CLAIMS

What is claimed is:

1. A method of determining the probability that a prostate tissue biopsy obtained from a subject would contain detectable prostate cancer, the method comprising:

i) subjecting a blood plasma sample of the subject to an immunoassay that measures a level of total prostate specific antigen (tPSA) in the blood plasma sample;

ii) if the tPSA level is above a threshold level, determining the probability that the prostate tissue biopsy would contain detectable prostate cancer by weighting the measured level of tPSA and a parameter indicative of whether the subject has had a prior biopsy of prostate tissue; and

iii) if the tPSA level is at or below the threshold level, subjecting the blood plasma sample to an immunoassay that measures levels of free prostate specific antigen (fPSA), intact prostate specific antigen (iPSA), and human kallikrein 2 (hK2) in the blood plasma sample, and determining the probability that the prostate tissue biopsy would contain detectable prostate cancer by weighting the measured levels of tPSA, fPSA, iPSA, and hK2 and a parameter indicative of whether the subject has had a prior biopsy of prostate tissue.

2. A method of determining the probability that a prostate tissue biopsy obtained from a subject would contain detectable prostate cancer, the method comprising:

i) subjecting a blood plasma sample of the subject to immunoassays that measure levels of free prostate specific antigen (fPSA), intact prostate specific antigen (iPSA), total prostate specific antigen (tPSA) and human kallikrein 2 (hK2); and

ii) determining the probability that the prostate tissue biopsy would contain detectable prostate cancer by weighting the measured levels of fPSA, iPSA, tPSA, and hK2 and a parameter indicative of whether the subject had a prior biopsy of prostate tissue.

3. A method of assessing whether a subject has prostate cancer, the method comprising:

i) obtaining a blood sample from the subject;

ii) determining the probability that a prostate tissue biopsy obtained from the subject would contain detectable prostate cancer, wherein

a) if a tPSA level measured using the blood sample is above a threshold level, the probability is based on weighting the tPSA level and a parameter indicative of whether the subject had a prior biopsy of prostate tissue, otherwise,

b) if the tPSA level is at or below the threshold level, the probability is based on weighting levels of tPSA, fPSA, iPSA, and hK2 measured using the blood sample and a parameter indicative of whether the subject had a prior biopsy of prostate tissue;

iii) determining whether the subject is a candidate for the prostate tissue biopsy based on the results of step ii); and

iv) if the subject is a candidate for the prostate tissue biopsy based on the results of step ii), obtaining the prostate tissue biopsy from the subject and determining whether the subject has prostate cancer based on an analysis of the prostate tissue biopsy.

4. A method of determining whether a subject has prostate cancer, the method comprising:

i) obtaining a prostate tissue biopsy from the subject, wherein the subject is indicated for the prostate tissue biopsy based on a probability that the prostate tissue biopsy would contain detectable prostate cancer, wherein

a) if a tPSA level measured using a blood sample obtained from the subject is above a threshold level, the probability is based on weighting the tPSA level and a parameter indicative of whether the subject had a prior biopsy of prostate tissue, otherwise,

b) if the tPSA level is at or below the threshold level, the probability is based on weighting levels of tPSA, fPSA, iPSA, and hK2 measured using the blood sample and a parameter indicative of whether the subject had a prior biopsy of prostate tissue; and

ii) determining whether the subject has prostate cancer based on an analysis of the prostate tissue biopsy.

5. The method of any one of claims 1 to 4, wherein the prostate cancer is a high grade prostate cancer.

6. The method of any one of claims 1 to 5, wherein the probability that a subject has prostate cancer is further determined by weighting a parameter indicative of the subject's age.

7. The method of claim 1or 6, wherein the probability that a subject has prostate cancer is further determined by weighting a parameter indicative of the outcome of a digital rectal examination performed on the subject.

8. The method any one of claims 1 to 7, wherein the probability that a subject has prostate cancer is further determined by weighting a cubic spline term based on the measured tPSA level.

9. The method any one of claims 1 to 8, wherein the probability that a subject has prostate cancer is further determined by weighting a cubic spline term based on the measured fPSA level.

10. The method of any one of claims 1 to 9, wherein the immunoassay that measures the level of fPSA comprises:

contacting fPSA present in the plasma blood sample with a first capture antibody specific for fPSA under conditions in which the first capture antibody binds to fPSA, thereby producing a capture-antibody-fPSA complex; and

detecting the capture-antibody-fPSA complex using a first tracer.

