Instrument-Based Assays for Cell Therapy Products

Advantages of Cell Therapy Characterization Assays from HemoGenix®

Cell characterization and functionality are some of the most important properties required for a cell therapy product. HemoGenix® can help you achieve that goal.

- Assays available for hematopoietic stem and progenitor cells, immune cells and mesenchymal stem cells (MSC).
- Assay available for umbilical cord blood (UCB), normal and mobilized peripheral blood (PB, mPB), bone marrow (BM), purified cells (e.g. $CD34^+$, $CD133^+$), immune cells and subsets, and MSCs from multiple sources.
- Choose between absorbance, fluorescence or bioluminescence assays.
- All bioluminescence assays are calibrated, standardized and validated, and provide unsurpassed accuracy and sensitivity.
- Fast, non-subjective readout with automated and high throughput capability.
- Hematopoietic cell assays include serum-containing or serum-free, cell population-specific reagents incorporating Suspension Expansion Culture™ (SEC™) Technology. No colony counting required. No methylcellulose used that leads to errors, high variation and questionable statistics.
- Mesenchymal stem cell assays include high performance MSCGro™ medium with low serum, serum-free or humanized formulations.
- Rapid 3-5 day assay turnaround. Hematopoietic cell assays can be extended to 7 days for increased sensitivity.
- Always reliable and reproducible, with low coefficients of variation (CVs).
- All bioluminescence assays are compliant with FDA and EMA guidelines, and AABB, Jacie-FACT, NetCord-FACT and NMDP Standards.

Assays using an Absorbance Readout:

- **HemoLIGHT™-96 PCA^{EQ}**: CFU-equivalent assay.
- **HemoLIGHT™-96 PMT**: Time to Engraftment and Patient Monitoring after Transplantation assays.
- **ImmunoLight™-96 & ImmunoLight™-96 MLC**: Immune cell assays.
- **MSCLight™-96**: Mesenchymal stem cell assays.

Assays using a Fluorescence Readout:

- **HemoFLUOR™-96 PCA^{EQ}**: CFU-equivalent assay.
- **HemoFLUOR™-96 PMT**: Time to Engraftment and Patient Monitoring after Transplantation assays.
- **ImmunoFluor™-96 & ImmunoFluor™-96 MLC**: Immune cell assays.
- **MSCFluor™-96**: Mesenchymal stem cell assays.

Assays using a Bioluminescence Readout:

- **HALO®-96 PCA^{EQ}**: CFU-equivalent assay.
- **STEMpredict™**: Cord blood unit bankability assay.
- **HALO®-96 SPC-QC**: Quality control assay.
- **HALO®-96 PRS**: Potency reference standard assay.
- **HALO®-96 PQR**: Potency, Quality & Release assay.
- **HALO®-96 PMT**: Time to Engraftment and Patient Monitoring after Transplantation assays.
- **ImmunoGlo™ & ImmunoGlo™-MLC**: Immune cell assays.
- **MSCGlo™-96, MSCGlo™-96 HuQC and MSCGlo™-96 PRS & PQR**: Mesenchymal stem cell assays.

Only from HemoGenix®.
Promoting "Best Practice Criteria Testing":
Where Science and Results Matter

www.hemogenix.com | Tel: 719-264-6250 | Fax: 719-264-6253 | info@hemogenix.com

Cell Therapy Assays

The Assay Readouts

The Absorbance Assay Readout

- Incorporates a customized reagent that measures the amount of soluble formazan by absorbance at 490nm produced by a MTS tetrazolium reduction colorimetric reaction.
- No solubilization step as in a MTT reaction.
- Results in approx. 3 hours after cell culture.

The Fluorescence Assay Readout

- Incorporates a customized reagent that detects protease activity only in living cells.
- Fluorescence produced only when the substrate is cleaved by protease activity to produce a fluorescence signal proportional to the number of living cells.
- Fluorescence measured in a plate fluorometer or multiplate reader with emission at 380-400nm and excitation at 505nm.
- Results in approx. 2 hours after cell culture.

The Bioluminescence Assay Readout

- The most sensitive of all assays incorporating Bioluminomics™ technology.
- Includes standards and controls.
- Measures cell proliferation using an ATP luciferin/luciferase bioluminescence reaction.
- Results using a plate luminometer available after culture within 30 min.
- Calibrated, fully standardized and validated assays for BLA and IND submissions.
- Standardization allows results to be compared over time.

Assay Kit Contents

Absorbance Assay Kit Contents

- Master Mix or specialized medium for cell growth
- MTS reagent
- Sterile, 96-well plate(s)
- Sterile, adhesive foil covers
- Assay manual

Fluorescence Assay Kit Contents

- Master Mix or specialized medium for cell growth
- GF-AFC reagent
- Sterile, 96-well plates
- Non-sterile, 96-well plate(s)
- Sterile, adhesive foil covers
- Assay manual

Bioluminescence Assay Kit Contents

- Master Mix or specialized medium for cell growth
- ATP standard
- ATP controls
- ATP Enumeration Reagent
- Sterile, 96-well plates
- Non-sterile, 96-well plates
- Sterile, adhesive foil covers
- Assay manual

Take the Next Step.
Change to "Best Practice Criteria Testing"

HemoGenix®
Changing the Paradigm

Assays You Can Trust
Innovative Expertise You Can Count On

www.hemogenix.com | Tel: 719-264-6250 | Fax: 719-264-6253 | info@hemogenix.com