

Healthcare Provider 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 overtreatment with men opting for unnecessary and potentially harmful, invasive prostate biopsies (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;

✓ Total PSA ✓ Percent free PSA

and three to five clinical features;

✓ Age ✓ Previous negative biopsies ✓ DRE ✓ Prostate volume (MRI) ✓ PI-RADS (MRI)

These lab results and clinical features 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 who have an elevated total PSA and/or an abnormal DRE and without a previous history of prostate cancer(3-8).



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 4X more specific than PSA at detecting clinically significant prostate cancer.

* ClarityDX Prostate +MRI+DRE

This improved specificity can be used to better inform clinical decision-making regarding the need for further screening.



The ClarityDX Prostate test is flexible to the availability of MRI and DRE data due to four optimized risk models that provide high accuracy for predicting clinically significant prostate cancer in a variety of clinical settings.

Validation					
	AUC	Sensitivity	Specificity	PPV	NPV
PSA	0.72	95%	12%	46%	78%
% Free PSA	0.72	95%	11%	46%	72%
1 ClarityDX Prostate	0.82	95%	32%	52%	89%
2 ClarityDX Prostate DRE	0.82	95%	35%	54%	91%
3 ClarityDX Prostate MRI	0.87	95%	45%	50%	94%
4 ClarityDX Prostate + MRI + DRE	0.87	95%	47%	51%	94%

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



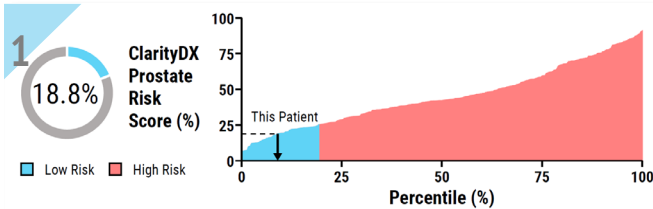
Care Path with ClarityDX Prostate

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 Canadian Urology Association (CUA) guidelines as an adjunctive strategy to be performed after a high PSA level is detected and before a biopsy and or MRI is performed (3).



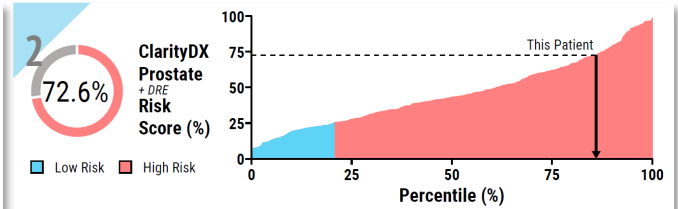
Interpreting ClarityDX Prostate Results

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 prostate cancer and is reported with the patient's risk associated with their age group. A risk score above the threshold indicates a high risk for clinically significant prostate cancer.



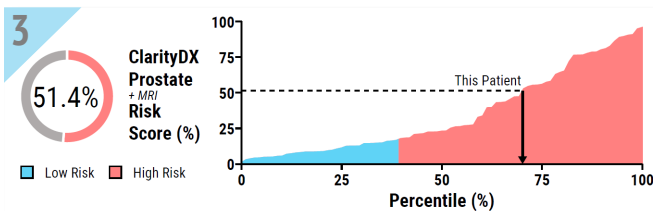
This risk score indicates an 18.8% probability of grade group ≥ 2 prostate cancer on biopsy and that this patient is in the 9th percentile of risk for their age group of between 60 and 65.^c

Test Name	Result	Units	Reference Interval
Total PSA	3.5*	ABNORMAL ng/mL	<3*
Free PSA	1.75	ng/mL	See % Free PSA below
% Free PSA	50.0	%	>25*
ClarityDX Prostate Risk Score	18.8	%	<25*



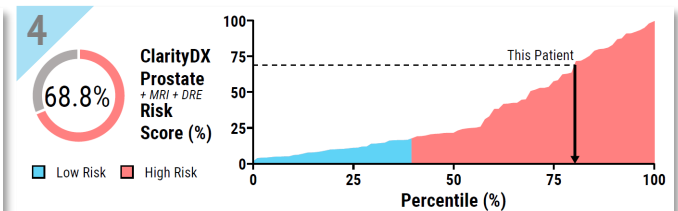
This risk score indicates a 72.6% probability of grade group ≥ 2 prostate cancer on biopsy and that this patient is in the 85th percentile of risk for their age group of between 60 and 65.^c

Test Name	Result	Units	Reference Interval
Total PSA	3.5*	ABNORMAL ng/mL	<3*
Free PSA	0.35*	ABNORMAL ng/mL	See % Free PSA below
% Free PSA	10.0*	ABNORMAL %	>25*
ClarityDX Prostate + DRE Risk Score	72.6*	ABNORMAL %	<25*



This risk score indicates a 51.4% probability of grade group ≥ 2 prostate cancer on biopsy and that this patient is in the 70th percentile of risk for their age group of between 60 and 65.^c

Test Name	Result	Units	Reference Interval
Total PSA	3.5*	ABNORMAL ng/mL	<3*
Free PSA	0.35*	ABNORMAL ng/mL	See % Free PSA below
% Free PSA	10.0*	ABNORMAL %	>25*
ClarityDX Prostate + MRI Risk Score	51.4*	ABNORMAL %	<17*



This risk score indicates a 68.8% probability of grade group ≥ 2 prostate cancer on biopsy and that this patient is in the 80th percentile of risk for their age group of between 60 and 65.^c

Test Name	Result	Units	Reference Interval
Total PSA	3.5*	ABNORMAL ng/mL	<3*
Free PSA	0.35*	ABNORMAL ng/mL	See % Free PSA below
% Free PSA	10.0*	ABNORMAL %	>25*
ClarityDX Prostate + MRI + DRE Risk Score	68.8*	ABNORMAL %	<17*

References

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