11 The method of claim 10, wherein the first tracer is a 5A10 antibody.

12. The method of claim 10 or 11, wherein the first capture antibody is a H117 antibody.

13. The method of any one of claims 1 to 12, wherein the immunoassay that measures the level of iPSA comprises:

contacting iPSA present in the plasma blood sample with a second capture antibody specific for iPSA and nicked PSA, under conditions in which the second capture antibody binds at least to iPSA, thereby producing a capture-antibody- iPSA complex; and

detecting the capture-antibody- iPSA complex using a second tracer.

14. The method of claim 13, wherein the second tracer comprises a 4D4 antibody.

15. The method of claim 1 or 14, wherein the second capture antibody is a 5A10 Fab.

16. The method of any one of claims 1 to 15, wherein the immunoassay that measures the level of tPSA comprises:

contacting tPSA present in the plasma blood sample with a third capture antibody specific for tPSA under conditions in which the third capture antibody binds to tPSA, thereby producing a capture-antibody-tPSA complex; and

detecting the capture-antibody-tPSA complex using a third tracer.

17. The method of claim 16, wherein the third tracer comprises a H50 antibody.

18. The method of claim 16 or 17, wherein the third capture antibody is a H117 antibody.

19. The method of any one of claims 1 to 18, wherein the immunoassay that measures the level of hK2 comprises:

contacting PSA in the plasma blood sample with blocking antibodies specific for PSA;

contacting hK2 present in the plasma blood sample with a fourth capture antibody specific for hK2 under conditions in which the fourth capture antibody binds to hK2, thereby producing a capture-antibody-hK2 complex; and

detecting the capture-antibody-hK2 complex using a fourth tracer.

20. The method of claim 19, wherein the fourth tracer comprises a 7G1 antibody.

21. The method of claim 19 to 20, wherein the fourth capture antibody is a 6H10 $F(ab)_2$.

22. The method of any one of claims 19 to 21, wherein the blocking antibodies comprise a 5H7 antibody, a 5H6 antibody, and a 2E9 antibody.

23. The method of any one of claims 10 to 22, wherein each or any capture antibody is bound to a solid support.

24. The method of any one of claims 10 to 23, wherein each or any tracer comprises a Europium label.

25. An immunoassay method that measures the level of iPSA in a sample, the method comprising:

contacting iPSA present in the sample with a capture antibody specific for iPSA and nicked PSA under conditions in which the capture antibody binds at least to iPSA, thereby producing a capture-antibody- iPSA complex;

combining the capture-antibody-iPSA complex with an appropriate tracer in a buffer having a pH in a range of 6.5 to less than 7.75 such that the tracer binds to the capture-antibody- iPSA complex; and

detecting tracer bound to the capture-antibody- iPSA complex.

26. An immunoassay method that measures the level of iPSA in a sample, the method comprising:

contacting iPSA present in the sample with a capture antibody specific for iPSA and nicked PSA under conditions in which the capture antibody binds at least to iPSA, thereby producing a capture-antibody- iPSA complex, wherein the capture antibody is a Fab;

combining the capture-antibody- iPSA complex with an appropriate tracer under conditions in which the tracer binds to the capture-antibody- iPSA complex; and

detecting the tracer bound to the capture-antibody- iPSA complex.

27. The method of 26, wherein the Fab is a 5A10 Fab.

28. An immunoassay method that measures the level of hK2 in a sample, the method comprising:

contacting hK2 present in the sample with a capture antibody specific for hK2 and nicked PSA under conditions in which the capture antibody binds at least to hK2, thereby producing a capture-antibody-hK2 complex, wherein the capture antibody is a Fab;

combining the capture-antibody-hK2 complex with an appropriate tracer; and detecting the tracer bound to the capture-antibody-hK2 complex.

29. The method of 28, wherein the Fab is a $F(ab)_2$.

30. The method of 31, wherein the $F(ab)_2$ is 6H10 $F(ab)_2$.

31. A method for evaluating a sample, the method comprising:

(a) subjecting a sample to immunoassays that measure levels of fPSA, iPSA, tPSA and hK2,

wherein the immunoassay that measures the level of fPSA comprises contacting fPSA present in the sample with a H117 capture antibody to produce a capture-antibody-fPSA complex, and detecting the capture-antibody-fPSA complex using a 5A10 tracer antibody,

wherein the immunoassay that measures the level of iPSA comprises contacting iPSA present in the sample with a 5A10 Fab capture antibody to produce a capture-antibody- iPSA complex, and detecting the capture-antibody- iPSA complex using a 4D4 tracer antibody,

wherein the immunoassay that measures the level of tPSA comprises contacting tPSA present in the sample with a H117 capture antibody to produce a capture-antibody-tPSA complex, and detecting the capture-antibody-tPSA complex with a H50 tracer antibody,

wherein the immunoassay that measures the level of hK2 comprises contacting PSA in the plasma blood sample with blocking antibodies, contacting hK2 present in the sample with a 6H10 $F(ab)_2$ capture antibody to produce a capture-antibody-hK2 complex, and detecting the capture-antibody-hK2 complex with a 7G1 tracer antibody; and

