVEGlo™, MTT etc).
- Growth factor/cytokine assays production and release assays.
- Chemokine release assays.
- Chemotaxis/cell migration assays in real time.
- Intracellular antigen expression by flow cytometry.
- Cell cycle analysis.
- Apoptosis assays: Annexin/PI, TUNEL, caspases.
- Oxidative DNA damage using OxyFLOW™.
- Immunomodulatory assays.
- Gene expression assays (not performed by HemoGenix®).

MSCGro™ Growth and Differentiation Media

Growth Media

- Low serum, complete media
- Serum-free, complete media
- Humanized, complete media
- Humanized, serum-free

Differentiation Media and Detection

- Osteogenesis differentiation media detected by alkaline phosphatase and osteocalcin.
- Chondrogenesis differentiation media detected by CD44, collagen and aggrecan.
- Adipogenesis differentiation media detected by fat and leptin.

Contract Services Workflow

- The CSO of HemoGenix® will advise and consult with our clients regarding the best assays to perform 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.
- Procurement of test items (target cells) for study.
- Initiate study on arrival of tissues.
- Completion of study usually less than 1 week for HALO® or up to 2 weeks for CAMEO™.
- 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.

Species

Mesenchymal stem cells can be obtained from multiple sources and from most of the following species:

- Human
- Non-human primate
- Horse
- Dog
- Rat
- Mouse



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