

CLAIMS

We claim:

- 5 1. A method of predicting responsiveness of an individual to a DNA-damage therapeutic agent comprising
 - a. measuring expression levels of at least five biomarkers in a test sample obtained from the individual, wherein the at least five biomarkers are selected from the biomarkers in Table 2B;
 - b. deriving a combined test score that captures the expression levels;
 - 10 c. providing a threshold score comprising information correlating the combined test score and responsiveness;
 - d. and comparing the combined test score to the threshold score; wherein responsiveness is predicted when the combined test score exceeds the threshold score.
- 15 2. The method of claim 1, wherein the at least five biomarkers are selected from the group consisting of CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.
- 20 3. The method of claim 2, wherein the combined test score captures the expression levels of all 44 biomarkers of Table 2B, and wherein responsiveness is predicted when the combined test score exceeds a threshold score calculated using the weights of Table 2B.
- 25 4. The method of any one of claims 1-3, wherein the DNA-damage therapeutic agent comprises one or more substances selected from the group consisting of: a DNA damaging agent, a DNA repair targeted therapy, an inhibitor of DNA damage signalling, an inhibitor of DNA damage induced cell cycle arrest, a histone deacetylase inhibitor, and a heat shock protein inhibitor.
- 30 5. The method of claim 4, wherein the DNA-damage therapeutic agent comprises one or more of an anthracycline, a cisplatin, a carboplatin, a cyclophosphamide, an oxaliplatin, a busulphan, an irinotecan, a topotecan, an etoposide, a doxorubicin, an epirubicin, and an ionising radiation.
- 35 6. The method of claim 4, wherein the DNA-damage therapeutic agent comprises one or more of a DNA-PK inhibitor, Nu7441, Nu7026, an inhibitor of homologous recombination, an inhibitor of

nucleotide excision repair, a PARP inhibitor, AG014699, AZD2281, ABT-888, MK4827, BSI-201, INO-1001, TRC-102, an APEX 1 inhibitor, an APEX 2 inhibitor, a Ligase III inhibitor, and an inhibitor of the Fanconi anemia pathway.

- 5 7. The method of any one of claims 1-6, wherein the individual is suspected of having or has been diagnosed as having a cancer.
8. The method of claim 7, wherein the cancer is selected from the group consisting of melanoma, colon cancer, breast cancer, and ovarian cancer.
- 10 9. The method of claim 8, wherein the cancer is breast cancer and the DNA-damage therapeutic agent comprises a combination of a 5-fluorouracil, an anthracycline and a cyclophosphamide.
10. The method of claim 9, wherein the anthracycline is epirubicin.
- 15 11. The method and claim 9, wherein the anthracycline is doxorubicin.
12. The method of claim 9, wherein a taxane is to be co-administered with the DNA-damage therapeutic agent.
- 20 13. The method of claim 8, wherein the cancer is ovarian cancer and the DNA-damage therapeutic agent comprises a platinum-containing agent.
14. The method of claim 13, wherein the DNA-damage agent is to be co-administered with a taxane.
- 25 15. The method of any one of claims 7-14, wherein the cancer is associated with one or more mutations in the Fanconi anemia/BRCA pathway.
16. A method of diagnosing an individual for having a cancer associated with a DNA damage response deficiency (DDR) comprising
 - 30 a. measuring expression levels of at least five biomarkers in a test sample obtained from the individual, wherein the at least five biomarkers are selected from the biomarkers in Table 2B;
 - b. deriving a combined test score that captures the expression levels;
 - c. providing a threshold score comprising information correlating the combined test score and a
35 diagnosis of the cancer;

- d. and comparing the combined test score to the threshold score; wherein the individual is diagnosed as having the cancer when the test score exceeds the threshold score.

17. The method of claim 16, wherein the at least five biomarkers are selected from the group consisting of CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.

18. The method of claim 17, wherein the combined test score captures the expression levels of all 44 biomarkers of Table 2B, and wherein the individual is diagnosed as having the cancer when the combined test score exceeds a threshold score calculated using the weights of Table 2B.

19. The method of any one of claims 16-18, wherein the cancer is selected from melanoma, colon cancer, breast cancer, and ovarian cancer.

20. The method of claim 19, wherein the cancer is associated with one or more mutations in the Fanconi anemia/BRCA pathway.

