[006] There is therefore an urgent need for more specific and/or more accurate detection methods for prostate cancer, to assist in early diagnosis and selection of the most appropriate therapeutic interventions. Early detection significantly reduces mortality from prostate cancer, making improved diagnostic and prognostic methods an important objective.

[007] Given the deficiencies associated with current techniques of diagnosis and/or prognosis of prostate cancer, the ability to utilise other biomarkers to assist in the detection of prostate cancer would be highly advantageous. However, the identification of clinically relevant biomarkers associated with prostate cancer remains problematic.

[008] Accordingly, there remains a need to identify alternative biomarkers to detect prostate cancer and/or to provide one or more advantages in the art.

SUMMARY

[009] The present disclosure is based on the determination that specific endosomal and/or lysosomal associated markers may be used to detect prostate cancer in a subject.

[0010] In one aspect the present invention is directed to a method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, thereby detecting a prostate cancer in the subject, wherein: the method comprises detecting two or more selected markers, and determining the ratio of the level of one selected marker to another selected marker; and an increased ratio of an early endosomal marker to a late endosomal marker as compared to non-malignant tissue is indicative of a prostate cancer in the subject. In another aspect, the present invention refers to a method of detecting a prostate cancer in a subject, the method comprising:processing a sample obtained from the subject to allow detection of a marker selected from an endosomal associated marker and/or a lysosomal associated marker; detecting one or more of an altered presence, level, secretion and distribution of the selected marker in the processed sample; and identifying a prostate cancer in the subject. Certain ~~embodiments~~ examples of the present disclosure provide a method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, thereby detecting a prostate cancer in the

~~[0010]~~ subject.

[0011] Certain ~~embodiments~~ examples of the present disclosure provide a method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0012] Certain ~~embodiments~~ examples of the present disclosure provide a method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, wherein one or more of an altered presence, level, secretion and distribution of the selected marker is indicative of a prostate cancer in the subject.

[0013] Certain ~~embodiments~~ examples of the present disclosure provide a method of detecting a prostate cancer in a subject, the method comprising:

obtaining a biological sample from the subject;

processing the sample to allow detection of a marker selected from an endosomal associated marker and/or a lysosomal associated marker;

detecting one or more of an altered presence, level, secretion and distribution of the selected marker in the processed sample; and

identifying a prostate cancer in the subject.

[0014] Certain ~~embodiments~~ examples of the present disclosure provide a method of detecting a prostate cancer in a subject, the method comprising:

obtaining a biological sample from the subject;

processing the sample to allow detection of a marker selected from an endosomal associated marker and/or a lysosomal associated marker;

detecting one or more of the presence, level, secretion and distribution of the selected marker in the processed sample;

comparing one or more of the presence, level, secretion and distribution of the selected marker with one or more other markers known to be indicative of the presence or absence of prostate cancer in the subject; and

identifying prostate cancer in the subject.

[0015] Certain embodiments of the present disclosure provide a method of identifying a subject suffering from or susceptible to a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0016] Certain ~~embodiments~~ examples of the present disclosure provide a method of identifying a subject suffering from or susceptible to a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, wherein one or more of an altered presence, level, secretion and distribution of the selected marker is indicative that the subject is suffering from or susceptible to a prostate cancer.

[0017] Certain embodiments of the present disclosure provide a method of screening for a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0018] Certain ~~embodiments~~ examples of the present disclosure provide a method of screening for a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, wherein one or more of an altered presence, level, secretion and distribution of the selected marker is indicative of prostate cancer in the subject.

[0019] Certain ~~embodiments~~ examples of the present disclosure provide method of treating a prostate cancer in a subject, the method comprising:

detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject; and

treating the subject based on one or more of the presence, level, secretion and distribution of the selected marker detected.

[0020] Certain embodiments of the present disclosure provide a method of diagnosis for detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0021] Certain embodiments of the present disclosure provide a method of determining the likelihood and/or risk of a subject suffering from, or being susceptible to, a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0022] Certain embodiments of the present disclosure provide a method for determining the progression of a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

[0023] Certain embodiments of the present disclosure provide a kit for performing a method as described herein.

[0024] Certain ~~embodiments~~ examples of the present disclosure provide a method of treating a prostate cancer in a subject, the method comprising:

detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject; and

treating the subject based on one or more of the presence, level, secretion and distribution of the selected marker detected.

