

MSCGlo™-96 PQR

Potency, Quality and Release Criteria Assay for Mesenchymal Stem/Stromal Cell (MSC) Therapeutic Products

Ensure that the MSC products you manufacture are of the highest potency and quality so that they can be released for use.

Advantages of using MSCGlo™-96 PQR

- MSCGlo™-96 PQR can be used with MSCs derived from most MSC sources, including bone marrow, umbilical cord blood and adipose tissue and requires a MSC reference standard of the same material and source (see below).
- Complies with FDA and EMA guidelines and regulations for potency assays.
- Fully standardized and validated according to FDA guidelines.
- Requires just 90,000 cells to measure MSC potency.
- Includes high performance MSCGro™ growth medium available with low serum, serum free or humanized.
- Incorporates ATP bioluminescence technology, the most advanced and sensitive readout available.
- Rapid turnaround: Usually 3-5 day culture for most MSC samples.
- Assay calibration and standardization allows results to be compared over time and between different tissues.
- Always reliable and reproducible, with low coefficients of variation (CVs).
- MSCGlo™-96 PRS is used to establish MSC reference standards for use with MSCGlo™-96 PQR (see next page).
- Potency of samples performed by HemoGenix® as a contract service includes a Certificate of Potency Analysis.

LUMENESC™-96 PQR Assay Principle

- First establish MSC reference standards for the MSC source to be tested using the MSCGlo™-96 PRS assay kit (see next page).
- Prepare a sample of the MSC for which potency is to be measured and measure the cell count.
- Prepare the MSC reference standard.
- Prepare a minimum 3-point cell dose response in MSCGro™ medium for both the sample and reference standard.
- Dispense 0.1ml into replicate wells of the sterile 96-well plate provided.
- After culture, measure MSC proliferation using the ATP bioluminescence reagents included with the kit.
- The slope of the 3-point dose response for the sample and reference standard determines the potency ratio.
- The amount of proliferation (as a function of ATP concentration) at a single cell dose determines stem cell "quality".
- Both the potency ratio and "quality" is used to release the MSC lot for use.

MSCGlo™-96 PQR has been designed and developed so that:

- The processing laboratory can perform the assay rapidly and accurately. Alternatively, let HemoGenix® 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 Your #1 Priority.



Assays You Can Trust
Innovative Expertise You Can Count On

MSCGlo™-96 PQR

Establishing a Reference Standard using MSCGlo™-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 lot.
- 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® has now developed an assay, MSCGlo™-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.

MSCGlo™-96 PQR Kit Contents:

- MSCGro™ medium of choice
- ATP standard
- ATP controls
- ATP Monitoring Reagent
- Sterile, 96-well plates.
- Non-sterile, 96-well plates
- Sterile, adhesive foil covers.
- Assay manual

MSCGlo™-96 PRS Kit Contents:

- Cryopreserved MSC reference standard derived from bone marrow or umbilical cord blood. Please contact HemoGenix® for further RS sources.
- MSCGro™ Medium of choice
- ATP standard.
- ATP controls.
- ATP Monitoring Reagent.
- Sterile, 96-well plates.
- Non-sterile, 96-well plates.
- Sterile, adhesive foil covers.
- Assay manual.

MSCGlo™-96 PQR Assay Kit Ordering Information

Catalog Number	MSCGro™ Medium	Number of Plates/Kit
KLMC-LSP-1	Low serum	1
KLMC-LSP-2	Low serum	2
KLMC-SFP-1	Serum free	1
KLMC-SFP-2	Serum free	2
KLMC-HMP-1	Humanized	1
KLMC-HMP-2	Humanized	2

For more information, catalog numbers and ordering of MSCGlo™-96 PRS assay kits, please go to the online HemoGenix® catalog.



Assays You Can Trust
Innovative Expertise You Can Count On