CLAIMS

1. An anti-human CEACAM5 antibody Fab fragment selected from the group consisting of the following (a) and (b):

(a) an anti-human CEACAM5 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region consisting of an amino acid sequence from amino acid positions 1 to 121 of SEQ ID NO: 2 and a light chain comprising a light chain variable region consisting of an amino acid sequence from amino acid positions 1 to 112 of SEQ ID NO: 4; and

(b) an anti-human CEACAM5 antibody Fab fragment comprising a heavy chain fragment comprising a heavy chain variable region derived from a heavy chain variable region consisting of an amino acid sequence from amino acid positions 1 to 121 of SEQ ID NO: 2 by the modification of glutamic acid at amino acid position 1 of SEQ ID NO: 2 into pyroglutamic acid, and a light chain comprising a light chain variable region consisting of an amino acid sequence from amino acid positions 1 to 112 of SEQ ID NO: 4.

2. The anti-human CEACAM5 antibody Fab fragment according to claim 1 selected from the group consisting of the following (a) and (b):

(a) an anti-human CEACAM5 antibody Fab fragment comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 4; and

(b) an anti-human CEACAM5 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 by the modification of glutamic acid at amino acid position 1 of SEQ ID NO: 2 into pyroglutamic acid, and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 4.

3. The anti-human CEACAM5 antibody Fab fragment according to claim 2, comprising a heavy chain fragment consisting of the amino acid sequence represented by SEQ ID NO: 2 and a light chain consisting of the amino acid sequence represented by SEQ ID NO: 4.

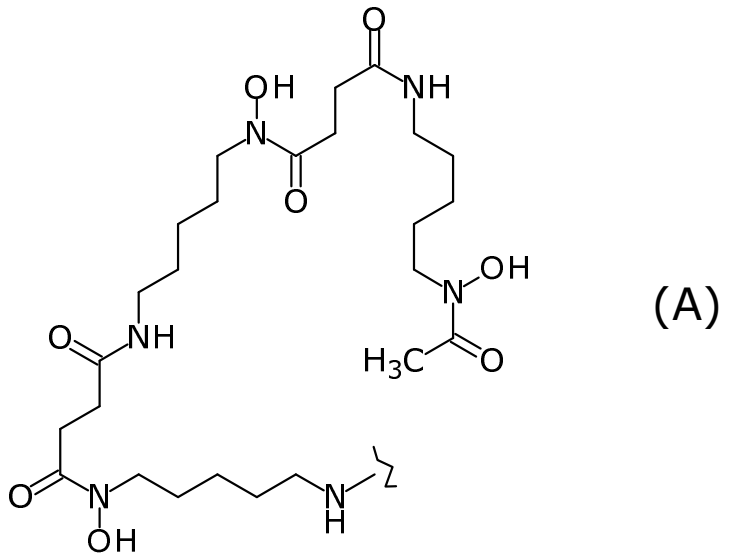
4. A conjugate comprising a labeling moiety and an anti-human CEACAM5 antibody Fab fragment according to any one of claims 1 to 3.

5. The conjugate according to claim 4, wherein the labeling moiety is (i) a ligand and a linker, (ii) a ligand, (iii) a fluorescent dye and a linker, or (iv) a fluorescent dye.

6. The conjugate according to claim 5, wherein the labeling moiety is (i) a ligand and a linker, or (ii) a ligand.

7. The conjugate according to claim 6, wherein the ligand is a ligand represented by the following formula (A):

[Chemical Formula 1]

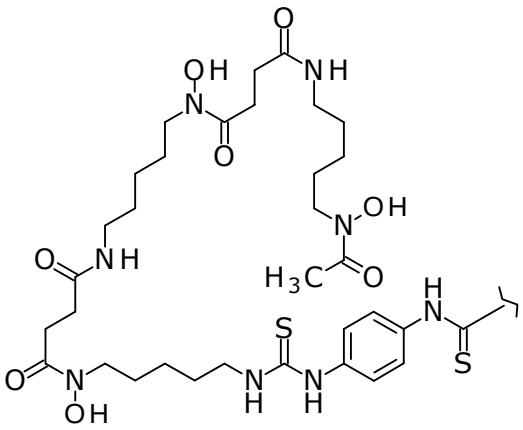


(A)

wherein the wavy line represents binding to the anti-human CEACAM5 antibody Fab fragment or the linker.