[0025] Certain embodiments of the present disclosure provide an isolated or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSSSQSEESDLGEGGKKRESEA (SEQ ID NO. 3), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

[0026] Certain embodiments of the present disclosure provide an isolated and/or purified antibody binding to an epitope in an amino acid sequence in the human APPL1 protein comprising one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSSSQSEESDLGE GGKKRESEA (SEQ ID NO. 3), and/or an equivalent region of a homolog, ortholog or paralog of the protein.

[0027] Certain embodiments of the present disclosure provide an isolated and/or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of PNTFKTLDSWRDEFLIQASPRDPENFPFVVLGNKI (SED ID NO. 4), DPENFPFVVLGNKIDLENRQVATKRAQAWCYSKNN (SEQ ID NO. 5), ALKQETEVELYNEFPEPIKLDKNDRAKASAESCSC (SEQ ID NO. 6), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

CLAIMS

1. A method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, thereby detecting a prostate cancer in the subject.

2. The method according to claim 1, wherein the selected marker comprises one or more of an early endosomal marker, a late endosomal marker, a marker associated with endosomal biogenesis, a marker associated with endosomal trafficking and a marker associated with endosomal recycling.

3. The method according to claims 1 or 2, wherein the selected marker comprises one or more of CATHEPSIN B, CAPTHESIN D, α-GALACTOSIDASE, RAB7, LIMP-1, LIMP-2, TFR1, TFR2, STAMP2, SORT1 (SORTILIN), APPL1, EEA-1, LAMP-1, RAB4, APPL2, RAB5, RAB11, MPR, PAP, ACTIN, M6PR, IGFR2, MYO1B, PDCD6IP, SDCBP, SDC1, STX7, STX12, FGF1, FGF2, FGF3, FGFR1, FGFR2, FGFR3, NOX2, NOX4, and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

4. The method according to any one of claims 1 to 3, wherein one or more of an altered presence, altered level, altered secretion and altered distribution of the selected marker is indicative of prostate cancer in the subject.

5. The method according to claim 4, wherein one or more of an increased level of RAB5 protein and/or mRNA, an increased secretion of RAB5 protein, an increased level of APPL1 protein and/or mRNA, an increased secretion of APPL1 protein, an increased level of EEA1 protein and/or mRNA, an increased secretion of EEA1 protein, an increased level of LIMP-2 protein and/or mRNA, an increased level of TFR1 protein and/or mRNA, an increased level of TFR2 protein and/or mRNA, an increased level of RAB4 protein and/or mRNA, an increased secretion of RAB4 protein, an increased level of APPL2 protein and/or mRNA, a decreased level of LAMP1 protein and/or mRNA, an increased secretion of RAB11 protein, a decreased secretion of RAB7 protein, a decreased level of CAPTHESIN B protein or mRNA, a decreased level of

CAPTHESIN D protein or mRNA, an increased level of α-GALACTOSIDASE protein or mRNA, a decreased level of STX7 protein or mRNA, a decreased level of STX12 protein or mRNA, an increased secretion of PDCD6IP protein, a decreased secretion of SDCBP protein, a decreased secretion of SORT1 protein, a decreased level of FGF1 protein or mRNA, a decreased level of FGF2 protein or mRNA, an increased level of FGF3 protein or mRNA, a decreased level of FGFR1 protein or mRNA, a decreased level of FGFR2 protein or mRNA, an increased level of FGFR3 protein or mRNA, an increased level of NOX2 protein or mRNA, and increased level of NOX4 protein or mRNA, an increased nuclear and/or nucleoli level of APPL1 protein, an increased nuclear membrane level of RAB7 protein, and an enlarged LIMP2 protein positive vesicles, is indicative of prostate cancer in the subject.

6. The method according to claims 4 or 5, wherein an altered presence, altered level, altered expression, altered secretion and altered distribution is as compared to one or more of non-malignant tissue, prostatic intraepithelial neoplasia, primary prostate cancer and metastatic prostate cancer.

