CLAIMS

What is claimed is:

1. A method of detecting allogeneic therapeutic cells a in blood sample comprising:

a. assaying allogeneic therapeutic cells and human peripheral blood mononuclear cells to identify one or more markers positive for allogeneic therapeutic cells and one or more markers positive for patient peripheral blood mononuclear cells;

b. comparing the one or more markers positive for allogeneic therapeutic cells and the one or more markers positive for patient peripheral blood mononuclear cells to identify one or more unique markers which distinguishes the allogeneic therapeutic cells from the patient peripheral blood mononuclear cells;

c. providing a blood sample from a patient that has been treated with allogeneic therapeutic cells;

d. analyzing the sample using an assay method to detect the one or more unique markers positive for the allogeneic therapeutic cells; and

e. distinguishing between the patient peripheral blood mononuclear cells and allogeneic therapeutic cells based on the detection of the one or more unique markers,

wherein the allogeneic therapeutic cells are selected from the group consisting of human umbilical cord tissue-derived cells, human umbilical cord blood-derived cells, placental-derived cells, mesenchymal stem cell derived cells, liver cells, pancreatic islet cells, cardiomyocytes, and insoluble collagenous bone matrix cells..

2. The method of claim 1, wherein the one or more positive marker for patient peripheral blood mononuclear cells comprises CD45.

3. The method of claim 1, wherein the assay method in step b. is selected from the group consisting of flow cytometry, ELISA, immunohistochemistry, nucleic acid detection, PCR, and combinations thereof.

4. The method of claim 1, further comprising performing an enrichment step between steps (c) and (d).

5. The method of claim 4, wherein the enrichment step is magnetic capture technology.

6. The method of claim 1, wherein the step of distinguishing comprises differentiating between allogeneic therapeutic cells administered to the patient and peripheral blood mononuclear cells from the patient.

7. The method of claim 1, wherein the patient is a human, non-human primate, mouse, rat, hamster, guinea pig, dog, or pig.

8. A kit for use in the method of detecting allogeneic therapeutic cells in a blood sample of claim 1, comprising a marker profile having one or more markers positive allogeneic therapeutic cells and one or more markers positive for patient peripheral blood mononuclear cells.

9. The method of claim 2, wherein the allogenic therapeutic cells are human umbilical cord tissue-derived cells, and wherein the one or more unique markers for human umbilical cord tissue-derived cells comprises CD10, CD13, NRP1 , LAMP1, DKK3, NRP1, or LAMB1 .

10. The method of claim 9, wherein the positive marker for patient peripheral blood mononuclear cells is CD45 and the positive marker for human umbilical cord tissue derived cells is CD10.

11. The method of claim 10, further comprising CD13 as the positive marker for human umbilical cord tissue-derived cells.

12. The method of claim 10, further comprising one or more of NRP1, DKK3, and LAMP1 as the positive marker for human umbilical cord tissue-derived cells.

13. A method of detecting human umbilical cord tissue-derived cells in a blood sample comprising the steps of:

a. providing a blood sample containing human umbilical cord tissue-derived cells;

b. isolating the human umbilical cord tissue-derived cell/peripheral blood mononuclear cell fraction from the blood sample;

c. removing any plasma;

d. analyzing the human umbilical cord tissue-derived cell/ peripheral blood mononuclear cell fraction by flow cytometry for CD45 as a positive marker for peripheral blood mononuclear cell and CD13 as a positive marker for human umbilical cord tissue-derived cells; and

e. detecting the presence of the human peripheral blood mononuclear cells and human umbilical cord tissue-derived cells based on the detection of CD45 as a marker positive for human peripheral blood mononuclear cells and CD13 as a marker positive for human umbilical cord tissue-derived cells.

14. The method of claim 13, further comprising analyzing for CD10 as a marker positive for human umbilical cord tissue-derived cells.

15. The method of claim 10 or 13, wherein the human umbilical cord tissue-derived cells are isolated from human umbilical cord tissue substantially free of blood, are capable of self-renewal and expansion in culture, have the potential to differentiate, and have the following characteristics: (1) express CD10, CD13, CD44, CD90, and HLA ABC; (2) do not express CD31, CD34, CD45, HLA-DR and CD117; (3) do not express hTERT or telomerase; (4) express oxidized low density lipoprotein receptor 1, reticulon, chemokine receptor ligand 3, and/or granulocyte chemotactic protein; and (4) express, relative to a human fibroblast, mesenchymal stem cell, or iliac crest bone marrow cell, increased levels of interleukin 8 or reticulon 1.

