

Potency Assays for Cell Therapy

The 7-Day Predictive Engraftment Potential Assay

- Accurate cell proliferation data provides stem cell potency (strength), identity, purity and quality information in a single assay.
- For cord blood, bone marrow, mobilized peripheral blood or purified cells (e.g. CD34+, CD133+ etc).
- Provide the transplantation physician with the most qualified information on the stem cell product in the shortest possible time prior to use.
- Establish in-house reference standards (using HALO® RS) that allow the potency ratio (measure of potency) to be determined.
- Fully compliant with FDA potency assay regulations and guidelines for hematopoietic cell therapy products.
- HALO® SC-IPS has a Master File with the FDA that can be referenced in an IND or BLA to the FDA. For more information, please contact Preferred Cell Systems™.
- Fully standardized, verified and validated according to FDA guidelines.
- Proficiency testing performed and completed during the assay standardization procedure. No additional costly and time-consuming proficiency testing required.
- Measurement assurance parameters provide proficiency and the trust in your results.
- Measurement of strength or potency is performed using a modified “Slope-Ratio Concentration-Response Model” standardized by the U.S. Pharmacopeia.
- Makes “potency” testing using TNC, viability, CD34 or CFU assays obsolete.
- Suspension Expansion Culture™ (SEC™) Technology provides high accuracy and precision and makes dispensing methylcellulose obsolete.
- 96-well plate format means smaller sample and reagent volumes with faster setup.
- Short 7-day incubation to predict engraftment potential.
- Let the plate reader acquire and calculate results in just 5 minutes or less.
- Directly compare stem cell potency, identity, purity and quality from different donors and processing procedures over time.
- Includes everything needed to culture and measure stem cell potency, identity, purity and quality. Just prepare and add cells.
- Time-efficient and highly cost-effective.
- Easy to learn in just 1 day.

Potency Assay Kits Available

Assay	Assay Type	Tissue	Catalog Number
HALO® SC-IPS	Potency (Strength)	All	K2-PQR-1
HALO® RS ⁽²⁾	In-house RS	Cord blood	K2-PRS-1CB
HALO® RS	In-house RS	Cord blood CD34 ⁺	K2-PRS-1CB34
HALO® RS	In-house RS	Bone marrow	K2-PRS-1BM
HALO® RS	In-house RS	Bone marrow CD34 ⁺	K2-PRS-1BM34
HALO® RS	In-house RS	Mobilized PB	K2-PRS-1mPB
HALO® RS	In-house RS	Mobilized PB CD34 ⁺	K2-PRS-1mPB34

(1) A reference standard is needed to estimate the potency ratio.

(2) HALO® RS assay kits include a vial of cryopreserved cells used to compare with the in-house preparation of the same tissue.

Preferred Cell Systems™