(b) evaluating the sample based on the measured levels of fPSA, iPSA, tPSA and hK2.

32. The method of claim 31, wherein each or any of the capture antibodies is bound to a solid support.

33. The method of claim 31 or 32, wherein each or any of the tracer antibodies comprises a Europium label.

34. The method of any one of claims 31 to 33, wherein the blocking antibodies comprise a 5H7 antibody, a 5H6 antibody, and a 2E9 antibody.

35. A method for determining a probability of an event associated with prostate cancer, the method comprising:

receiving, via an input interface, information indicative of the level of tPSA present in a blood plasma sample of a subject;

receiving, via an input interface, information about whether the subject had a prior biopsy of prostate tissue;

evaluating, using at least one processor, a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer.

36. A method for determining a probability of an event associated with prostate cancer, the method comprising:

receiving, via an input interface, information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject;

receiving, via an input interface, information about whether the subject had a prior biopsy of prostate tissue;

evaluating, using at least one processor, a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer.

37. The method of claim 36, wherein the event is a prostate tissue biopsy containing detectable prostate cancer.

38. The method of claim 36, wherein the event is a prostate tissue biopsy containing detectable high-grade prostate cancer.

39. A computer for determining a probability of an event associated with prostate cancer, the computer comprising:

an input interface configured to receive information indicative of the level of tPSA present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue;

at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

an output interface configured to output an indication of the probability of the event associated with prostate cancer.

40. A computer for determining a probability of an event associated with prostate cancer, the computer comprising:

an input interface configured to receive information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue;

at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

an output interface configured to output an indication of the probability of the event associated with prostate cancer.

41. A system for determining a probability of an event associated with prostate cancer, the system comprising:

a) a detector configured to measure a level of tPSA present in a blood plasma sample of a subject; and

b) a computer in electronic communication with the detector, wherein the computer comprises:

i) an input interface configured to receive information from the detector indicative of the measured level of tPSA, and to receive information about whether the subject had a prior biopsy of prostate tissue;

ii) at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of the level of tPSA and the information about whether the subject had a prior biopsy of prostate tissue; and

iii) an output interface configured to output an indication of the probability of the event associated with prostate cancer.

42. A system for determining a probability of an event associated with prostate cancer, the system comprising:

a) a detector configured to measure levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject; and

b) a computer in electronic communication with the detector, wherein the computer comprises:

i) an input interface configured to receive information from the detector indicative of the measured levels of tPSA, fPSA, iPSA, and hK2, and to receive information about whether the subject had a prior biopsy of prostate tissue;

ii) at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

iii) an output interface configured to output an indication of the probability of the event associated with prostate cancer.

43. A computer-readable storage medium encoded with a plurality of instructions that, when executed by a computer, perform a method for determining a probability of an event associated with prostate cancer, wherein the method comprises:

evaluating a logistic regression model based, at least in part, on information indicative of the level of tPSA present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer.

44. A computer-readable storage medium encoded with a plurality of instructions that, when executed by a computer, perform a method for determining a probability of an event associated with prostate cancer, wherein the method comprises:

evaluating a logistic regression model based, at least in part, on information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue to determine a

probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer.

45. The computer or system or computer-readable storage medium of any one of claims 39 to 44, wherein the event is a prostate tissue biopsy containing detectable prostate cancer.

46. The computer or system or computer-readable storage medium of any one of claims 39 to 44, wherein the event is a prostate tissue biopsy containing detectable high-grade prostate cancer.

