

# HALO<sup>®</sup>-96 PQR

## Potency, Quality and Release Criteria Assays for Hematopoietic Cellular Therapy Products

*The only commercially available assay that can ensure hematopoietic stem cell therapy products are of the highest potency and quality to be released for transplantation.*

### Advantages of using HALO<sup>®</sup>-96 PQR

- Accuracy for predicting engraftment potential: >90%.
- Complies with FDA and EMA guidelines and regulations for potency assays.
- Fully standardized and validated according to FDA guidelines.
- Master File with the FDA (can be included with BLA or IND submissions).
- Incorporates ATP Bioluminomics™ technology, the most advanced and sensitive, non-subjective and non-radioactive assay readout available.
- Uses high-throughput, serum-free, Suspension Expansion Culture™ (SEC™) technology for fast, easy to use and accurate setup with high throughput capability.
- Rapid 5 day assay turnaround. Can be extended to 7 days for increased sensitivity and work schedule.
- Assay standardization allows results to be compared over time and between different tissues.
- Always reliable and reproducible, with low coefficients of variation (CVs).
- HALO<sup>®</sup>-96 PQR is an FDA, AABB and FACT alternative potency assay.
- Potency of samples performed by HemoGenix<sup>®</sup> as a contract service includes a Certificate of Potency Analysis.

### HALO<sup>®</sup>-96 PQR Assay Principle

- Prepare mononuclear cell (MNC) suspension from umbilical cord blood, mobilized peripheral blood bone marrow or purified cells (e.g. CD34<sup>+</sup>).
- Using the assay culture reagents for both CFC-GEMM and HPP-SP stem cell populations, perform a dose response for the sample tissue and reference standard (see below).
- After 5 to 7 days incubation measure stem cell proliferation using the ATP bioluminescence reagents included with the kit.
- Compare the stem cell proliferation potential for the sample and reference standard to determine the potency ratio.
- Compare the proliferation ability of the sample and reference standard to determine the “quality” of both stem cell populations.
- The potency ratio and “quality” of both stem cell populations is compared to acceptance criteria to release the cell batch for use.

### HALO<sup>®</sup>-96 PQR has been specifically designed and developed so that:

- The processing laboratory can perform the assay rapidly and accurately. Alternatively, let HemoGenix<sup>®</sup> perform the assays for you as a contract potency service. A Certificate of Potency Analysis (CoPA) is provided.
- The laboratory or medical director can rely on the results and make an informed decision (together with other tests) to release the product for use.
- The patient can receive the highest potency and quality stem cell therapeutic product available.

**Make Potency and Quality of Your Stem Cell Therapeutic Products Your #1 Priority.**



Assays You Can Trust  
Innovative Expertise You Can Count On

# HALO<sup>®</sup>-96 PQR

## Establishing a Reference Standard - HALO<sup>®</sup>-96 PRS

- To measure potency, a reference standard of the same material to that of the sample is required.
- Since a universal reference standard is not available, an in-house reference standard must be established prior to measuring the potency of a cell sample batch.
- The reference standard is used when the potency of a cellular therapeutic product is to be measured in order to determine the potency ratio.
- HemoGenix<sup>®</sup> has now developed an assay, HALO<sup>®</sup>-96 PRS, that helps you establish your own in-house reference standards. **Please note** that since the assays are fully standardized and validated, results can be reliably compared between different reference standard preparations and sample lots.

### HALO<sup>®</sup>-96 PQR Kit Contents:

- HALO<sup>®</sup>-96 PQR Master Mix for CFC-GEMM (hematopoietic stem cell).
- HALO<sup>®</sup>-96 PQR Master Mix for HPP-SP (lympho-hematopoietic stem cell).
- ATP standard.
- ATP controls.
- ATP Monitoring Reagent.
- Sterile, 96-well plates.
- Non-sterile, 96-well plates.
- Sterile, adhesive foil covers.
- Assay manual.

### HALO<sup>®</sup>-96 PRS Kit Contents:

- Cryopreserved reference standard cells for umbilical cord blood, mobilized peripheral blood, bone marrow or purified stem cells.
- HALO<sup>®</sup>-96 PQR Master Mix for CFC-GEMM.
- HALO<sup>®</sup>-96 PQR Master Mix for HPP-SP.
- ATP standard.
- ATP controls.
- ATP Monitoring Reagent.
- Sterile, 96-well plates.
- Non-sterile, 96-well plates.
- Sterile, adhesive foil covers.
- Assay manual.

## HALO<sup>®</sup>-96 PQR Assay Kit Ordering Information

Catalog Number	Tissue	Number of Plates/Kit
K2-PQR-1	Umbilical cord blood, mobilized peripheral blood, bone marrow or purified cells from these tissues	1
K2-PQR-2		2
K2-PQR-4		4

For more information, catalog numbers and ordering of HALO<sup>®</sup>-96 PRS assay kits, please go to the online HemoGenix<sup>®</sup> catalog.

### More Information on Hematopoietic Stem Cell Potency

Karen M. Hall, Holli Harper and Ivan N. Rich (2012). Hematopoietic Stem Cell Potency for Cellular Therapeutic Transplantation, *Advances in Hematopoietic Stem Cell Research*, Rosana Pelayo (Ed.), ISBN: 978-953-307-930-1, InTech, Available from: <http://www.intechopen.com/articles/show/title/hematopoietic-stem-cell-potency-for-cellular-therapeutic-transplantation>