

## Physician Brochure



### Background »

PSA testing can find prostate cancer early before it spreads from the prostate. However, PSA tests can also give false positives and find indolent prostate cancer that doesn't need treatment, for example, only 1 in 4 positive PSA tests is due to prostate cancer (1,2). PSA testing can lead to overdiagnosis and men opting for unnecessary invasive prostate biopsies, with potential harmful side effects (1,2).

PSA  
Screening  
Test



ClarityDX<sup>®</sup>  
prostate  
**Risk Score**



Informed  
Decision



**MRI / Biopsy /  
Intervention**  
**Continue  
Monitoring**



### What is ClarityDX Prostate?



ClarityDX Prostate is a test that combines lab results for;

01

Total PSA

02

Percent free PSA

and three clinical features;

01

Age

02

DRE

03

Previous negative  
biopsies

These lab markers are used to calculate the risk of having clinically significant prostate cancer, defined as Gleason Grade Group 2 or higher, ( $GG \geq 2$ ) on prostate biopsy.

The ClarityDX Prostate test is indicated for use at the primary care level to aid in the decision for prostate biopsy in men between 40 to 75 years of age who have an abnormal age-based PSA of 3 ng/ml and above and/or an abnormal DRE, and without a previous history of prostate cancer (3,4).





## Why use ClarityDX Prostate?

The ClarityDX Prostate test was developed using data from five independent cohorts totaling 3,448 men.

The study demonstrates that ClarityDX Prostate is up to 3X more specific than PSA at detecting clinically significant prostate cancer.

This improved specificity can be used to better inform clinical decision-making whether to proceed to prostate biopsy and/or mpMRI.

### Validation

	AUC	Sensitivity	Specificity	PPV	NPV
PSA	0.72	95%	12%	46%	78%
% Free PSA	0.72	95%	11%	46%	72%
ClarityDX Prostate	0.82	95%	35%	54%	91%

AUC: Receiver Operating Characteristic Area Under the Curve      NPV: Negative Predictive Value      PPV: Positive Predictive Value



## Care Path with ClarityDX Prostate



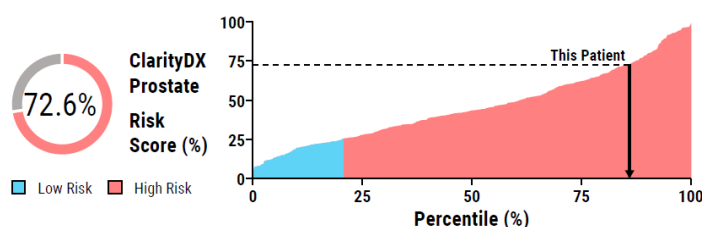
ClarityDX Prostate is intended to be done as a reflex test after elevated PSA levels are detected and before a prostate biopsy. This fits perfectly within the CUA (Canadian Urology Association) guidelines as an adjunctive strategy to be performed after a high PSA level is detected and before a biopsy and or mpMRI is performed (3,4).



## Interpreting ClarityDX Prostate Results

The ClarityDX Prostate Test Report provides the patient's total PSA, % free PSA, and the ClarityDX Prostate Risk Score. The risk score is provided as a percent probability of GG 2 and above prostate cancer and is reported with the patient's risk associated with their age group.

A risk score of 25% or above indicates a high risk for clinically significant prostate cancer.



This risk score indicates a 72.6% probability of grade group  $\geq 2$  prostate cancer on biopsy and that this patient is in the 85th percentile of risk for their age group of between 60 and 65.

Test Name	Result	Units	Reference Interval
Total PSA	3.5* HIGH	ng/mL	<3 <sup>a</sup>
Free PSA	0.35* LOW	ng/mL	See % Free PSA below
% Free PSA	10.0* LOW	%	>25 <sup>b</sup>
<b>ClarityDX Prostate Risk Score</b>	<b>72.6* HIGH</b>	<b>%</b>	<b>&lt;25<sup>c</sup></b>

### References

- (1) Mason et al. 2022. Can Urol Assoc J. 16(4).
- (2) Brenner et al. 2022. CMAJ. 194 (17).

- (3) Paproski et al. 2023. MP 9.8 CUA. 17. 6S2. p S117-S118.
- (4) Wallis et al. 2023. JCO. 41. 5023-5023.



Test performed by Nanostics Clinical Lab  
CPSA Accreditation Facility No. L0526000

10150 102 Street, Edmonton, AB, Canada  
T5J 5E2 (C) 2024 Nanostics, Inc.