47. The method of any one of claims 1 to 24, wherein each or any immunoassay is performed using a microfluidic device.

48. A method of determining whether a subject is a candidate for a prostate tissue biopsy, the method comprising:

i) obtaining a blood sample from the subject;

ii) determining the probability that the prostate tissue biopsy would contain detectable prostate cancer using the blood sample obtained in step i), wherein

a) if a tPSA level measured using the blood sample is above a threshold level, the probability is based on weighting the tPSA level and a parameter indicative of whether the subject had a prior biopsy of prostate tissue, otherwise,

b) if the tPSA level is at or below the threshold level, the probability is based on weighting levels of tPSA, fPSA, iPSA, and hK2 measured using the blood sample and a parameter indicative of whether the subject had a prior biopsy of prostate tissue; and

iii) determining whether the subject is a candidate for the prostate tissue biopsy based on the probability that the prostate tissue biopsy will contain detectable prostate cancer as determined in step ii).

CLAIMS

1. A method of determining the probability that a prostate tissue biopsy obtained from a subject would contain detectable high-grade prostate cancer, the method comprising:

i) subjecting a blood plasma sample of the subject to an immunoassay that measures a level of total prostate specific antigen (tPSA) in the blood plasma sample;

ii) if the tPSA level is above a threshold level, determining the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer by weighting the measured level of tPSA and a parameter indicative of whether the subject has had a prior biopsy of prostate tissue; and

iii) if the tPSA level is at or below the threshold level, subjecting the blood plasma sample to an immunoassay that measures levels of free prostate specific antigen (fPSA), intact prostate specific antigen (iPSA), and human kallikrein 2 (hK2) in the blood plasma sample, and determining the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer by weighting the measured levels of tPSA, fPSA, iPSA, and hK2 and a parameter indicative of whether the subject has had a prior biopsy of prostate tissue.

2. A method of determining the probability that a prostate tissue biopsy obtained from a subject would contain detectable high-grade prostate cancer, the method comprising:

i) subjecting a blood plasma sample of the subject to immunoassays that measure levels of free prostate specific antigen (fPSA), intact prostate specific antigen (iPSA), total prostate specific antigen (tPSA) and human kallikrein 2 (hK2); and

ii) determining the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer by weighting the measured levels of fPSA, iPSA, tPSA, and hK2 and a parameter indicative of whether the subject had a prior biopsy of prostate tissue.

3. The method of any one of claims 1-2, wherein the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer is determined by also

weighting a parameter indicative of the subject's age.

4. The method of any one of claims 1-3, wherein the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer is determined by also weighting a parameter indicative of the outcome of a digital rectal examination performed on the subject.

5. The method of any one of claims 1-4, wherein the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer is determined by also weighting a cubic spline term based on the measured tPSA level.

6. The method of any one of claims 1-5, wherein the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer is determined by also weighting a cubic spline term based on the measured fPSA level.

7. The method of any one of claims 1-6, wherein the immunoassay that measures the level of fPSA comprises:

contacting fPSA present in the blood plasma sample with a first capture antibody specific for fPSA under conditions in which the first capture antibody binds to fPSA, thereby producing a capture-antibody-fPSA complex; and

detecting the capture-antibody-fPSA complex using a first tracer.

8. The method of claim 7, wherein the first tracer is a 5A10 antibody.

9. The method of any one of claims 7-8, wherein the first capture antibody is a H117 antibody.

10. The method of any one of claims 1-9, wherein the immunoassay that measures the level of iPSA comprises:

contacting iPSA present in the blood plasma sample with a second capture antibody specific for iPSA and nicked PSA, under conditions in which the second

capture antibody binds at least to iPSA, thereby producing a capture-antibody- iPSA complex; and

detecting the capture-antibody- iPSA complex using a second tracer.

11. The method of claim 10, wherein the second tracer comprises a 4D4 antibody.

12. The method of any one of claims 10-11, wherein the second capture antibody is a 5A10 Fab.

13. The method of any one of claims 1-12, wherein the immunoassay that measures the level of tPSA comprises:

contacting tPSA present in the blood plasma sample with a third capture antibody specific for tPSA under conditions in which the third capture antibody binds to tPSA, thereby producing a capture-antibody-tPSA complex; and

detecting the capture-antibody-tPSA complex using a third tracer.

14. The method of claim 13, wherein the third tracer comprises a H50 antibody.

15. The method of any one of claims 13-14, wherein the third capture antibody is a H117 antibody.

16. The method of any one of claims 1-15, wherein the immunoassay that measures the level of hK2 comprises:

contacting PSA in the blood plasma sample with blocking antibodies specific for PSA;

contacting hK2 present in the blood plasma sample with a fourth capture antibody specific for hK2 under conditions in which the fourth capture antibody binds to hK2, thereby producing a capture-antibody-hK2 complex; and

detecting the capture-antibody-hK2 complex using a fourth tracer.

