

CLAIMS

1. A method of quality assessing stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states for use in cell therapy for levels of cell contamination, the method comprising the steps of
 - 5 (i) determining a micro-RNA expression profile of the stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states to be assessed for a particular group or subset of micro-RNAs;
 - (ii) providing a reference micro-RNA expression profile of the particular group or

10 subset of micro-RNAs which is derived from a cell sample of stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states that conforms to a predetermined standard for the use of stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states in the cell therapy;
 - 15 (iii) comparing the micro-RNA expression profile determined in step (i) with the reference micro-RNA expression profile provided in step (ii); and
 - (iv) determining from the comparison of micro-RNA expression profiles a quality assessment as to the suitability of the stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states

20 for use in the cell therapy.
2. A method according to Claim 1, in which the qualities being assessed further comprise the maintenance of cell identity, phenotypic stability and functional capability and in which the particular group or subset of micro-RNAs includes micro-RNAs derived from cells of known identity and/or known phenotypic stability and/or known functional capability and

25 determined to be a marker of the cells identity, phenotypic stability or functional capability.
3. A method according to Claim 1 or 2, in which conformity to pre-determined safety standards of the stem cells for use in stem cell therapy is thereby assessed.
4. A method according to Claim 3, in which predetermined safety standard concerns tumourigenicity.

5. A method according to any preceding claim, in which the particular group or subset of micro-RNAs includes micro-RNAs that are identified as reliable markers of undesirable or uncharacterized alterations of the cell system being monitored for stem cell therapy.
6. A method according to any preceding claim, in which the cells to be assessed are stem cells.
7. A method according to any of Claims 1 to 6, in which the stem cells to be quality assessed for use in stem cell therapy are cultured from an *in vitro* cell culture and/or passage thereof.
8. A method according to any of Claims 1 to 7, in which the stem cells are mesenchymal stem cells.
9. A method according to any of Claims 1 to 5, in which the cells to be assessed are induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating states.
10. A method according to Claim 9, in which the quality assessing further comprises assessing degree of pluripotency.
11. A method according to any preceding claim, in which the step of comparing the micro-RNA expression profile of the cell sample with the reference expression profile comprises identifying correlations between micro-RNA profiles.
12. A method according to Claim 11, in which the correlations may comprise positive and/or negative correlations between the expression of one or more micro-RNAs.
13. A method according to Claim 12, in which a positive correlation is an expression of a micro-RNA in the sample to be quality assessed and in the reference micro-RNA profile and a negative correlation is expression of a micro-RNA in the sample to be quality assessed which exhibits differential expression in the reference microRNA profile.
14. A method according to any preceding claim, in which the method is other than to distinguish one differentiative cell state from another.
15. Use of micro-RNA molecules for quality assessing stem cells or induced pluripotent stem cells or their intermediate stages of differentiating to one or more terminal differentiating

states for use in cell therapy, in which the qualities being assessed comprise levels of cell contamination.