[0020] MSC potency assays have been developed wherein the MSCs are stimulated with LPS; however, these potency assays produce "irrelevant" stimulations (*e.g.,* irrelevant because LPS stimulation is a mimic of bacterial infection and MSCs are not used as an anti-bacterial agent). These assays are further irrelevant since MSCs generally do not express TLR4 or CD14, which are both required for LPS stimulation and signaling. Hence, an objective of the present application is to provide a potency assay that accurately determines the ability of mesenchymal stem cells (MSC) to produce immunomodulatory cytokines in response to pro-inflammatory cytokines, such as TNF-α. Ideally, measurements are made for physiologically meaningful components.

[0021] Provided herein are methods for assessing MSC potency, e.g., assessing the potency of MSCs in a preparation of cells (e.g., a preparation of MSCs that belong to a lot of cells intended for therapeutic use). The methods provided herein utilize a TNF-α stimulation step, prior to assessing cell or cell lot potency, to assess whether the MSCs produce anti-inflammatory cytokines, and to what level, as compared to standard cell potency assays used in the art which only involve detecting the presence of cell surface receptors or biomarkers and fail to assess whether the cells are capable of expressing the molecules associated with stimulation of said receptors or biomarkers. It has been determined that incorporating the TNF-α stimulation step results in potency assay with increased reliability and decreased variability across MSC preparations taken from same cell lot, as well as MSC preparations comprising the same cell type but taken from different cell lots.

[0021a] In one aspect, the present disclosure refers to a method for assessing the potency of human mesenchymal stem cells (MSCs), comprising: stimulating a population of MSCs with a pro-inflammatory cytokine or other pro-inflammatory molecule; identifying anti-inflammatory cytokine production from said MSCs; and quantifying levels of the anti-inflammatory cytokine production from said MSCs.

BREIF DESCRIPTION OF DRAWINGS

[0022] FIG. 1 depicts the production levels of anti-inflammatory cytokines after stimulation of MSCs with recombinant human TNFα.

[0023] FIG. 2 depicts the viability of MSCs after stimulation with recombinant human TNFα.

[0024] FIG. 3 depicts the production levels of anti-inflammatory cytokines after stimulation of MSCs with recombinant human TNFα over 24 hours.

[0025] FIG. 4 depicts the production levels of IL-8 and IL-13 after MSCs were sensitized to IL-17A stimulation but exposure to recombinant human TNFα for 1 hour.