21. A method of detecting a cancer with DNA damage response deficiency related immune signalling in an individual comprising:

- a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers comprise at least one biomarker selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

- b. deriving a test score that captures the expression levels;

- c. providing a threshold score comprising information correlating the test score and detection of the cancer;

- d. and comparing the test score to the threshold score; wherein the cancer with DNA damage response deficiency related immune signalling is detected when the test score exceeds the threshold score.

22. The method of claim 21, wherein the one or more biomarkers are:

a. CXCL10 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. IDO1 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of CXCL10, MX1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1; or

c. selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3.

23. A method of selecting an appropriate therapy to treat a cancer with DNA damage response deficiency related immune signalling in an individual comprising:

a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers comprise at least one biomarker selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. deriving a test score that captures the expression levels;

c. providing a threshold score comprising information correlating the test score and selection of the appropriate therapy;

d. and comparing the test score to the threshold score; wherein a therapeutic agent appropriate for treatment of the individual is selected when the test score exceeds the threshold score.

24. A method of selecting an appropriate therapy to treat a cancer with DNA damage response deficiency related immune signalling in an individual comprising:

a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers comprise at least one biomarker selected from

the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. deriving a test score that captures the expression levels;

c. providing a threshold score comprising information correlating the test score and selection of the appropriate therapy;

d. and comparing the test score to the threshold score; wherein a therapeutic agent that targets tumors with abnormal DNA damage response is selected when the test score exceeds the threshold score.

25. A method of selecting an appropriate therapy to treat a cancer with DNA damage response deficiency related immune signalling in an individual comprising:

a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers comprise at least one biomarker selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. deriving a test score that captures the expression levels;

c. providing a threshold score comprising information correlating the test score and selection of the appropriate therapy;

d. and comparing the test score to the threshold score; wherein a therapeutic agent that inhibits expression of at least one of the biomarkers is selected when the test score exceeds the threshold score.

26. The method of any one of claims 23 to 25, wherein the one or more biomarkers are:

a. CXCL10 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. IDO1 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of CXCL10, MX1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1; or

c. selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3.

27. The method of any one of claims 21 to 26, wherein the cancer is melanoma, leukemia, brain cancer, prostate cancer, liver cancer, ovarian cancer, stomach cancer, colorectal cancer, throat cancer, breast cancer, skin cancer, lung cancer, sarcoma, cervical cancer, testicular cancer, bladder cancer, endocrine cancer, endometrial cancer, esophageal cancer, glioma, lymphoma, neuroblastoma, osteosarcoma, pancreatic cancer, pituitary cancer or renal cancer.

28. Use of a therapeutic agent in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune signalling as determined according to the method of claim 21 or claim 22.

29. Use of a therapeutic agent that targets tumors with abnormal DNA damage response in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune signalling as determined according to the method of claim 21 or claim 22.

30. Use of a therapeutic agent that inhibits expression of at least one of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1 in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune signalling as determined according to the method of claim 21 or claim 22.

31. Use of a therapeutic agent in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune

signalling as determined by the level of expression of one or more biomarkers selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.

32. Use of a therapeutic agent that targets tumors with abnormal DNA damage response in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune signalling as determined by the level of expression of one or more biomarkers selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.

33. Use of a therapeutic agent that inhibits expression of at least one of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1 in the manufacture of a medicament for treating a cancer in an individual, wherein the cancer displays DNA damage response deficiency related immune signalling as determined by the level of expression of one or more biomarkers selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.

34. The use according to any one of claims 28 to 33, wherein the one or more biomarkers are:
a. CXCL10 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5,

OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1;

b. IDO1 and at least 2, at least 3, or at least 4 additional biomarkers selected from the group consisting of CXCL10, MX1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, APOL3, CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1; or

c. selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3.

35. The use according to any one of claims 28 to 34, wherein the cancer is melanoma, leukemia, brain cancer, prostate cancer, liver cancer, ovarian cancer, stomach cancer, colorectal cancer, throat cancer, breast cancer, skin cancer, lung cancer, sarcoma, cervical cancer, testicular cancer, bladder cancer, endocrine cancer, endometrial cancer, esophageal cancer, glioma, lymphoma, neuroblastoma, osteosarcoma, pancreatic cancer, pituitary cancer or renal cancer.

36. The method of claim 1 or 16, wherein the at least five biomarkers are selected from CXCL10, MX10, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3.

