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

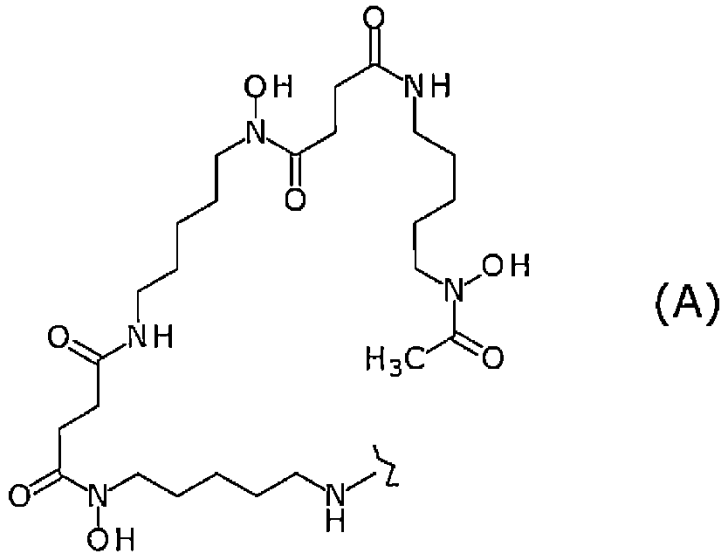
from a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 4 by the modification of glutamine at amino acid position 1 of SEQ ID NO: 4 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 6.

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 ligand is a ligand represented by the following formula (A):

[Chemical Formula 1]

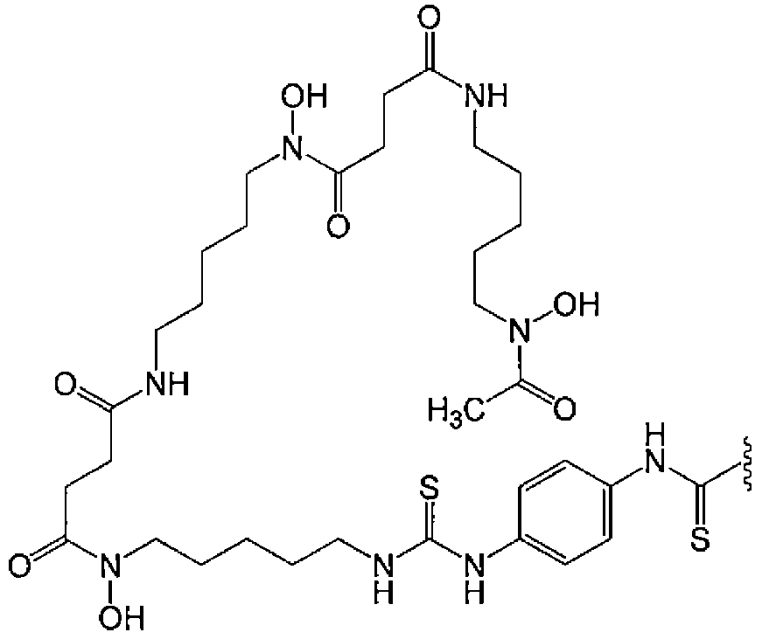


(A)

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

10. The conjugate according to claim 9, 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.

11. The conjugate according to claim 10, 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.

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

(a) the conjugate according to claim 11 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).

13. The conjugate according to any one of claims 8 to 12, further comprising a metal.

14. The conjugate according to claim 13, wherein the metal is a metal radioisotope.

15. The conjugate according to claim 14, wherein the metal is ^{89}Zr.

16. The conjugate according to claim 12, further comprising ^{89}Zr.

17. A polynucleotide comprising 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.

18. A polynucleotide comprising 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.

19. An expression vector comprising 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.

20. An expression vector comprising 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.

21. A host cell selected from the group consisting of the following (a) and (b):
(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; and
(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.

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

(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; and

(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.

23. 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.

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 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.

25. 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 23 or 24; and covalently binding the Fab fragment to the labeling moiety.

26. The method for producing a conjugate according to claim 25, 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.

27. The method for producing a conjugate according to claim 26, further comprising the step of labeling the ligand of the conjugate with a metal radioisotope.

28. The method for producing a conjugate according to claim 25, 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.

29. Use of the conjugate according to any of claims 7 to 16 for the production of a medicament for the diagnosis of a cancer expressing human MUC1.

30. The use of the conjugate according to claim 29, wherein the conjugate is the conjugate according to claims 16.

31. The use of the conjugate to claim 29, wherein the cancer is breast cancer or bladder cancer.

32. A pharmaceutical composition comprising one or more conjugate according to any of claims 7 to 16, and a pharmaceutically acceptable carrier.

33. The pharmaceutical composition according to claim 32, wherein the conjugate is the conjugate according to claims 16.

34. Use of the conjugate according to any one of claims 7 to 16 for the production of a medicament for treating a cancer expressing human MUC1.

35. The use of the conjugate according to claim 34, wherein the cancer is breast cancer or bladder cancer.

36. Use of the conjugate according to any one of claims 7 to 16 for the production of

a medicament for the diagnosis of breast cancer or bladder cancer and/or for treating breast cancer or bladder cancer.

37. Use of the conjugate according to any one of claims 7 to 16 for the production of a medicament for treatment of breast cancer or bladder cancer.