7. The method according to claim 6, wherein LIMP2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared non-malignant prostate, LAMP1 protein or mRNA is decreased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, LAMP1 protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate cancer, CAPTHESIN B protein or mRNA is decreased in primary prostate cancer as compared to non-malignant tissue, CAPTHESIN B protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, ACID CERAMIDASE protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, ACID CERAMIDASE protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, ACID CERAMIDASE protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate cancer, APPL1 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue, APPL2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, APPL2 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue, APPL2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic

prostate cancer, APPL2 protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate cancer, RAB5 protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, EEA1 protein or mRNA is decreased in metastatic prostate cancer as compared non-malignant prostate, EEA1 protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, RAB4A protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, RAB4A protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, RAB4A protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to primary prostatic cancer, RAB4A protein or mRNA is decreased in primary prostate cancer as compared to metastatic prostate cancer, MYO1B protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, MYO1B protein or mRNA is decreased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, MYO1B protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, PDCD6IP protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, PDCD6IP protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, SDCBP protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, STX7 protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, FGFR1 protein or mRNA is increased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, FGFR2 protein or mRNA is decreased in primary prostate cancer as compared to non-malignant tissue, NOX2 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue and NOX4 protein or mRNA is increased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia.

8. The method according to any one of claims 1 to 7, wherein the method comprises obtaining a biological sample from the subject and processing the biological sample to allow detection of the selected marker.

9. The method according to claim 8, wherein the biological sample comprises one or more of a blood sample, a plasma sample, a serum sample, a biopsy and a prostate tissue sample.

10. The method according to any one of claims 1 to 9, wherein the detecting of the selected marker comprises polymerase chain reaction.

11. The method according to any one of claims 1 to 10, wherein the detecting of the selected marker comprises immunological detection.

12. The method according to any one of claims 1 to 11, wherein the method comprises detecting two or more selected markers.

13. The method according to claim 12, wherein the method comprises determining the ratio of the level of one selected marker to another selected marker.

14. The method according to claim 13, wherein an altered ratio as compared to non-malignant tissue is indicative of a prostate cancer in the subject.

15. The method according to claim 14, wherein an increased ratio of an early endosomal marker to a late endosomal marker as compared to non-malignant tissue is indicative of a prostate cancer in the subject.

16. The method according to any one of claims 1 to 15, wherein the method comprises comparing the presence and/or level of the selected marker with the presence and/or level of one or more other markers associated with an altered risk of prostate cancer and/or one or more other markers known to be indicative of the presence or absence of prostate cancer in the subject.

17. The method according to claim 16, wherein the one or more other markers comprises prostate specific antigen.

18. The method according to any one of claims 1 to 17, wherein the method further comprises obtaining information relating to one or more clinical characteristics of the subject and using the information in combination with one or more of the presence, level, secretion and distribution of the selected marker to detect prostate cancer in the subject.

19. The method according to any one of claims 1 to 18, wherein the method comprises using a computer processor means to process data associated with one or more of the presence, level, secretion and distribution of the selected marker, and optionally one or more clinical characteristics, to generate a likelihood and/or risk of the presence of prostate cancer in the subject.

20. The method according to any one of claims 1 to 19, wherein the prostate cancer is selected from a prostatic intraepithelial neoplasia, a primary prostate cancer, and a metastatic prostate cancer.

21. The method according to any one of claims 1 to 20, wherein the method is used to diagnose prostate cancer in the subject, to screen for prostate cancer in the subject, for assessing prognosis, to determine the metastatic potential of a prostate cancer, to identify a subject suffering from prostate cancer, to identify a subject susceptible to prostate cancer, to determine the rate of relapse of prostate cancer in the subject, to determine the risk of mortality from prostate cancer in the subject, to stratify the prostate cancer, to discriminate between prostate cancer and not having prostate cancer in the subject, to determine whether the prostate cancer is an organ confined cancer, to discriminate between prostate cancer and one or more of benign prostatic hyperplasia, prostatitis and an inflammatory condition of the prostate, to determine pathogenic progression, to assess whether the prostate cancer is slowing growing, indolent, or aggressive, to exclude the presence of prostate cancer in the subject, to identify a subject suitable for treatment and/or surgery for prostate cancer, and to determine the likelihood or risk of a subject having prostate cancer.

22. A method of detecting a prostate cancer in a subject, the method comprising:

obtaining a biological sample from the subject;

processing the sample to allow detection of a marker selected from an endosomal associated marker and/or a lysosomal associated marker;

detecting one or more of an altered presence, level, secretion and distribution of the selected marker in the processed sample; and

identifying a prostate cancer in the subject.

23. A method of screening for a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

24. The method according to claim 23, wherein the method is used to identify a subject suffering from, or susceptible to, a prostate cancer.

25. The method according to claim 23, wherein the method is used to exclude a subject not suffering from, or not susceptible to, a prostate cancer.