CLAIMS

We claim:

- 5 1. A method of predicting responsiveness of an individual to a DNA-damage therapeutic agent comprising
 - a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers are selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3;
 - 10 b. deriving a test score that captures the expression levels;
 - c. providing a threshold score comprising information correlating the test score and responsiveness;
 - d. and comparing the test score to the threshold score; wherein responsiveness is predicted when the test score exceeds the threshold score.
- 15 2. The method of claim 1, further comprising measuring an expression level of one or more biomarkers in the test sample, wherein the one or more biomarkers are selected from the group consisting of CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4,
20 SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.
- 25 3. The method of claim 2, wherein the test score captures the expression levels of all of the biomarkers, and wherein responsiveness is predicted when the test score exceeds a threshold score at a value of 0.3681.
- 30 4. The method of any one of claims 1-3, wherein the DNA-damage therapeutic agent comprises one or more substances selected from the group consisting of: a DNA damaging agent, a DNA repair targeted therapy, an inhibitor of DNA damage signalling, an inhibitor of DNA damage induced cell cycle arrest, a histone deacetylase inhibitor, and a heat shock protein inhibitor.

5. The method of claim 4, wherein the DNA-damage therapeutic agent comprises one or more of an anthracycline, a cisplatin, a carboplatin, a cyclophosphamide, an oxaliplatin, a busulphan, an irinotecan, a topotecan, an etoposide, a doxorubicin, an epirubicin, and an ionising radiation.

5 6. The method of claim 4, wherein the DNA-damage therapeutic agent comprises one or more of a DNA-PK inhibitor, Nu7441, Nu7026, an inhibitor of homologous recombination, an inhibitor of nucleotide excision repair, a PARP inhibitor, AG014699, AZD2281, ABT-888, MK4827, BSI-201, INO-1001, TRC-102, an APEX 1 inhibitor, an APEX 2 inhibitor, a Ligase III inhibitor, and an inhibitor of the Fanconi anemia pathway.

10 7. The method of any one of claims 1-6, wherein the individual is suspected of having or has been diagnosed as having a cancer.

15 8. The method of claim 7, wherein the cancer is selected from the group consisting of a breast cancer and an ovarian cancer.

9. The method of claim 8, wherein the cancer is breast cancer and the DNA-damage therapeutic agent comprises a combination of a 5-fluorouracil, an anthracycline and a cyclophosphamide.

20 10. The method of claim 9, wherein the anthracycline is epirubicin.

11. The method and claim 9, wherein the anthracycline is doxorubicin.

25 12. The method of claim 9, wherein a taxane is to be co-administered with the DNA-damage therapeutic agent.

13. The method of claim 8, wherein the cancer is ovarian cancer and the DNA-damage therapeutic agent comprises a platinum-containing agent.

30 14. The method of claim 13, wherein the DNA-damage agent is to be co-administered with a taxane.

15. The method of any one of claims 7-14, wherein the cancer is associated with one or more mutations in the Fanconi anemia/BRCA pathway.

5 16. A method of diagnosing an individual for having a cancer or being susceptible to developing the cancer associated with a DNA damage response deficiency (DDR) comprising

a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein the one or more biomarkers are selected from the group consisting of CXCL10, MX1, IDO1, IF144L, CD2, GBP5, PRAME, ITGAL, LRP4, and APOL3;

b. deriving a test score that captures the expression levels;

10 c. providing a threshold score comprising information correlating the test score and a diagnosis of the cancer;

d. and comparing the test score to the threshold score; wherein the individual is diagnosed as having the cancer or being susceptible to developing the cancer when the test score exceeds the threshold score.

15 17. The method of claim 16, further comprising measuring an expression level of one or more biomarkers in the test sample wherein the biomarkers are selected from the group consisting of CDR1, FYB, TSPAN7, RAC2, KLHDC7B, GRB14, AC138128.1, KIF26A, CD274, CD109, ETV7, MFAP5, OLFM4, PI15, FOSB, FAM19A5, NLRC5, PRICKLE1, EGR1, CLDN10, ADAMTS4, SP140L, ANXA1, RSAD2, ESR1, IKZF3, OR211P, EGFR, NAT1, LATS2, CYP2B6, PTPRC, PPP1R1A, and AL137218.1.

20 18. The method of claim 17, wherein the test score captures the expression levels of all of the biomarkers, and wherein the individual is diagnosed as having the cancer or being susceptible to developing the cancer when the test score exceeds a threshold score at a value of 0.3681.

25 19. The method of any one of claims 16-18, wherein the cancer is selected from breast cancer and ovarian cancer.

20. The method of claim 19, wherein the cancer is associated with one or more mutations in the Fanconi anemia/BRCA pathway.