TRINOVABIOCHEM
European Distributor of
Preferred Cell Systems™

POTENCY Measurement of MSC/MPS Cells

SC-IPS = Stem Cell Identity Purity Strength

MSCGlo™ RS

MSCGlo™ SC-IPS Potency

ATP Bioluminescence, Reference-Standard-Based Potency Assays for Mesenchymal Stem/ Progenitor Cells (MSC/MPCs)

Regulatory Requirements for Potency Testing (FDA & EMA):

- A reference standard of the same material in order to determine the potency (Strength) ratio
- Measurement of the active ingredients (Identity, Purity)
- A standardized and validated assay

1. Establishing a Reference Standard with MSCGlo™ RS:

ATP Bioluminescence Reference Standard-Based Potency Assay for MSC/MPCs

MSCGlo™ RS is used to establish your first in-house RS. The assay includes a vial of cord blood, peripheral blood or bone marrow cryopreserved cells that are used to compare to your own preparation.

- Contains cryopreserved reference standard cells to establish an in-house reference standard
- Standardized and validated ATP-bioluminescence assay to establish a cell dose-response curve to determine the proliferation potential
- Instrument based assay readout

2. Potency Measurement with MSCGlo™ SC-IPS/Potency:

ATP Bioluminescence Reference Standard-Based Potency Assay for MSC/MPCs to determine Stem Cell Identity, Purity and Strength

MSCGlo™ SC-IPS/Potency does not include RS material. You will use your in-house established RS (e.g. with MSCGlo™ RS) to measure the potency ratio of the sample.

- Reference standard-based potency assay
- "Active ingredients" are the mesenchymal stem & progenitor cells
- Uses the "Slope-Ratio Concentration-Response Model" to determine the measure of potency, the potency ratio, as it is standardized e.g. in the European Pharmocopoeia
- Includes ATP standards and controls which, together with the reference standard, allows the assay to be validated

TRINOVABIOCHEM

MSCGlo™ RS MSCGlo™ SC-IPS Potency

Determination of the Reference-Standard Based Potency of Mobilized Peripheral Blood Cells

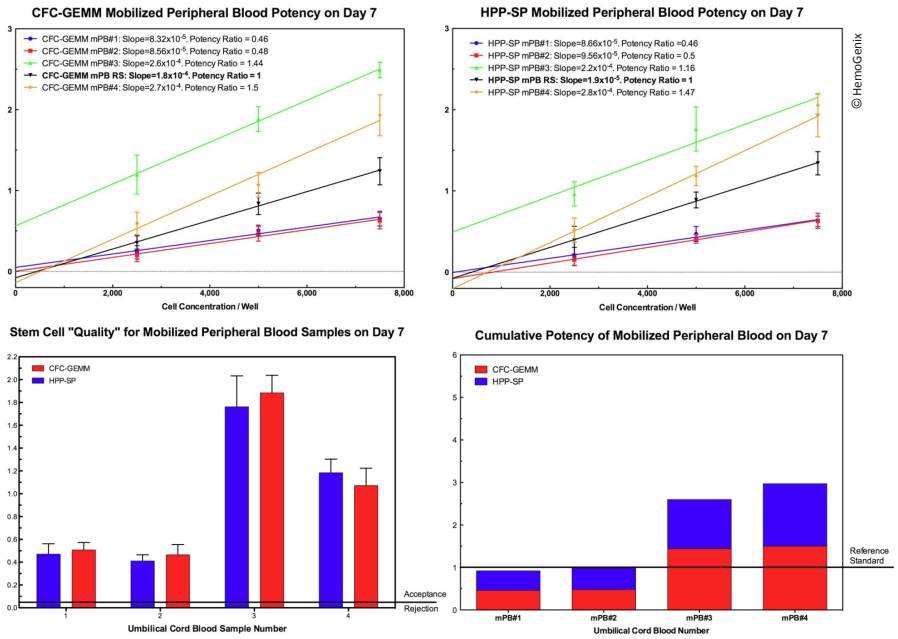

Fig. 1 and 2 (upper row) :
A 3-point cell dose-response for the sample tissue and reference standard from an in vitro culture using the assay kit reagents for both CFC-GEMM (SC-GEMM) and HPP-SP (SC-HPP); ATP bioluminescence measurement after 7 days of incubation.
▶ The slope of the 3-point dose-response for the sample and reference standard determines the potency ratio.
▶ The amount of proliferation (as a f unction of ATP concentration) at a single cell dose determines stem cell "quality".

Fig. 3 and 4 (lower row):
Stem cell "quality" and cumulative potency of both stem cell populations is compared to acceptance criteria to release the cell lot for use.

MSCGlo™ RS Assays Kits Available to Establish an In-House Reference Standard (RS) for MSCs

MSC Source	Formulation	Catalog No	Plates/Kit	Samples/Kit
Cord blood	MSCGrow - Low serum complete medium	KLMC-LSRS-1CB	1 x 96-well	1 + RS
Cord blood	MSCGrow - Serum-free, xeno-free complete medium	KLMC-SFRS-1CB	1 x 96-well	1 + RS
Cord blood	MSCGrow - Humanized complete medium	KLMC-HMRS-1CB	1 x 96-well	1 + RS
Cord blood	CRUX RUFA Human Platelet Lysate	KLMC-CRRS-1CB	1 x 96-well	1 + RS
Bone marrow	MSCGrow - Low serum complete medium	KLMC-LSRS-1BM	1 x 96-well	1 + RS
Bone marrow	MSCGrow - Serum-free, xeno-free complete medium	KLMC-SFRS-1BM	1 x 96-well	1 + RS
Bone marrow	MSCGrow - Humanized complete medium	KLMC-HMRS-1BM	1 x 96-well	1 + RS
Bone marrow	CRUX RUFA Human Platelet Lysate	KLMC-CRRS-1BM	1 x 96-well	1 + RS

MSCGlo™ SC-IPS/Potency Assays Kits Available to Determine MSC Identity, Purity and Strength

Source	Formulation	Catalog No	Plates/Kit	Samples/Kit
Any	MSCGrow - Low serum	KLMC-LSP-1	1 x 96-well	1 + RS
Any	MSCGrow - Serum-free	KLMC-SFP-1	1 x 96-well	1 + RS
Any	MSCGrow - Humanized	KLMC-HMP-1	1 x 96-well	1 + RS
Any	CRUX RUFA Human Platelet Lysate	KLMC-CRP-1	1 x 96-well	1 + RS

About Us

TRINOVA BIOCHEM is the European distributor of Preferred Cell Systems™ (PCS™) - the exclusive manufacturer of all products originally produced by HemoGenix®. Preferred Cell Systems™ develops innovative, high-quality in vitro Assays and cell culture Media for Stem Cell Research, Cellular Therapy, In Vitro Toxicology and Regenerative Medicine.

TRINOVA BIOCHEM GmbH
Rathenaustrasse 2
35394 Giessen/GERMANY
Fon: + 49 (0) 641 94390-0
Fax: + 49 (0) 641 94390-22
info@trinova.de / order@trinova.de
www.trinova.de

TB-MSCGloPotency/RS_08-17/11-18