26. A method of identifying a subject suffering from, or susceptible to, a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

27. A method of diagnosis for detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

28. A method of determining the likelihood and/or risk of a subject suffering from, or being susceptible to, a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

29. A method for determining the progression of a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

30. The method according to claim 29, wherein the method comprises determining biochemical recurrence of the cancer, relapse rate and/or survival rate.

31. The method according to claim 30, wherein the level of the marker is indicative of a reduced relapse rat and/or increased survival rate.

32. The method according to claim 30, wherein the marker comprises one or more

of LIMP2, CATHEPSIN B, CAPTHESIN D, α-GALACTOSIDASE, RAB5A, EEA1, RAB7A, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

33. The method according to claim 32, wherein the marker comprises one or more of decreased or lower LIMP2, increased or higher CATHEPSIN B, increased or higher CAPTHESIN D, increased or higher α-GALACTOSIDASE, decreased or lower RAB5A, decreased or lower EEA1, increased or higher RAB7A, increased or higher M6PR, decreased or lower IGFR2, decreased or lower SORT1, decreased or lower MYO1B, increased or higher PDCD6IP, increased or higher STX12, increased or higher FGF2, increased or higher FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

34. The method according to any one of claims 29 to 33, wherein the method further comprises identifying the level of PSA expression in the subject and stratifying the expression of the marker on the basis of the PSA expression level in the subject.

35. The method according to claim 34, wherein the PSA is a level indicative of a low risk of prostate cancer.

36. The method according to claim 35, wherein the PSA level is less than 10 ng/ml.

37. The method according to claim 35 or 36, wherein the PSA is a level of 7.8 ng/ml or less.

38. The method according to any one of claims 35 to 27, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, α-GALACTOSIDASE, RAB5A, EEA1, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one

of the aforementioned.

39. The method according to claim 38, wherein the marker comprises one or more of decreased or lower LIMP2, increased or higher CATHEPSIN B, increased or higher α-GALACTOSIDASE, decreased or lower RAB5A, decreased or lower EEA1, increased or higher M6PR, decreased or lower IGFR2, decreased or lower SORT1, decreased or lower MYO1B, increased or higher PDCD6IP, increased or higher SDC1, increased or higher STX12, increased or higher FGF2, increased or higher FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

40. The method according to claim 30, wherein the level of the marker is indicative of an increased relapse rat and/or decreased survival rate.

41. The method according to claim 40, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, CAPTHESIN D, α-GALACTOSIDASE, RAB5A, EEA1, RAB7A, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

42. The method according to claim 40, wherein the marker comprises one or more of increased or higher LIMP2, decreased or lower CATHEPSIN B, decreased or lower CAPTHESIN D, decreased or lower α-GALACTOSIDASE, increased or higher RAB5A, increased or higher EEA1, decreased or lower RAB7A, decreased or lower M6PR, increased or higher IGFR2, increased or higher SORT1, increased or higher MYO1B, decreased or lower PDCD6IP, decreased or lower STX12, decreased or lower FGF2, decreased or lower FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

43. The method according to any one of claims 40 to 43, wherein the method further comprises identifying the level of PSA expression in the subject and stratifying

the expression of the marker on the basis of the PSA expression level in the subject.

44. The method according to claim 43, wherein the PSA is a level indicative of a low risk of prostate cancer.

45. The method according to claim 44, wherein the PSA level is less than 10 ng/ml.

46. The method according to claim 44 or 45, wherein the PSA is a level of 7.8 ng/ml or less.

47. The method according to any one of claims 44 to 46, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, α-GALACTOSIDASE, RAB5A, EEA1, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

48. The method according to claim 47, wherein the marker comprises one or more of increased or higher LIMP2, decreased or lower CATHEPSIN B, decreased or lower α-GALACTOSIDASE, increased or higher RAB5A, increased or higher EEA1, decreased or lower M6PR, increased or higher IGFR2, increased or higher SORT1, increased or higher MYO1B, decreased or lower PDCD6IP, decreased or lower SDC1, decreased or lower STX12, decreased or lower FGF2, decreased or lower FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

49. A kit for performing the method of any one of claims 1 to 48.

50. A method of treating a prostate cancer in a subject, the method comprising:

detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject; and

treating the subject based on one or more of the presence, level, secretion and distribution of the selected marker detected.

