CLAIMS

1. An anti-human MUC1 antibody Fab fragment selected from the group consisting of the following (a) and (b):

(a) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 8 or SEQ ID NO: 10 and a light chain comprising a light chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 12; and

(b) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region derived from a heavy chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 8 or SEQ ID NO: 10 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 8 or SEQ ID NO: 10 into pyroglutamic acid, and a light chain comprising a light chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 12.

2. The anti-human MUC1 antibody Fab fragment according to claim 1 which is selected from the group consisting of the following (a) and (b):

(a) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 or SEQ ID NO: 4 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6; and

(b) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment derived from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 or SEQ ID NO: 4 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 2 or SEQ ID NO: 4 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6.

3. The anti-human MUC1 antibody Fab fragment according to claim 1 which is

selected from the group consisting of the following (a) and (b):
(a) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 10 and a light chain comprising a light chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 12; and
(b) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region derived from a heavy chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 10 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 10 into pyroglutamic acid, and a light chain comprising a light chain variable region consisting of the amino acid sequence represented by SEQ ID NO: 12.

4. The anti-human MUC1 antibody Fab fragment according to claim 3 which is selected from the group consisting of the following (a) and (b):
(a) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 4 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6; and
(b) an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment derived from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 4 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 4 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6.

5. The anti-human MUC1 antibody Fab fragment according to claim 4 which is an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 4 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6.

6. The anti-human MUC1 antibody Fab fragment according to claim 4 which is an anti-human MUC1 antibody Fab fragment comprising a heavy chain fragment

derived from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 4 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 4 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6.

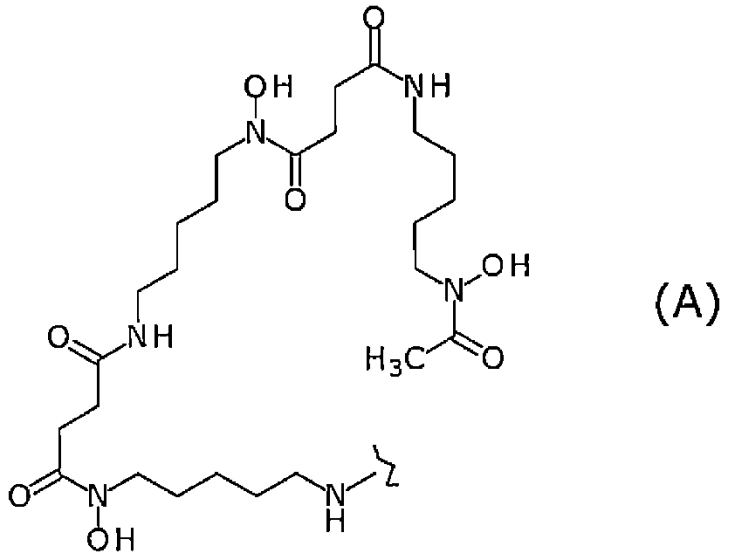
7. A conjugate comprising one or more labeling moiety and the anti-human MUC1 antibody Fab fragment according to any one of claims 1 to 6.

8. The conjugate according to claim 7, wherein the labeling moiety is (i) a ligand and a linker, (ii) a ligand.

9. The conjugate according to claim 8, wherein the labeling moiety is (i) a ligand and a linker or (ii) a ligand.

10. The conjugate according to claim 9, wherein the ligand is a ligand represented by the following formula (A):

[Chemical Formula 1]

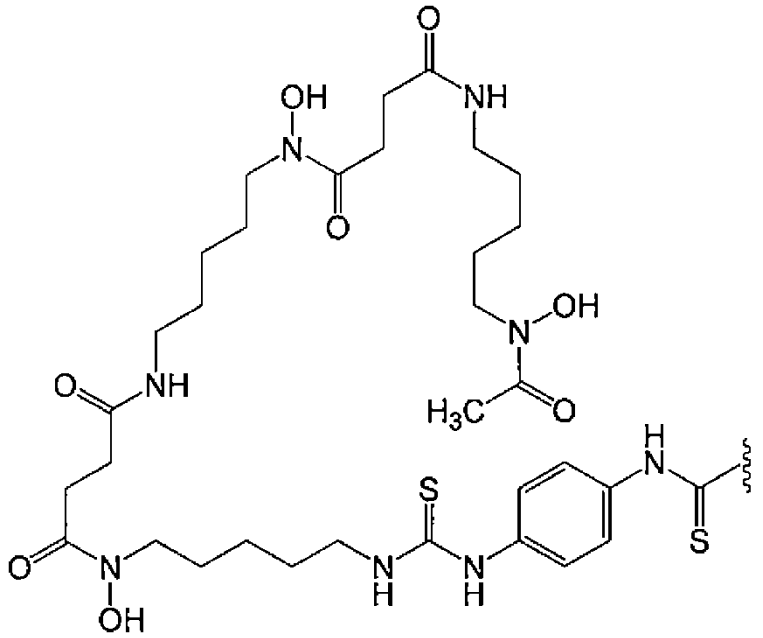


(A)

wherein the wavy line represents binding to the anti-human MUC1 antibody Fab fragment or the linker.

