Table SI.Inclusion and exclusion criteria forthe initial clinical trial.

A, Inclusion criteria
The following inclusion criteria must all be met for a specimen to be registered in this clinical performance test. 1. Urine specimen from a male adult aged 19 or older 2. Residual specimens stored in the Human Bio-Resource Bank at Chungbuk National University Hospital. 3. Urine specimens collected during the period from 90 days or less (≤90 days) before the prostate biopsy date up until the day before the prostatectomy. ☞ However, if a prostatectomy was performed without a prior prostate biopsy, urine specimens collected within 90 days (≤90 days) before the prostatectomy can be registered for the clinical performance test. 4. Residual urine specimens that meet the following definitions of positive or negative specimens. 5. Specimens for which the following clinical information isavailable at the time of specimen collection 6. Specimens that have been stored at frozen temperatures(-4˚C or below). 7. Specimens that have been anonymized to prevent identificationof the specimen provider. ※ Definitions of positive and negative specimens - Positive specimen In cases where histological or pathological examination results in a diagnosis of prostate cancer. -Negative specimen In cases where histological or pathological examination does not result in a diagnosis of prostate cancer: ☞ For other tumor groups, even if there are no histological or pathological examination results for prostate cancer, the specimen can be registered as negative if there is no history of suspected prostate cancer, including findings of prostate hyperplasia, and a confirmed diagnosis of bladder or kidney cancer (based on histological and pathological examination results in the EMR). ※Clinical information for specimens that need to be collected. - Age - Specimen collection date - History of cancer - History of urologic conditions - PSA test date - PSA levels - Date of prostatectomy - Date of biopsy - Histopathology results - Prostate cancer diagnosis status
B, Exclusion criteria
Specimens that meet any of the following exclusion criteria cannot be registered for the clinical performance test: 1. Specimens that have undergone heat inactivation[a] [a]Heat inactivation: The loss of function of biological macromolecules, such as proteins, due to heat exposure.

2. Specimens diagnosed with malignant tumors other than urothelial carcinoma (UCC), urinary tract infection (UTI), or other tumor groups (bladder cancer, kidney cancer) at the time of specimen collection.

☞ However, specimens diagnosed with urinary tract infection may be registered if no bacteria are confirmed in bacterial culture tests.

3. Specimens with a volume <1 ml, where the insufficient quantity makes it difficult to proceed with testing.

4. Specimens deemed unsuitable for registration in the clinical performance test due to issues in the collection and storage procedures, as determined by the principal investigator (specific reasons will be recorded in the case report form).

☞ Specimens not collected or stored according to the institution’s regulations will be excluded from this clinical performance test.

Table SII. The inclusion and exclusion criteria forthe pivotal clinical trial.

A, Inclusion criteria
The following criteria for both specimen donors and specimens must be met in order for a specimen to be registered for this clinical performance test: Specimen donor inclusion criteria 1. Male adults aged 40 or older 2. Individuals who have undergone a prostate biopsy after confirming that their blood PSA level is between 3 and 10 ng/ml. Specimen inclusion criteria 3. Residual urine specimens stored in the Human Bio-Resource Bank at Chungbuk National University Hospital. 4. Specimens collected during the period between the PSA test and the prostate biopsy. ☞ In cases where a prostatectomy was performed after the prostate biopsy, specimens collected during the period between the biopsy and the prostatectomy may also be registered. 5. Residual urine specimens that meet the following definition. 6. Specimens for which the following clinical information is available at the time of specimen collection 7. Specimens that have been stored at room temperature (15-25˚C) within 48 h, or refrigerated (2-8˚C) for less than one week, or subsequently stored at frozen temperatures (-18˚C or below) for longer periods. 8. Specimens that have been anonymized to prevent identification of the specimen provider. ※ Definitions of positive and negative specimens - Positive specimens In cases where the blood PSA level is between 3 and 10 ng/ml, and histological or pathological examination has been conducted, resulting in a diagnosis of prostate cancer. -Negative specimen In cases where the blood PSA level is between 3 and 10 ng/ml, and histological or pathological examination has been conducted, resulting in no diagnosis of prostate cancer. ※Clinical information for specimens that need to be collected. - Age - Specimen collection date - History of cancer - History of urologic conditions - PSA test date - PSA levels - Date of prostatectomy - Date of biopsy - Histopathology results - Prostate cancer diagnosis status - Gleason score - TNM stage

B, Exclusion criteria

Specimens that meet any of the following specimen provider and specimen exclusion criteria are not eligible for enrollment in a clinical performance study.

Specimen provider exclusion criteria

1.History of prostate cancer diagnosis at time of specimen collection

Specimen exclusion criteria

2. Thermal inactivated[a] specimens

[a]*Thermal inactivation:* The *loss of function of a biopolymer, such as a protein, when heat is applied.*

3. Specimens diagnosed with one or more of the following at the time of specimen collection: UTI, malignancy.

☞ *However, specimens diagnosed with UTIs that are not confirmed by bacterial culture may be registered.*

4. Specimens with less than 1 ml of specimen collected and determined to be insufficient for testing.
5. Specimens that have a history of use in developmental, analytical, or exploratory clinical performance trials involving investigational medical devices.

UTI, urinary tract infection.

Table SIII. Clinical characteristics of the patients enrolled in the clinical trials.