51. An isolated or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSS SQSEESDLGE GGKKRESEA (SEQ ID NO. 3), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

52. An isolated and/or purified antibody binding to an epitope in an amino acid sequence in the human APPL1 protein comprising one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSS SQSEESDLGE GGKKRESEA (SEQ ID NO. 3), and/or an equivalent region of a homolog, ortholog or paralog of the protein.

53. An isolated and/or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of PNTFKTLDSWRDEFLIQASPRDPENFPFVVLGNKI (SED ID NO. 4), DPENFPFVVLGNKIDLENRQVATKRAQAWCYSKNN (SEQ ID NO. 5), ALKQETEVELYNEFPEPIKLDKNDRAKASAESCSC (SEQ ID NO. 6), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

54. An isolated and/or purified antibody binding to an epitope in an amino acid sequence in the human RAB7 protein comprising one or more of PNTFKTLDSWRDEFLIQASPRDPENFPFVVLGNKI (SED ID NO. 4), DPENFPFVVLGNKIDLENRQVATKRAQAWCYSKNN (SEQ ID NO. 5), ALKQETEVELYNEFPEPIKLDKNDRAKASAESCSC (SEQ ID NO. 6), and/or an equivalent region of a homolog, ortholog or paralog of the protein.

55. A method of detecting an APPL1 protein or a fragment thereof, the method comprising using an antibody according to claims 51 or 52 to detect the APPL1 protein or fragment thereof.

56. A method of detecting a RAB7 protein or a fragment thereof, the method comprising using an antibody according to claims 53 or 54 to detect the RAB7 protein or fragment thereof.

57. A method of detecting a prostate cancer in a subject, the method comprising using an antibody according any one of claims 51 to 54 to detect an APPL1 or RAB7 protein, and/or a fragment, derivative or a processed form thereof from the subject.

58. A method of identifying a selected marker for diagnosis and/or prognosis of a prostate cancer, the method comprising:

identifying a marker selected from an endosomal associated marker and/or a lysosomal associated marker; and

determining the ability of the selected marker to diagnose and/or prognose a prostate cancer;

thereby identifying the marker as a selected marker for diagnosis and/or prognosis of a prostate cancer.

CLAIMS

1. A method of detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject, thereby detecting a prostate cancer in the subject, wherein:

the method comprises detecting two or more selected markers, and determining the ratio of the level of one selected marker to another selected marker; and

an increased ratio of an early endosomal marker to a late endosomal marker as compared to non-malignant tissue is indicative of a prostate cancer in the subject.

2. The method according to claim 1, wherein the early endosomal marker is selected from APPL1 and EEA1, and the late endsomal marker is selected from SDC1 and RAB7.

3. The method according to claim 1 or claim 2, wherein the selected marker comprises one or more of an early endosomal marker, a late endosomal marker, a marker associated with endosomal biogenesis, a marker associated with endosomal trafficking and a marker associated with endosomal recycling.

4. The method according to any one of claim 1 to 3, wherein the selected marker comprises one or more of CATHEPSIN B, CATHEPSIN D, α-GALACTOSIDASE, LIMP-1, LIMP-2, TFR1, TFR2, STAMP2, SORT1 (SORTILIN), LAMP-1, RAB4, APPL2, RAB5, RAB11, MPR, PAP, ACTIN, M6PR, IGFR2, MYO1B, PDCD6IP, SDCBP, STX7, STX12, FGF1, FGF2, FGF3, FGFR1, FGFR2, FGFR3, NOX2, NOX4, and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

5. The method according to any one of claims 1 to 4, wherein one or more of an altered presence, altered level, altered secretion and altered distribution of the selected marker is indicative of prostate cancer in the subject.

6. The method according to claim 5, wherein one or more of an increased level of RAB5 protein and/or mRNA, an increased secretion of RAB5 protein, an increased level of APPL1 protein and/or mRNA, an increased secretion of APPL1 protein, an increased level of

