HALO®-96 SPC-QC

Stem Cell "Quality" Assays for Hematopoietic Cellular Therapy Products

Ensure that your manufacturing processes deliver the highest quality stem cell therapeutic product.

Advantages of Using HALO®-96 SPC-QC in the Stem Cell Processing Laboratory

- Replaces all other functional assays with a non-subjective, quantitative measure of stem cell "quality" (proliferation ability).
- Fast, easy to learn and use, and is the only fully standardized and validated assay available for hematopoietic stem cell therapy products.
- Use the assay to monitor every manufacturing procedure to ensure stem cell yield, consistency and stability.
- Incorporates ATP Bioluminomics™ technology, the most advanced and sensitive assay readout available.
- Uses high-performance, serum-free, Suspension Expansion Culture™ (SEC™) technology for fast and accurate setup with high throughput capability.
- Rapid 5 day assay turnaround. Can be extended to 7 days for increased sensitivity and to accommodate work schedules.
- Results after cell culture available within 30 min.
- Full assay plate readout time, 5 min. or less.
- Assay standardization allows results to be compared over time and between different tissues.
- Always reliable and reproducible, with low coefficients of variation (CVs).
- FDA, AABB or FACT alternative "quality" assay.

HALO®-96 SPC-QC Assay Principle

- Prepare mononuclear cell (MNC) suspension from umbilical cord blood, mobilized peripheral blood bone marrow or purified , "enriched" cells (e.g. $CD34^+$, $CD133^+$).
- Perform an *in vitro* culture using the assay kit reagents for CFC-GEMM or CFC-GEMM and HPP-SP stem cell populations using a single cell dose.
- Prior to processing the sample plate after 5 or 7 days of culture, perform an ATP standard curve and controls (included with the kit) to calibrate and standardize the assay.
- Process the sample plate by adding the ATP Enumeration Reagent, mixing, incubating the plate for 10 min. and reading the results in a plate luminometer.
- The amount of proliferation (as a function of ATP concentration) at a single cell dose determines stem cell "quality", which can be compared prior to and after a manufacturing or cryopreservation procedure.

If maintaining consistently high quality of your hematopoietic stem cell therapeutic products is your priority, let HemoGenix® help you achieve your goal.

HemoGenix®
Changing the Paradigm

Assays You Can Trust
Innovative Expertise You Can Count

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HALO®-96 SPC-QC

HALO®-96 SPC-QC Assay Kit Ordering Information

Catalog Number	Cell Population Detected	Number of Samples/Kit	Number of Plates/Kit
K2-1QC-1	CFC-GEMM 1	16	1
K2-1QC-2	CFC-GEMM 1	32	2
K2-1QC-4	CFC-GEMM 1	64	4
K2-2QC-1	HPP-SP 2 + CFC-GEMM 1	8	1
K2-2QC-2	HPP-SP 2 + CFC-GEMM 1	16	2
K2-2QC-4	HPP-SP 2 + CFC-GEMM 1	32	4

CFC-GEMM 1 = primitive hematopoietic stem cell population.
HPP-SP 2 = primitive lympho-hematopoietic stem cell population.

HALO®-96 SPC-QC Kit Contents:

- HALO®-96 SPC-QC Master Mix for CFC-GEMM or CFC-GEMM and HPP-SP stem cell populations.
- ATP standard.
- ATP controls.
- ATP Enumeration Reagent.
- Sterile, 96-well plates.
- Non-sterile, 96-well plates.
- Sterile, adhesive foil covers.
- Assay manual.

Other Assays from HemoGenix® Specifically Designed for Cellular Therapy and Regenerative Medicine

- **STEMpredict™:** The most rapid stem cell functionality and viability assay available to determine cord blood bankability.
- **HALO®-96 PQR:** A potency, quality and release assay for hematopoietic stem cell therapeutic products.
- **HALO®-96 PMT:** To determine time to engraftment and hematopoietic and lympho-hematopoietic reconstitution.
- **ImmunoGlo™-96, ImmunoFluor™-96 or ImmunoLight™-96:** Lymphocyte proliferation assays.
- **ImmunoGlo™-MLC, ImmunoFluor™-MLC or ImmunoLight™-MLC:** Mixed Lymphocyte Culture/Reaction (MLC/MLR) assays.
- **MSCGlo™-96 HuQC:** Quality control for mesenchymal stem/stromal cell (MSC) processing.
- **MSCGlo™-96 PQR:** Potency, quality and release assay for mesenchymal stem/stromal cells (MSCs).