8. The conjugate according to claim 6, wherein the labeling moiety is (i) a ligand and a linker, wherein the ligand and the linker are a group represented by the following formula (A'):

[Chemical Formula 2]



(A')

wherein the wavy line represents binding to the anti-human CEACAM5 antibody Fab fragment.

9. The conjugate according to claim 8, wherein the anti-human CEACAM5 antibody Fab fragment is bound to the carbon atom of a labeling moiety terminal C(=S) group via an amino group in the Fab fragment.

10. The conjugate according to claim 6 represented by the following formula (I):

$(L\text{-}X)_p\text{-}Ab$ (I)

wherein Ab is the anti-human CEACAM5 antibody Fab fragment;

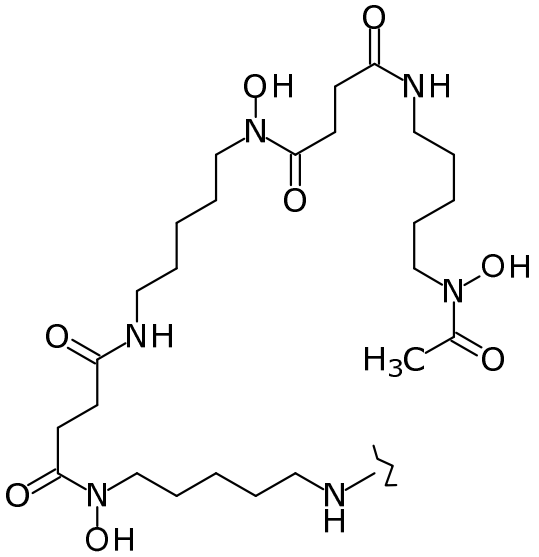
L is the ligand;

X is the linker or a bond; and

p is a natural number of 1 to 25.

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

[Chemical Formula 3]

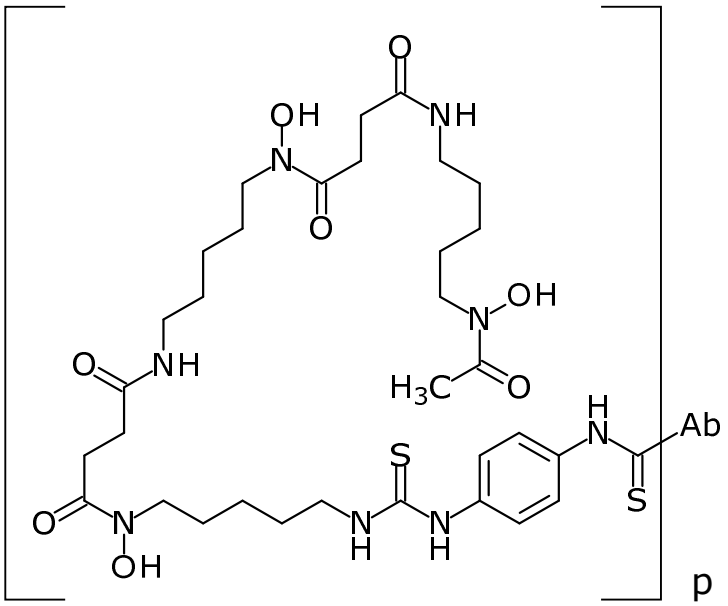


(A)

wherein the wavy line represents binding to X (or Ab when X is a bond).

12. The conjugate according to claim 8 or 11 represented by the following formula (II):

[Chemical Formula 4]



(II)

wherein Ab is the anti-human CEACAM5 antibody Fab fragment; and

p is a natural number of 1 to 25, wherein

Ab is bound to the carbon atom of labeling moiety terminal C(=S) via an amino group in the Ab.

