Claims

1. An isolated antibody, or antigen-binding fragment thereof, specific for folate receptor alpha (FRα) comprising

a. a light chain CDR1 having the amino acid sequence of SEQ ID NO: 10, a light chain CDR2 having the amino acid sequence of SEQ ID NO: 11, a light chain CDR3 having the amino acid sequence of SEQ ID NO: 12, a heavy chain CDR1 having the amino acid sequence of SEQ ID NO: 14, a heavy chain CDR2 having the amino acid sequence of SEQ ID NO: 15, and a heavy chain CDR3 having the amino acid sequence of SEQ ID NO: 16; or

b. a light chain CDR1 having the amino acid sequence of SEQ ID NO: 18, a light chain CDR2 having the amino acid sequence of SEQ ID NO: 19, a light chain CDR3 having the amino acid sequence of SEQ ID NO: 20, a heavy chain CDR1 having the amino acid sequence of SEQ ID NO: 22, a heavy chain CDR2 having the amino acid sequence of SEQ ID NO: 23, and a heavy chain CDR3 having the amino acid sequence of SEQ ID NO: 24.

2. The isolated antibody or antigen-binding fragment of claim 1, wherein the antibody is a murine antibody, a chimeric antibody, or a humanized antibody.

3. The isolated antibody of claim 1a comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO: 13 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO: 17.

4. The isolated antibody of claim 1b comprising a light chain variable region comprising the amino acid sequence of SEQ ID NO:21 and a heavy chain variable region comprising the amino acid sequence of SEQ ID NO:25.

5. An isolated antibody specific for folate receptor alpha (FRα) produced by the cell line deposited with the ATCC having accession number PTA-11884 or PTA-11886.

6. A method of detecting folate receptor alpha (FRα) or FRα-expressing cancer in a biological sample, comprising exposing the sample to the antibody of claim 1 or 5, or antigen-binding fragment thereof, and detecting folate receptor alpha (FRα).

7. The method of claim 6, wherein the biological sample is derived from a human, rodent, nonhuman primate, rabbit, or dog.

8. A method of diagnosing a folate receptor alpha-expressing cancer in a subject, comprising:

a. exposing a biological sample of the subject to the antibody of claim 1 or claim 5, or an antigen-binding fragment thereof;

b. quantifying the amount of folate receptor alpha (FRα) present in the sample;

c. comparing the amount of folate receptor alpha (FRα) present in the sample to a known standard; and

d. determining whether the subject's folate receptor alpha (FRα) levels fall within the levels of folate receptor alpha (FRα) associated with cancer.

9. The method of claim 8, wherein a finding that the subject's adenocarcinoma cells express folate receptor alpha indicates that the subject will have a higher probability of an improved 5-year survival rate than if the adenocarcinoma cells do not express folate receptor alpha.

10. A method of monitoring a folate receptor alpha-expressing cancer in a subject, comprising:

a. exposing a biological sample of the subject to-the antibody of claim 1 or claim 5, or an antigen-binding fragment thereof;

b. quantifying the amount of folate receptor alpha (FRα) present in the sample that is bound by the antibody or antigen-binding fragment thereof;

c. comparing the amount of folate receptor alpha (FRα) present in the sample to either

i. a known standard, or

ii. a biological sample obtained from the subject at an earlier point in time; and

d. determining whether the subject's folate receptor alpha (FRα) levels are indicative of cancer progression, regression or stable disease.

11. The method of any of claims 6 to 10, wherein the biological sample is derived from urine, blood, serum, plasma, saliva, ascites, circulating cells, circulating tumor cells, cells that are not tissue associated, tissues, surgically resected tumor tissue, biopsies, fine needle aspiration samples, or histological preparations.

12. The method of claim 8, wherein the cancer is breast cancer, thyroid cancer, colorectal cancer, endometrial cancer, fallopian tube cancer, ovarian cancer.

13. The method of claim 12, wherein the cancer is lung cancer.

14. The method of claim 13, wherein the lung cancer is adenocarcinoma.

15. The method of claim 8 or 10, wherein the known standard comprises

a. folate receptor alpha (FRα) levels derived from subjects identified as being free of cancer or a preparation of folate receptor alpha protein at a known concentration;

b. FRα levels derived from subjects identified as having early-stage folate receptor alpha-expressing cancer;

c. FRα levels derived from subjects identified as having mid-stage folate receptor alpha-expressing cancer; or

d. FRα levels derived from subjects identified as having late-stage folate receptor alpha-expressing cancer.

16. The method of claim 15, wherein the cancer is breast cancer, thyroid cancer, colorectal cancer, endometrial cancer, fallopian tube cancer, ovarian cancer or lung cancer.

17. The method of any one of claims 10 to 16, wherein the method is conducted following treatment of the subject for cancer.

18. The method of any one of claims 6 to 17, wherein the antibody, or antibody fragment, is labeled.

19. The method of claim 18, wherein the label is a radiolabel, a fluorescent label, an epitope tag, biotin, a chromophore label, an ECL label, or an enzyme.

20. The method of any one of claims 6 to 19, wherein the exposed folate receptor alpha (FRα) is or is not bound to a cell.

21. The method of any one of claims 6 to 20, wherein the presence of folate receptor alpha (FRα) in the sample is detected using western blot, immunohistochemistry, flow cytometry, radioimmunoassay, immunoprecipitation, electrochemiluminescence immunoassay (ECLIA), or ELISA.

22. The method of claim 8 or 9, wherein the subject's folate receptor alpha (FRα) levels are indicative of the type of cancer afflicting the subject.

23. The method of claim 22, wherein the cancer is lung adenocarcinoma or squamous cell lung carcinoma.

24. The isolated antibody of any one of claims 1 to 5, wherein the antibody is detectably labeled.

25. The antibody of claim 24, wherein the detectable label is a radiolabel, a fluorescent label, an epitope tag, biotin, a chromophore label, an ECL label, or an enzyme.

26. The antibody of claim 25, wherein the label is ruthenium, ^{111}In-DOTA, ^{111}In-diethylenetriaminepentaacetic acid (DTPA), horseradish peroxidase, alkaline phosphatase and beta-galactosidase, or poly-histidine.

27. The method of any one of claims 6 to 16, wherein the antibody, or antigen-binding fragment, is affixed to a solid support.

28. The method of claim 8 or claim 9 further comprising predicting a favorable outcome for a subject having adenocarcinoma that expresses folate receptor alpha (FRα), wherein a favorable outcome is defined as having an increased 5-year survival rate.