

CLAIMS

1. A system for providing a T cell product, comprising a master cell bank of T cell and/or a working cell bank of T cell, wherein the
5 master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from a human, wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times by expansion culture of not more than 5 times.
- 10 2. The system according to claim 1, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from an induced pluripotent stem cell.
- 15 3. The system according to claim 1 or 2, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell with suppressed expression of at least one kind of HLA gene.
4. The system according to any one of claims 1 to 3, wherein the T
20 cell prepared from the master cell bank of T cell and/or working cell bank of T cell comprises an exogenous gene.
5. The system according to claim 4, wherein the exogenous gene is a CAR gene or an exogenous TCR gene.
- 25 6. The system according to any one of claims 1 to 5, wherein the T cell product comprises two or more kinds thereof.
7. The system according to any one of claims 1 to 6, wherein the T
30 cell prepared from the master cell bank of T cell and/or working cell bank of T cell is expansion cultured.
8. The system according to claim 7, wherein the T cell prepared from the master cell bank of T cell and/or working cell bank of T cell is
35 expansion cultured by stimulating the cell with a CD30 agonist.
9. The system according to any one of claims 7 to 8, wherein the expansion cultured T cell is frozen.

10. The system according to any one of claims 6 to 9, wherein T cell product collection comprising two or more kinds of T cell products is constructed by collecting the T cell products.

5 11. The system according to any one of claims 1 to 10, wherein a tumor-specific antigen or a tumor-associated antigen expressed in a tumor of a test subject is identified.

12. The system according to claim 11, wherein a T cell product
10 expressing a CAR or an exogenous TCR that recognizes and binds to the identified antigen from a T cell product collection comprising two or more kinds of T cell products is selected.

13. A method for producing a T cell product, comprising a process of
15 constructing a master cell bank of T cell and/or a working cell bank of T cell, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from a human, wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times
20 by expansion culture of not more than 5 times.

14. The method for producing a T cell product according to claim 13, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from an induced pluripotent stem
25 cell.

15. The method for producing a T cell product according to claim 13 or 14, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell with suppressed expression of at
30 least one kind of HLA gene.

16. The method for producing a T cell product according to any one of claims 13 to 15, further comprising a process of introducing a nucleic acid comprising an exogenous gene into a T cell prepared from
35 the master cell bank of T cell and/or working cell bank of T cell.

17. The method for producing a T cell product according to claim 16, wherein the exogenous gene is a CAR gene or an exogenous TCR gene.

18. The method for producing a T cell product according to any one of claims 13 to 17, further comprising a process of expansion culturing a T cell.

5 19. The method for producing a T cell product according to claim 18, wherein the process of expansion culturing the T cell comprises a process of stimulating the cell with a CD30 agonist.

20. A master cell bank of T cell and/or a working cell bank of T cell
10 comprising a T cell derived from a human, wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times by expansion culture of not more than 5 times.

15 21. The master cell bank of T cell and/or working cell bank of T cell according to claim 20, comprising a T cell derived from an induced pluripotent stem cell.

22. The master cell bank of T cell and/or working cell bank of T cell
20 according to claim 20 or 21, comprising a T cell with suppressed expression of at least one kind of HLA gene.

23. A master cell bank collection of T cell and/or a working cell bank collection of T cell comprising two or more kinds of the master
25 cell banks of T cell and/or working cell banks of T cell according to any one of claims 20 to 22.

24. A method for constructing a master cell bank of T cell and/or a working cell bank of T cell, comprising the following processes:

30 (1) a process of differentiating an induced pluripotent stem cell free of a chimeric antigen receptor (CAR) gene into a T cell for CAR-T therapy,

(2) a process of stocking the differentiated T cell, and

(3) a process of characterization of the differentiated T cell,
35 wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from a human,

wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times by expansion culture of not more than 5 times.

25. A method for constructing a master cell bank of T cell and/or a working cell bank of T cell, comprising the following processes:

- (1) a process of differentiating an induced pluripotent stem cell free of an exogenous T cell receptor (TCR) gene into a T cell for TCR-T therapy,
- (2) a process of stocking the differentiated T cell, and
- (3) a process of characterization of the differentiated T cell, wherein the master cell bank of T cell and/or working cell bank of T cell comprise(s) a T cell derived from a human, wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times by expansion culture of not more than 5 times.

26. The method according to claim 24, wherein the induced pluripotent stem cell has an exogenous T cell receptor (TCR) gene.

27. The method according to any one of claims 24 to 26, wherein at least one kind of HLA gene is deleted in the induced pluripotent stem cell.

28. The method according to any one of claims 24 to 27, wherein the T cell expresses CD8 $\alpha\beta$.

29. A master cell bank of T cell and/or a working cell bank of T cell constructed by the method according to any one of claims 24 to 28.

30. A method for producing a T cell product expressing a CAR or an exogenous TCR, comprising the following processes:

- (1) a process of preparing a T cell from the master cell bank of T cell and/or the working cell bank of T cell according to claim 29,
- (2) a process of introducing a CAR gene or an exogenous TCR gene into the prepared T cell, and
- (3) a process of expansion culturing the T cell into which the CAR gene or exogenous TCR gene has been introduced, wherein T cells constituting the master cell bank of T cell and/or working cell bank of T cell can be proliferated at least not less than 10^{10} times by expansion culture of not more than 5 times.

31. The method according to claim 30, wherein the CAR or exogenous TCR recognizes and binds to a tumor-specific antigen or a tumor-associated antigen.

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32. The method according to claim 30 or 31, wherein the process (3) comprises a process of stimulating the T cell with a CD30 agonist.

33. A T cell product produced by the method according to any one of
10 claims 30 to 32.

34. A method for constructing a T cell product collection comprising two or more kinds of T cell products, comprising a process of collecting the T cell product according to claim 33.

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35. A T cell product collection constructed by the method according to claim 34.

36. A method for providing a T cell product suitable for a test
20 subject, comprising the following processes:

(1) a process of identifying a tumor-specific antigen or a tumor-associated antigen expressed in the tumor of the test subject, and

(2) a process of selecting a T cell product that expresses a
25 CAR or an exogenous TCR that recognizes and binds to the identified antigen from the T cell product collection according to claim 35.