17. The method of claim 16, wherein the fourth tracer comprises a 7G1 antibody.

18. The method of any one of claims 16-17, wherein the fourth capture antibody is a 6H10 $F(ab)_2$.

19. The method of any one of claims 16-18, wherein the blocking antibodies comprise a 5F7 antibody, a 5H6 antibody, and a 2E9 antibody.

20. The method of any one of claims 7-19, wherein each or any capture antibody is bound to a solid support.

21. The method of any one of claims 7-20, wherein each or any tracer comprises a Europium label.

22. A method for determining a probability of an event associated with prostate cancer, the method comprising:

receiving, via an input interface, information indicative of the level of tPSA present in a blood plasma sample of a subject;

receiving, via an input interface, information about whether the subject had a prior biopsy of prostate tissue;

evaluating, using at least one processor, a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

23. A method for determining a probability of an event associated with prostate

cancer, the method comprising:

receiving, via an input interface, information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject;

receiving, via an input interface, information about whether the subject had a prior biopsy of prostate tissue;

evaluating, using at least one processor, a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

24. A computer for determining a probability of an event associated with prostate cancer, the computer comprising:

an input interface configured to receive information indicative of the level of tPSA present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue;

at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

an output interface configured to output an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

25. A computer for determining a probability of an event associated with prostate cancer, the computer comprising:

an input interface configured to receive information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue;

at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

an output interface configured to output an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

26. A system for determining a probability of an event associated with prostate cancer, the system comprising:

a) a detector configured to measure a level of tPSA present in a blood plasma sample of a subject; and

b) a computer in electronic communication with the detector, wherein the computer comprises:

i) an input interface configured to receive information from the detector indicative of the measured level of tPSA, and to receive information about whether the subject had a prior biopsy of prostate tissue;

ii) at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a

probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of the level of tPSA and the information about whether the subject had a prior biopsy of prostate tissue; and

iii) an output interface configured to output an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

27. A system for determining a probability of an event associated with prostate cancer, the system comprising:

a) a detector configured to measure levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject; and

b) a computer in electronic communication with the detector, wherein the computer comprises:

i) an input interface configured to receive information from the detector indicative of the measured levels of tPSA, fPSA, iPSA, and hK2, and to receive information about whether the subject had a prior biopsy of prostate tissue;

ii) at least one processor programmed to evaluate a logistic regression model based, at least in part, on the received information to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

iii) an output interface configured to output an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

28. A computer-readable storage medium encoded with a plurality of instructions that, when executed by a computer, perform a method for determining a probability of an event associated with prostate cancer, wherein the method comprises:

evaluating a logistic regression model based, at least in part, on information indicative of the level of tPSA present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the tPSA value and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

29. A computer-readable storage medium encoded with a plurality of instructions that, when executed by a computer, perform a method for determining a probability of an event associated with prostate cancer, wherein the method comprises:

evaluating a logistic regression model based, at least in part, on information indicative of levels of tPSA, fPSA, iPSA, and hK2 present in a blood plasma sample of a subject and information about whether the subject had a prior biopsy of prostate tissue to determine a probability of an event associated with prostate cancer in the subject, wherein evaluating the logistic regression model comprises:

determining the probability of the event associated with prostate cancer based, at least in part, on the information indicative of levels of tPSA, fPSA, iPSA, and hK2 and the information about whether the subject had a prior biopsy of prostate tissue; and

outputting an indication of the probability of the event associated with prostate cancer;

wherein the event associated with prostate cancer is a prostate tissue biopsy containing detectable high-grade prostate cancer.

30. The method of any one of claims 1-21, wherein each or any immunoassay is performed using a microfluidic device.

31. A method of determining whether a subject is a candidate for a prostate tissue biopsy, the method comprising:

i) obtaining a blood sample from the subject;

ii) determining the probability that the prostate tissue biopsy would contain detectable high-grade prostate cancer using the blood sample obtained in step i), wherein

a) if a tPSA level measured using the blood sample is above a threshold level, the probability is based on weighting the tPSA level and a parameter indicative of whether the subject had a prior biopsy of prostate tissue, otherwise,

b) if the tPSA level is at or below the threshold level, the probability is based on weighting levels of tPSA, fPSA, iPSA, and hK2 measured using the blood sample and a parameter indicative of whether the subject had a prior biopsy of prostate tissue; and

iii) determining whether the subject is a candidate for the prostate tissue biopsy based on the probability that the prostate tissue biopsy will contain detectable high-grade prostate cancer as determined in step ii).