EEA1 protein and/or mRNA, an increased secretion of EEA1 protein, an increased level of LIMP-2 protein and/or mRNA, an increased level of TFR1 protein and/or mRNA, an increased level of TFR2 protein and/or mRNA, an increased level of RAB4 protein and/or mRNA, an increased secretion of RAB4 protein, an increased level of APPL2 protein and/or mRNA, a decreased level of LAMP1 protein and/or mRNA, an increased secretion of RAB11 protein, a decreased secretion of RAB7 protein, a decreased level of CATHEPSIN B protein or mRNA, a decreased level of CATHEPSIN D protein or mRNA, an increased level of α-GALACTOSIDASE protein or mRNA, a decreased level of STX7 protein or mRNA, a decreased level of STX12 protein or mRNA, an increased secretion of PDCD6IP protein, a decreased secretion of SDCBP protein, a decreased secretion of SORT1 protein, a decreased level of FGF1 protein or mRNA, a decreased level of FGF2 protein or mRNA, an increased level of FGF3 protein or mRNA, a decreased level of FGFR1 protein or mRNA, a decreased level of FGFR2 protein or mRNA, an increased level of FGFR3 protein or mRNA, an increased level of NOX2 protein or mRNA, and increased level of NOX4 protein or mRNA, an increased nuclear and/or nucleoli level of APPL1 protein, an increased nuclear membrane level of RAB7 protein, and an enlarged LIMP2 protein positive vesicles, is indicative of prostate cancer in the subject.

7. The method according to claim 5 or 6, wherein an altered presence, altered level, altered expression, altered secretion and altered distribution is as compared to one or more of non-malignant tissue, prostatic intraepithelial neoplasia, primary prostate cancer and metastatic prostate cancer.

8. The method according to claim 7, wherein LIMP2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared non-malignant prostate, LAMP1 protein or mRNA is decreased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, LAMP1 protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate cancer, CATHEPSIN B protein or mRNA is decreased in primary prostate cancer as compared to non-malignant tissue, CATHEPSIN B protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, ACID CERAMIDASE protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, ACID CERAMIDASE protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, ACID CERAMIDASE protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate

cancer, APPL1 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue, APPL2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, APPL2 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue, APPL2 protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, APPL2 protein or mRNA is increased in primary prostate cancer as compared to metastatic prostate cancer, RAB5 protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, EEA1 protein or mRNA is decreased in metastatic prostate cancer as compared non-malignant prostate, EEA1 protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, RAB4A protein or mRNA is decreased in metastatic prostate cancer as compared to non-malignant prostate, RAB4A protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, RAB4A protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to primary prostatic cancer, RAB4A protein or mRNA is decreased in primary prostate cancer as compared to metastatic prostate cancer, MYO1B protein or mRNA is increased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, MYO1B protein or mRNA is decreased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, MYO1B protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, PDCD6IP protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to metastatic prostate cancer, PDCD6IP protein or mRNA is decreased in prostatic intraepithelial neoplasia as compared to non-malignant prostate, SDCBP protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, STX7 protein or mRNA is decreased in metastatic prostate cancer as compared to primary prostate cancer, FGFR1 protein or mRNA is increased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia, FGFR2 protein or mRNA is decreased in primary prostate cancer as compared to non-malignant tissue, NOX2 protein or mRNA is increased in primary prostate cancer as compared to non-malignant tissue and NOX4 protein or mRNA is increased in metastatic prostate cancer as compared prostatic intraepithelial neoplasia.

9. The method according to any one of claims 1 to 8, wherein the method comprises obtaining a biological sample from the subject and processing the biological sample to allow detection of the selected marker.

10. The method according to claim 9, wherein the biological sample comprises one or more of a blood sample, a plasma sample, a serum sample, a biopsy and a prostate tissue sample.

11. The method according to any one of claims 1 to 10, wherein the detecting of the selected marker comprises polymerase chain reaction.

12. The method according to any one of claims 1 to 11, wherein the detecting of the selected marker comprises immunological detection.

13. The method according to any one of claims 1 to 12, wherein the method comprises comparing the presence and/or level of the selected marker with the presence and/or level of one or more other markers associated with an altered risk of prostate cancer and/or one or more other markers known to be indicative of the presence or absence of prostate cancer in the subject.

14. The method according to claim 13, wherein the one or more other markers comprises prostate specific antigen.

15. The method according to any one of claims 1 to 14, wherein the method further comprises obtaining information relating to one or more clinical characteristics of the subject and using the information in combination with one or more of the presence, level, secretion and distribution of the selected marker to detect prostate cancer in the subject.

16. The method according to any one of claims 1 to 15, wherein the method comprises using a computer processor means to process data associated with one or more of the presence, level, secretion and distribution of the selected marker, and optionally one or more clinical characteristics, to generate a likelihood and/or risk of the presence of prostate cancer in the subject.

17. The method according to any one of claims 1 to 16, wherein the prostate cancer is selected from a prostatic intraepithelial neoplasia, a primary prostate cancer, and a metastatic prostate cancer.

