

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[®]
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 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

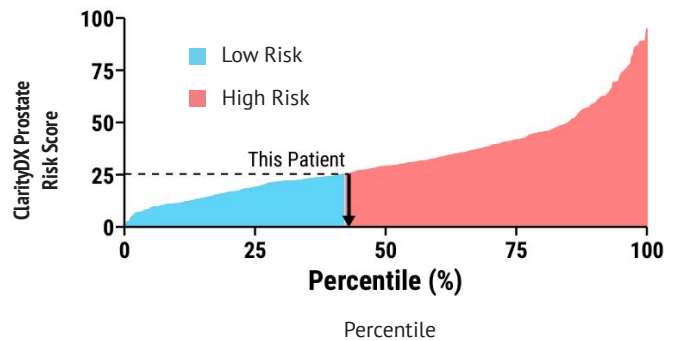
ClarityDX Prostate is intended to be done as a reflex test after elevated PSA levels are detected and before a prostate biopsy. This fits perfectly within the CUA (Canadian Urology Association) guidelines as an adjunctive strategy to be performed after a high PSA level is detected and before a biopsy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



Test Name	Low Risk	High Risk
Total PSA (1)	<3 ng/ml	>3 ng/ml
% Free PSA (1)	>25%	< 25%
ClarityDX Prostate Risk Score (3)	< 25%	>25%

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.