13. The conjugate according to any one of claims 10 to 12, wherein p is a natural number of 1 to 16.

14. The conjugate according to any one of claims 10 to 12, wherein p is a natural number of 1 to 10.

15. The conjugate according to any one of claims 5 to 14, further comprising a metal.

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

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

18. The conjugate according to claim 16 or 17 for use as a PET tracer.

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

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1.

20. A polynucleotide consisting of the following (a) and (b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of an anti-human CEACAM5 antibody Fab fragment according to claim 3; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3.

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

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1.

22. An expression vector comprising the following (a) and (b):

(a) a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of an anti-human CEACAM5 antibody Fab fragment according to claim 3; and

(b) a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3.

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

(a) a host cell transformed with an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the heavy chain fragment of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1 and a polynucleotide comprising a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) 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 anti-human CEACAM5 antibody Fab fragment (a) according to claim 1 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) according to claim 1.

24. A host cell selected from the group consisting of the following (a) to (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 CEACAM5 antibody Fab fragment according to claim 3 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3; 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 CEACAM5 antibody Fab fragment according to claim 3 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3.

25. A method for producing an anti-human CEACAM5 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 CEACAM5 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 anti-human CEACAM5 antibody Fab fragment (a) according to claim 1 and a polynucleotide comprising

a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) 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 anti-human CEACAM5 antibody Fab fragment (a) according to claim 1 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of anti-human CEACAM5 antibody Fab fragment (a) 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 anti-human CEACAM5 antibody Fab fragment (a) 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 anti-human CEACAM5 antibody Fab fragment (a) according to claim 1.

26. A method for producing an anti-human CEACAM5 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 CEACAM5 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 an anti-human CEACAM5 antibody Fab fragment according to claim 3 and a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3;
(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 CEACAM5 antibody Fab fragment according to claim 3 and an expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3; 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 CEACAM5 antibody Fab fragment according to claim 3, and a host cell transformed with an

expression vector comprising a polynucleotide comprising a nucleotide sequence encoding the light chain of the anti-human CEACAM5 antibody Fab fragment according to claim 3.

27. A method for producing a conjugate comprising a labeling moiety and an anti-human CEACAM5 antibody Fab fragment, comprising the steps of: preparing the anti-human CEACAM5 antibody Fab fragment by a method according to claim 25 or 26; and covalently binding the Fab fragment to the labeling moiety.

28. A method for producing a conjugate comprising a ligand and an anti-human CEACAM5 antibody Fab fragment, comprising the steps of: preparing the anti-human CEACAM5 antibody Fab fragment by a method according to claim 25 or 26; and covalently binding the Fab fragment to the ligand via a linker or directly.

29. A method for producing a conjugate comprising a labeling moiety labeled with a metal radioisotope and an anti-human CEACAM5 antibody Fab fragment, comprising the steps of: producing a conjugate comprising a ligand and an anti-human CEACAM5 antibody Fab fragment by a method according to claim 28; and binding the metal radioisotope to the ligand of the conjugate through a coordinate bond.

30. A composition for diagnosis comprising a conjugate according to any one of claims 15 to 18, and a pharmaceutically acceptable carrier.

31. The composition for diagnosis according to claim 30 which is a clinical staging drug.

32. The composition for diagnosis according to claim 30 or 31 for use in the diagnosis of colorectal cancer, breast cancer, lung cancer, thyroid gland cancer or a cancer resulting from the metastasis thereof.

33. The composition for diagnosis according to claim 32 for use in the diagnosis of colorectal cancer or a cancer resulting from the metastasis of colorectal cancer.

34. The composition for use in diagnosis according to claim 33, wherein the cancer resulting from the metastasis of colorectal cancer is metastatic liver cancer.

35. Use of a conjugate according to any one of claims 15 to 18 for the production of a composition for diagnosis of colorectal cancer, breast cancer, lung cancer, thyroid gland cancer or a cancer resulting from the metastasis thereof.

36. The conjugate according to any one of claims 15 to 18 for use in the diagnosis of colorectal cancer, breast cancer, lung cancer, thyroid gland cancer or a cancer resulting from the metastasis thereof.