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.

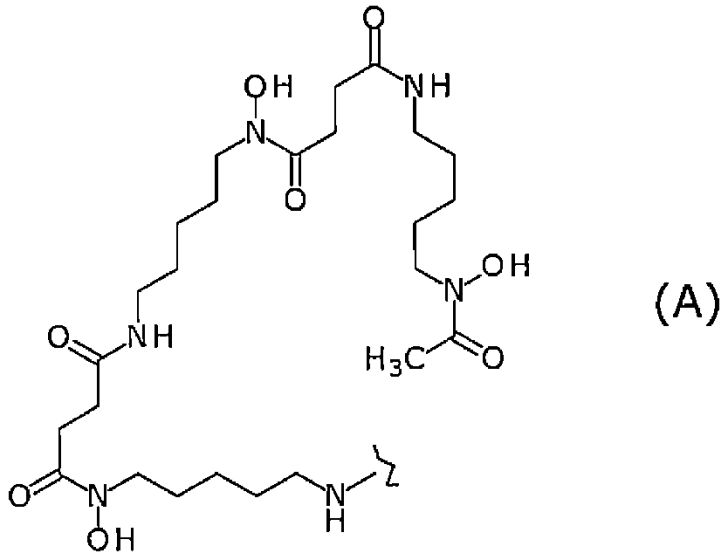
7. A conjugate comprising one or more labeling moiety and the anti-human MUC1 antibody Fab fragment according to any one of claims 1 to 6.

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~~9. The conjugate according to claim ~~9~~8, wherein the ligand is a ligand represented by the following formula (A):

[Chemical Formula 1]

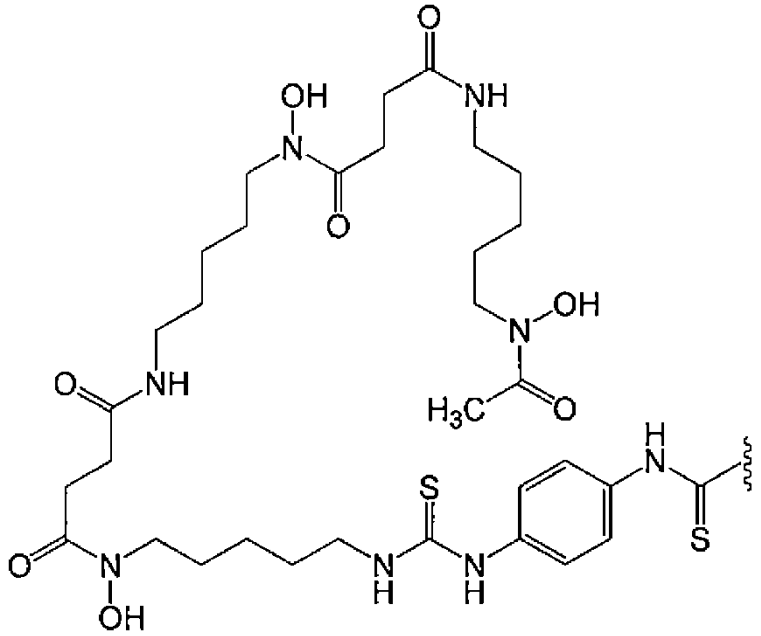


(A)

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

~~11~~10. The conjugate according to claim ~~10~~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.

~~12~~11. The conjugate according to claim ~~11~~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.

~~13~~12. A conjugate selected from the group consisting of the following (a) to (c):

(a) the conjugate according to claim ~~12~~ 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).

~~14~~13. The conjugate according to any one of claims ~~9~~ 8 to ~~13~~12, further comprising a metal.

~~15~~14. The conjugate according to claim ~~14~~13, wherein the metal is a metal radioisotope.

~~16~~15. The conjugate according to claim ~~15~~14, wherein the metal is ^{89}Zr.

~~17~~16. The conjugate according to claim ~~13~~12, further comprising ^{89}Zr.

~~18~~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.

~~19~~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.

~~20~~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.

~~21~~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.

~~22~~21. A host cell selected from the group consisting of the following (~~c~~a) and~~to~~ (~~d~~b):

(~~c~~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

(~~d~~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.

~~23~~22. A host cell selected from the group consisting of the following (a~~c~~) ~~to~~ and (~~d~~b):

(~~c~~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

(~~d~~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.

~~24~~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.

~~25~~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.

~~26~~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 ~~24~~ 23 or 24~~25~~; and covalently binding the Fab fragment to the labeling moiety.

~~27~~26. The method for producing a conjugate according to claim ~~26~~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.

~~28~~27. The method for producing a conjugate according to claim ~~27~~26, further comprising the step of labeling the ligand of the conjugate with a metal radioisotope.

~~29~~28. The method for producing a conjugate according to claim ~~26~~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.

~~30~~29. Use of the conjugate according to any of claims 7 to ~~17~~ 16 for the production of a medicament for the diagnosis of a cancer expressing human MUC1.

~~31~~30. The use of the conjugate according to claim ~~30~~29, wherein the conjugate is the conjugate according to claims ~~17~~16.

~~32~~31. The use of the conjugate to claim ~~30~~29, wherein the cancer is breast cancer or bladder cancer.

~~33~~32. A pharmaceutical composition comprising one or more conjugate according to any of claims 7 to ~~17~~16, and a pharmaceutically acceptable carrier.

~~34~~33. The pharmaceutical composition according to claim ~~33~~32, wherein the conjugate is the conjugate according to claims ~~17~~16.

~~35~~34. Use of the conjugate according to any one of claims 7 to ~~17~~ 16 for the production of a medicament for treating a cancer expressing human MUC1.

~~36~~35. The use of the conjugate according to claim ~~35~~34, wherein the cancer is breast cancer or bladder cancer.

~~37~~36. Use of the conjugate according to any one of claims 7 to ~~17~~ 16 for the production of a medicament for the diagnosis of breast cancer or bladder cancer and/or ~~a pharmaceutical composition~~ for treating breast cancer or bladder cancer.

~~38~~37. Use of the conjugate according to any one of claims 7 to ~~17~~ 16 for the production of a medicament for treatment of breast cancer or bladder cancer.