18. The method according to any one of claims 1 to 17, wherein the method is used to diagnose prostate cancer in the subject, to screen for prostate cancer in the subject, for assessing prognosis, to determine the metastatic potential of a prostate cancer, to identify a subject suffering from prostate cancer, to identify a subject susceptible to prostate cancer, to determine the rate of relapse of prostate cancer in the subject, to determine the risk of mortality from prostate cancer in the subject, to stratify the prostate cancer, to discriminate between prostate cancer and not having prostate cancer in the subject, to determine whether the prostate cancer is an organ confined cancer, to discriminate between prostate cancer and one or more of benign prostatic hyperplasia, prostatitis and an inflammatory condition of the prostate, to determine pathogenic progression, to assess whether the prostate cancer is slowing growing, indolent, or aggressive, to exclude the presence of prostate cancer in the subject, to identify a subject suitable for treatment and/or surgery for prostate cancer, and to determine the likelihood or risk of a subject having prostate cancer.

19. A method of detecting a prostate cancer in a subject, the method comprising:

processing a sample obtained from the subject to allow detection of a marker selected from an endosomal associated marker and/or a lysosomal associated marker;

detecting one or more of an altered presence, level, secretion and distribution of the selected marker in the processed sample; and

identifying a prostate cancer in the subject.

20. A method of screening for a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

21. The method according to claim 20, wherein the method is used to identify a subject suffering from, or susceptible to, a prostate cancer.

22. The method according to claim 21, wherein the method is used to exclude a subject not suffering from, or not susceptible to, a prostate cancer.

23. A method of identifying a subject suffering from, or susceptible to, a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker

and/or a lysosomal associated marker from the subject.

24. A method of diagnosis for detecting a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

25. A method of determining the likelihood and/or risk of a subject suffering from, or being susceptible to, a prostate cancer, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

26. A method for determining the progression of a prostate cancer in a subject, the method comprising detecting a marker selected from an endosomal associated marker and/or a lysosomal associated marker from the subject.

27. The method according to claim 26, wherein the method comprises determining biochemical recurrence of the cancer, relapse rate and/or survival rate.

28. The method according to claim 27, wherein the level of the marker is indicative of a reduced relapse rat and/or increased survival rate.

29. The method according to claim 27, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, CAPTHESIN D, α-GALACTOSIDASE, RAB5A, EEA1, RAB7A, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

30. The method according to claim 29, wherein the marker comprises one or more of decreased or lower LIMP2, increased or higher CATHEPSIN B, increased or higher CATHEPSIN D, increased or higher α-GALACTOSIDASE, decreased or lower RAB5A, decreased or lower EEA1, increased or higher RAB7A, increased or higher M6PR, decreased or lower IGFR2, decreased or lower SORT1, decreased or lower MYO1B, increased or higher PDCD6IP, increased or higher STX12, increased or higher FGF2, increased or higher FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of

the aforementioned.

31. The method according to any one of claims 26 to 30, wherein the method further comprises identifying the level of PSA expression in the subject and stratifying the expression of the marker on the basis of the PSA expression level in the subject.

32. The method according to claim 31, wherein the PSA is a level indicative of a low risk of prostate cancer.

33. The method according to claim 32, wherein the PSA level is less than 10 ng/ml.

34. The method according to claim 32 or 33, wherein the PSA is a level of 7.8 ng/ml or less.

35. The method according to any one of claims 32 to 34, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, α-GALACTOSIDASE, RAB5A, EEA1, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

36. The method according to claim 35, wherein the marker comprises one or more of decreased or lower LIMP2, increased or higher CATHEPSIN B, increased or higher α-GALACTOSIDASE, decreased or lower RAB5A, decreased or lower EEA1, increased or higher M6PR, decreased or lower IGFR2, decreased or lower SORT1, decreased or lower MYO1B, increased or higher PDCD6IP, increased or higher SDC1, increased or higher STX12, increased or higher FGF2, increased or higher FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

37. The method according to claim 27, wherein the level of the marker is indicative of an increased relapse rat and/or decreased survival rate.

