

CLAIMS

1. A urine miRNA marker for diagnosis of prostate cancer, wherein the miRNA marker is selected from one or more of the following 10 miRNAs: hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p and hsa-miR-4306.

2. The urine miRNA marker for diagnosis of prostate cancer according to claim 1, wherein the miRNA marker is obtained by screening as follows: removing any one of the 10 miRNAs including hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p and hsa-miR-4306, and then selecting any one or more of the remaining 9 miRNAs.

3. The urine miRNA marker for diagnosis of prostate cancer according to claim 1, wherein the miRNA marker is obtained by screening as follows: removing any two of the 10 miRNAs including hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p and hsa-miR-4306, and then selecting any one or more of the remaining 8 miRNAs.

4. The urine miRNA marker for diagnosis of prostate cancer according to claim 1, wherein the miRNA marker is obtained by screening as follows: removing any three of the 10 miRNAs including hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p and hsa-miR-4306, and then selecting any one or more of the remaining 7 miRNAs.

5. The urine miRNA marker for diagnosis of prostate cancer according to claim 1, wherein the miRNA marker is obtained by screening as follows: removing any four of the 10 miRNAs including hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p and hsa-miR-4306, and then selecting any one or more of the remaining 6 miRNAs.

6. The urine miRNA marker for diagnosis of prostate cancer according to claim 5, wherein the miRNA marker is selected from one or more of the following 6 miRNAs: hsa-miR-375, hsa-

miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p and hsa-miR-4306.

7. The urine miRNA marker for diagnosis of prostate cancer according to any one of claims 1 to 6, wherein when the number of the miRNA markers is at least 5, one of the miRNAs must be hsa-miR-199b-5p.

5 8. The urine miRNA marker for diagnosis of prostate cancer according to any one of claims 1 to 6, wherein when the number of the miRNA markers is at least 5, one of the miRNAs must be hsa-miR-518e-5p.

9. The urine miRNA marker for diagnosis of prostate cancer according to claim 1, wherein the miRNA marker includes any one or more of the following combinations:

10 hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

15 hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

20 hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

25 hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

5 hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

10 hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

15 hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-338-5p, hsa-miR-4306; or

20 hsa-miR-183-5p, hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-520d-5p, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

25 hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-

miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

5 hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-338-5p, hsa-miR-4306; or

10 hsa-miR-375, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-9-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

15 hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-199b-5p, hsa-miR-338-3p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-338-5p; or

20 hsa-miR-183-5p, hsa-miR-375, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-375, hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306; or

hsa-miR-520d-5p, hsa-miR-199b-5p, hsa-miR-518e-5p, hsa-miR-31-3p, hsa-miR-4306.

25 10. A diagnostic reagent for prostate cancer, comprising a reagent for specifically detecting the urine miRNA marker according to any one of claims 1 to 7.

11. A kit for diagnosis of prostate cancer, comprising the urine miRNA marker according to

any one of claims 1 to 7 as a standard and a corresponding primer for detecting the urine miRNA marker according to any one of claims 1 to 7.

12. Use of the urine miRNA marker according to any one of claims 1 to 7 in preparing a product for early diagnosis and/or recurrence monitoring; preferably, the product has one or more

5 of the following functions:

- 1) identification or auxiliary identification of prostate cancer;
- 2) diagnosis or auxiliary diagnosis of primary prostate cancer; and
- 3) diagnosis or auxiliary diagnosis of recurrent prostate cancer.

13. A method for early diagnosis and/or recurrence monitoring of prostate cancer by using the
10 urine miRNA marker according to any one of claims 1 to 7, comprising the following steps:

step 1, detecting the presence of miRNAs in a urine sample obtained from a subject;

step 2, measuring the expression level of at least one miRNA of the miRNA markers in the
urine sample; and

step 3, by using scores based on the previously measured expression levels of miRNAs,
15 conducting early diagnosis and/or recurrence monitoring of the possibility of prostate cancer in the
subject.