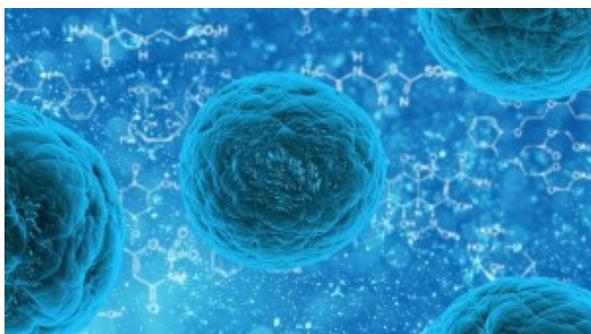


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A Standardized Protocol to Assess Stem Cell Potency

Steffen Porwollik January 29, 2015 Featured, Stem cells No Comment



— Three-dimensional image of a spherical human stem cell.

Image Source: [Pixabay](#).

A new compendium of protocols includes a standardized workflow detailing how to measure stem cell potency – a legally required step prior to administration of any stem cell therapy.

Stem cell therapy began about 30 years ago with bone marrow transplants

to treat blood cancers. It is an incredibly powerful strategy poised to heal, or alleviate, a plethora of diseases and symptoms that hitherto had been thought to be incurable and untreatable, including neurodegenerative disorders, heart disease and diabetes. No wonder the NIH is spending an estimated \$1 billion on stem cell research, annually.

However, stem cell therapeutics are difficult to standardize. Stem cells exist

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in various degrees of primitiveness which form a continuum of states that cannot be reliably quantified. Yet, the FDA requires strict determination of parameters such as potency prior to transplantation of cells into patients. Establishing standardized methods to measure such parameters in stem cells is challenging. A new compendium, aptly named “Stem Cell Protocols”, seeks to provide laboratories with some such methods. One chapter in this compendium is devoted to measuring stem cell potency. [1]

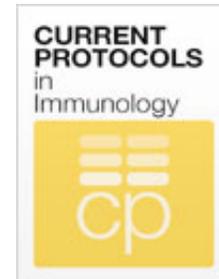
So what exactly is stem cell potency? Many think stem cell potency is simply “a stem cell’s ability to differentiate into other cell types”. However, potency is delineated by the authors of the protocol more as a pharmacological parameter: a biological activity of an active ingredient or component of a product, which produces the intended effect or response when given to the patient. Applied to standard drugs, this definition is easily understood and measured: the higher the drug’s potency, the lower its necessary therapeutic concentration. Since stem cells are regarded by the FDA as a type of “drug”, their potency also needs to be determined and reliably measured. But how?

In their outlined protocols for lympho-hematopoietic and mesenchymal stem cells, the researchers use commercially available kits that are based on converting intracellular ATP into luminescence. When stem cells actively divide, their intracellular ATP levels rise. The more intracellular ATP is present, the stronger the luminescence; and the steeper the slope of a luminescence curve established from different cell concentrations, the higher the potency of a stem cell population. These slopes are compared to a reference sample that needs to be established prior to measuring the experimental (unknown) cell population.

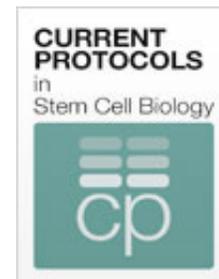
Standardization of the stem cell potency measurement protocol included steps necessary to cryopreserve and subsequently thaw cell populations, and the authors recommend the use of automatic rate-controlled freezers or BioCision’s CoolCell® containers for the freezing step. Surprisingly, their recommended thawing procedure included eyeballing of the process

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Protocols



Cryopreservation and Thawing of Cells



Standardized Cryopreservation of Pluripotent Stem Cells

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progression. Realizing the crucial nature of this step, the authors caution users that approximately 50% of the originally cryopreserved cells will be lost upon thawing. More precise, recently developed, thawing platforms such as BioCision's ThawSTAR™ would likely be able to improve that statistics.

(RSS) (44)



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(34)

Knowing how well the stem cell therapeutic will be able to engraft in the patient is imperative for successful stem cell therapy. Protocols such as the ones mentioned here go some way to maximizing therapeutic success by triaging cell lots with substandard potency. For good measure, the protocols also ensure that compliance with FDA regulations are met.

Reference:

[1] Harper, H. & Rich, I.N. Measuring the potency of a stem cell therapeutic. *Stem Cell Protocols* Vol. 1235, *Methods in Molecular Biology* (ed Rich, I. N.) Ch. 4, 33-48 (Springer New York). 2015.



👉 Cell Therapy, CoolCell, standardization, stem cell potency, stem cell protocol, ThawSTAR

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