38. The method according to claim 37, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, CATHEPSIN D, α-GALACTOSIDASE, RAB5A, EEA1, RAB7A,

M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

39. The method according to claim 37, wherein the marker comprises one or more of increased or higher LIMP2, decreased or lower CATHEPSIN B, decreased or lower CATHEPSIN D, decreased or lower α-GALACTOSIDASE, increased or higher RAB5A, increased or higher EEA1, decreased or lower RAB7A, decreased or lower M6PR, increased or higher IGFR2, increased or higher SORT1, increased or higher MYO1B, decreased or lower PDCD6IP, decreased or lower STX12, decreased or lower FGF2, decreased or lower FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

40. The method according to any one of claims 37 to 40, wherein the method further comprises identifying the level of PSA expression in the subject and stratifying the expression of the marker on the basis of the PSA expression level in the subject.

41. The method according to claim 40, wherein the PSA is a level indicative of a low risk of prostate cancer.

42. The method according to claim 41, wherein the PSA level is less than 10 ng/ml.

43. The method according to claim 41 or 42, wherein the PSA is a level of 7.8 ng/ml or less.

44. The method according to any one of claims 41 to 43, wherein the marker comprises one or more of LIMP2, CATHEPSIN B, α-GALACTOSIDASE, RAB5A, EEA1, M6PR, IGFR2, SORT1, MYO1B, PDCD6IP, SDC1, STX12, FGF2, FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

45. The method according to claim 44, wherein the marker comprises one or more of increased or higher LIMP2, decreased or lower CATHEPSIN B, decreased or lower α-

GALACTOSIDASE, increased or higher RAB5A, increased or higher EEA1, decreased or lower M6PR, increased or higher IGFR2, increased or higher SORT1, increased or higher MYO1B, decreased or lower PDCD6IP, decreased or lower SDC1, decreased or lower STX12, decreased or lower FGF2, decreased or lower FGF3 and/or a mRNA encoding one of the aforementioned, a fragment of one of the aforementioned, a derivative of one of the aforementioned, and a processed form of one of the aforementioned.

46. A kit for performing the method of any one of claims 1 to 45.

47. An isolated or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSS SQSEESDLGE GGKKRESEA (SEQ ID NO. 3), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

48. An isolated and/or purified antibody binding to an epitope in an amino acid sequence in the human APPL1 protein comprising one or more of ASNDHDAAINRYSRLSKKRENDKVKYEVTEDVYT (SED ID NO. 1), DEVASDPLYVPDPDPTKFPVNRNLTRKAGYLNARNKT (SEQ ID NO. 2), SEGQFVVLSS SQSEESDLGE GGKKRESEA (SEQ ID NO. 3), and/or an equivalent region of a homolog, ortholog or paralog of the protein.

49. An isolated and/or purified antibody raised to a polypeptide comprising an amino acid sequence of one or more of PNTFKTLDSWRDEFLIQASPRDPENFPFVVLGNKI (SED ID NO. 4), DPENFPFVVLGNKIDLENRQVATKRAQAWCYSKNN (SEQ ID NO. 5), ALKQETEVELYNEFPEPIKLDKNDRAKASAESCSC (SEQ ID NO. 6), an antigenic fragment of any of the aforementioned amino acid sequences, and/or a variant of any of the aforementioned amino acid sequences or an antigenic fragment thereof.

50. An isolated and/or purified antibody binding to an epitope in an amino acid sequence in the human RAB7 protein comprising one or more of PNTFKTLDSWRDEFLIQASPRDPENFPFVVLGNKI (SED ID NO. 4), DPENFPFVVLGNKIDLENRQVATKRAQAWCYSKNN (SEQ ID NO. 5),

ALKQETEVELYNEFPEPIKLDKNDRAKASAESCSC (SEQ ID NO. 6), and/or an equivalent region of a homolog, ortholog or paralog of the protein.

51. A method of detecting an APPL1 protein or a fragment thereof, the method comprising using an antibody according to claim 47 or 48 to detect the APPL1 protein or fragment thereof.

52. A method of detecting a RAB7 protein or a fragment thereof, the method comprising using an antibody according to claim 50 or 51 to detect the RAB7 protein or fragment thereof.

53. A method of detecting a prostate cancer in a subject, the method comprising using an antibody according any one of claims 47 to 50 to detect an APPL1 or RAB7 protein, and/or a fragment, derivative or a processed form thereof from the subject.

54. A method of identifying a selected marker for diagnosis and/or prognosis of a prostate cancer, the method comprising:

identifying a marker selected from an endosomal associated marker and/or a lysosomal associated marker; and

determining the ability of the selected marker to diagnose and/or prognose a prostate cancer;

thereby identifying the marker as a selected marker for diagnosis and/or prognosis of a prostate cancer.