Claims

1. A method of detecting allogeneic therapeutic cells in a blood sample comprising:

a. assaying allogeneic therapeutic cells and human peripheral blood mononuclear cells to identify one or more markers positive for allogeneic therapeutic cells and one or more markers positive for patient peripheral blood mononuclear cells;

b. comparing the one or more markers positive for allogeneic therapeutic cells and the one or more markers positive for patient peripheral blood mononuclear cells to identify one or more unique markers which distinguishes the allogeneic therapeutic cells from the patient peripheral blood mononuclear cells;

c. providing a blood sample from a patient that has been treated with allogeneic therapeutic cells;

d. analyzing the sample using an assay method to detect the one or more unique markers positive for the allogeneic therapeutic cells; and

e. distinguishing between the patient peripheral blood mononuclear cells and allogeneic therapeutic cells based on the detection of the one or more unique markers,

wherein the allogeneic therapeutic cells are selected from the group consisting of human umbilical cord tissue-derived cells, placental-derived cells, mesenchymal stem cell derived cells, liver cells, pancreatic islet cells, cardiomyocytes, and insoluble collagenous bone matrix cells.

2. The method of claim 1, wherein the one or more positive marker for patient peripheral blood mononuclear cells comprises CD45.

3. The method of claims 1 or 2, wherein the assay method in step b. is selected from the group consisting of flow cytometry, ELISA, immunohistochemistry, nucleic acid detection, PCR, and combinations thereof

4. The method of claim 1, further comprising performing an enrichment step between steps (c) and (d).

5. The method of claim 4, wherein the enrichment step is magnetic capture technology.

6. The method of claims 1 or 2, wherein the step of distinguishing comprises differentiating between allogeneic therapeutic cells administered to the patient and peripheral blood mononuclear cells from the patient.

7. The method of claim 1, wherein the patient is a human, non-human primate, mouse, rat, hamster, guinea pig, dog, or pig.

8. A kit for use in the method of detecting allogeneic therapeutic cells in a blood sample of claim I, comprising a marker profile having one or more markers positive allogeneic therapeutic cells and one or more markers positive for patient peripheral blood mononuclear cells.

9. The method of claims 1 or 2, wherein the allogenic therapeutic cells are human umbilical cord tissue-derived cells, and wherein the one or more unique markers for human umbilical cord tissue-derived cells comprises CD10, CD13, NRPI , LAMP1, DKK3, NRP1, or LAMB1.

10. The method of claim 9, wherein the positive marker for patient peripheral blood mononuclear cells is CD45 and the positive marker for human umbilical cord tissue derived cells is CD10.

11. The method of claim 10, further comprising CD13 as the positive marker for human umbilical cord tissue-derived cells.

12. The method of claim 10, further comprising one or more of NRPI, DKK3, and LAMP1 as the positive marker for human umbilical cord tissue-derived cells.

13. A method of detecting human umbilical cord tissue-derived cells in a blood sample comprising the steps of:

a. providing a blood sample containing human umbilical cord tissue-derived cells;

b. isolating the human umbilical cord tissue-derived cell/peripheral blood mononuclear cell fraction from the blood sample;

c. removing any plasma;

d. analyzing the human umbilical cord tissue-derived cell/ peripheral blood mononuclear cell fraction by flow cytometry for CD45 as a positive marker for peripheral

blood mononuclear cell and CD13 as a positive marker for human umbilical cord tissue-derived cells; and

e. detecting the presence of the human peripheral blood mononuclear cells and human umbilical cord tissue-derived cells based on the detection of CD45 as a marker positive for human peripheral blood mononuclear cells and CD13 as a marker positive for human umbilical cord tissue-derived cells.

14. The method of claim 13, further comprising analyzing for CD10 as a marker positive for human umbilical cord tissue-derived cells.

15. The method of claim 10 or 13, wherein the human umbilical cord tissue-derived cells are isolated from human umbilical cord tissue substantially free of blood, are capable of self-renewal and expansion in culture, have the potential to differentiate, and have the following characteristics: (1) express CD10, CD13, CD44, CD90, and HLA ABC; (2) do not express CD31, CD34, CD45, HLA-DR and CD117; (3) do not express hTERT or telomerase; (4) express oxidized low density lipoprotein receptor 1, reticulon, chemokine receptor ligand 3, and/or granulocyte chemotactic protein; and (4) express, relative to a human fibroblast, mesenchymal stem cell, or iliac crest bone marrow cell, increased levels of interleukin 8 or reticulon 1.

16. The method of claim 13, further comprising performing an enrichment step between steps (c) and (d).

17. The method of claim 16, wherein the enrichment step is magnetic capture technology.

18. The method of claims 13 or 14, further comprising one or more of NRPI, DKK3, and LAMP1 as the positive marker for human umbilical cord tissue-derived cells.