Variable	Initial clinical trial (PC*avs.* no tumor or BPH)			Pivotal clinical trial (PC*avs.* no tumor, PSA gray zone)		
	Positive (n=70)	Negative (n=70)	P-value	Positive (n=109)	Negative (n=139)	P-value
Age, years	67.50±6.19	63.97±9.30	0.0093[a]	69.19±6.79	64.56±7.92	<0.0001[a]
PSA, ng/ml	8.72 (5.08-13.57)	5.21 (3.34-9.13)	0.0009[b]	5.92 (4.63–7.63)	5.80 (4.50-7.23)	0.7687[b]

[a]Independent two-samples t-test; [b]Wilcoxon rank-sum test. Values are expressed as the mean±standard deviation or the median (interquartile range). PSA, prostate-specific antigen;PCa, prostate cancer; BPH, benign prostatic hyperplasia.

Table SIV. Diagnostic value of the mirCaP kit (hsv2-miR-H9 to hsa-miR-3659 expression ratio) in the initial clinical trial

Item	Positive (PCa) (n=70)	Negative (BPH or no tumor) (n=70)	P-value
hsv2-miR-H9 expression			0.6823
Mean±SD	4,657.36±971.50	4,572.54±1,430.91	
Median (Q1, Q3)	4,688.00 (3,980.00, 5,193.00)	4,682.50 (3,556.00, 5,530.00)	
Hsa-miR-3659 expression			<0.0001
Mean±SD	51.54±19.37	68.03±24.92	
Median (Q1, Q3)	47.00 (39.00, 60.00)	65.00 (51.00, 86.00)	
Expression ratio of hsv2-miR-H9/hsa-miR-3659			<0.0001
Mean ± SD	98.06±27.12	71.05±15.94	
Median (Q1, Q3)	94.50 (81.22, 111.40)	70.20 (60.88, 81.69)	

PCa, prostate cancer; BPH, benign prostatic hyperplasia; SD, standard deviation; Q,quartile.

Table SV. Cut-off value of the miRCaP kit for predicting PCa.

Method	AUC (95% CI)	Cut-off value
Euclidean method	0.8237(0.7539, 0.8934)	0.8064

PCa, prostate cancer; AUC, area under the curve.

Table SVI. Diagnostic value of the mirCaP kit (hsv2-miR-H9 to hsa-miR-3659 expression ratio) in the pivotal clinical trial.

Item	Positive (PCa) (n=109)	Negative (no tumor) (n=139)	P-value[a]
hsv2-miR-H9 expression			<0.0001
Mean±SD	6,015.83±2,580.58	3,676.90±1,941.26	
Median (Q1, Q3)	5,428.00 (4,276.00, 7,076.00)	3,395.50 (2,541.00, 4,243.00)	
Hsa-miR-3659 expression			<0.0001
Mean±SD	46.82±32.15	73.32±54.61	
Median (Q1, Q3)	39.00 (31.00, 53.00)	60.00 (38.00, 95.00)	
Expression ratio of hsv2-miR-H9/hsa-miR-3659			<0.0001
Mean ± SD	148.72±61.53	59.92±26.81	
Median (Q1, Q3)	137.57 (115.86, 168.85)	60.41 (39.88, 75.74)	

[a]Wilcoxon rank-sum test. PCa, prostate cancer; BPH, benign prostatic hyperplasia; SD, standard deviation; Q,quartile.

Table SVII. Diagnostic value of the miRCaP kit according to Gleason grade in the pivotal clinical trial.

A, Gleason grade 1		
Item	Positive[a] (n=18)	Negative[a] (n=0)
Result with themiRCaP kit		
Positive (n=17)	17	0
Negative (n=1)	1	0
Cut-off	80.64	
Sensitivity, %(95% CI)	94.44 (72.71, 99.86)	
Specificity, % (95% CI)	- (- , -)	
B, Gleason grade 2		
Item	Positive[a] (n=66)	Negative[a] (n=0)
Result with themiRCaP kit		
Positive (n=61)	61	0
Negative (n=5)	5	0
Cut-off	80.64	
Sensitivity, %(95% CI)	92.42 (83.20, 97.47)	
Specificity, % (95% CI)	- (- , -)	
C, Gleason grade 3		
Item	Positive[a] (n=13)	Negative[a] (n=0)
Result with themiRCaP kit		
Positive (n=13)	13	0
Negative (n=0)	0	0
Cut-off	80.64	
Sensitivity, %(95% CI)	100.00 (75.29, 100.00)	
Specificity, % (95% CI)	- (- , -)	
D, Gleason grade 4		
Item	Positive[a] (n=7)	Negative[a] (n=0)
Result with themiRCaP kit		
Positive (n=7)	7	0

Negative (n=0)	0	0
Cut-off	80.64	
Sensitivity, %(95% CI)	100.00 (59.04, 100.00)	
Specificity, % (95% CI)	- (- , -)	
E, Gleason grade 5		
Item	Positive[a] (n=5)	Negative[a] (n=0)
Result with themiRCaP kit		
Positive (n=5)	5	0
Negative (n=0)	0	0
Cut-off	80.64	
Sensitivity, %(95% CI)	100 (47.82, 100.00)	
Specificity, % (95% CI)	- (- , -)	

[a]Reference standard. CI, confidence interval.There was no observed difference in sensitivity according to the Gleason grade (P=0.736).