11. The conjugate according to claim 10, wherein the labeling moiety is a ligand and a linker represented by the following formula (A'):

[Chemical Formula 2]



(A')

wherein the wavy line represents binding to the anti-human MUC1 antibody Fab fragment.

12. The conjugate according to claim 11, wherein the anti-human MUC1 antibody Fab fragment is bound via an amino group thereof to the carbon atom of a labeling moiety terminal C(=S) group.

13. A conjugate selected from the group consisting of the following (a) to (c):

(a) the conjugate according to claim 12 wherein the anti-human MUC1 antibody Fab fragment is the anti-human MUC1 antibody Fab fragment according to claim 5;

(b) the conjugate according to claim 12 wherein the anti-human MUC1 antibody Fab fragment is the anti-human MUC1 antibody Fab fragment according to claim 6; and

(c) a conjugate which is a mixture of (a) and (b).

14. The conjugate according to any one of claims 9 to 13, further comprising a metal.

15. The conjugate according to claim 14, wherein the metal is a metal radioisotope.

16. The conjugate according to claim 15, wherein the metal is ^{89}Zr.

17. The conjugate according to claim 13, further comprising ^{89}Zr.

18. A polynucleotide selected from the group consisting of the following (a) and

(b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1.

19. A polynucleotide selected from the group consisting of the following (a) and (b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5.

20. An expression vector comprising the following (a) and/or (b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1.

21. An expression vector comprising the following (a) and/or (b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5.

22. A host cell selected from the group consisting of the following (a) to (d):

(a) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1;

(b) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1

antibody Fab fragment according to claim 1;

(c) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1; and

(d) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1.

23. A host cell selected from the group consisting of the following (a) to (d):

(a) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5;

(b) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5;

(c) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5; and

(d) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain

of the anti-human MUC1 antibody Fab fragment according to claim 5.

24. A method for producing an anti-human MUC1 antibody Fab fragment comprising the step of culturing a host cell selected from the group consisting of the following (a) to (c) to express the anti-human MUC1 antibody Fab fragment:

(a) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1;

(b) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1; and

(c) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 1, and a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 1.

25. A method for producing an anti-human MUC1 antibody Fab fragment comprising the step of culturing a host cell selected from the group consisting of the following (a) to (c) to express the anti-human MUC1 antibody Fab fragment:

(a) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab

fragment according to claim 5;

(b) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5; and

(c) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of the anti-human MUC1 antibody Fab fragment according to claim 5, and a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human MUC1 antibody Fab fragment according to claim 5.

26. A method for producing a conjugate comprising a labeling moiety and an anti-human MUC1 antibody Fab fragment, comprising the steps of: producing the anti-human MUC1 antibody Fab fragment by the method according to claim 24 or 25; and covalently binding the Fab fragment to the labeling moiety.

27. The method for producing a conjugate according to claim 26, wherein the step of covalently binding the Fab fragment to the labeling moiety is the step of i) binding the Fab fragment via a linker to a ligand or ii) covalently binding the Fab fragment directly to a ligand.

28. The method for producing a conjugate according to claim 27, further comprising the step of labeling the ligand of the conjugate with a metal radioisotope.

29. The method for producing a conjugate according to claim 26, wherein the step of covalently binding the Fab fragment to the labeling moiety is the step of i) binding the Fab fragment via a linker to a fluorescent dye or ii) covalently binding the Fab fragment directly to a fluorescent dye.

30. A composition for diagnosis comprising one or more conjugate according to

any of claims 7 to 17, and a pharmaceutically acceptable carrier.

31. The composition for diagnosis according to claim 30, wherein the conjugate is the conjugate according to claims 17.

32. The composition for diagnosis according to claim 31, wherein the conjugate is the conjugate according to claim 17.

33. The composition for diagnosis according to any one of claims 30 to 32 which is used in the diagnosis of a cancer expressing human MUC1.

34. The composition for diagnosis according to claim 33, wherein the cancer is breast cancer or bladder cancer.

35. A pharmaceutical composition comprising one or more conjugate according to any of claims 7 to 17, and a pharmaceutically acceptable carrier.

36. The pharmaceutical composition according to claim 35, wherein the conjugate is the conjugate according to claims 17.

37. The pharmaceutical composition according to any one of claims 35 and 36 which is a pharmaceutical composition for treating a cancer expressing human MUC1.

38. The pharmaceutical composition according to claim 37, wherein the cancer is breast cancer or bladder cancer.

39. Use of the conjugate according to any one of claims 7 to 17 for the production of a composition for the diagnosis of breast cancer or bladder cancer and/or a pharmaceutical composition for treating breast cancer or bladder cancer.

40. The conjugate according to any one of claims 7 to 17 for use in the diagnosis and/or treatment of breast cancer or bladder cancer.