The Physician Pack contains:
Physician Brochure
ClarityDX Prostate® Requisition Form
APL Third Party Requisition Form

CHECKLIST FOR PHYSICIANS

1. Complete the patient information, physician information, and clinical information sections of the ClarityDX Prostate® Requisition Form (including the results from DRE).
2. Fill out the Patient and Provider sections of the APL Third Party Requisition Form.
3. Instruct the patient to:
   - Book an appointment at their preferred APL lab for sample collection either online at **www.albertaprecisionlabs.ca** or 1-877-702-4486.
   - Go to the Nanostics website at **https://www.nanosticsdx.com/clarity-dx-prostate/** to order and pay for the test by credit card or cheque.
   - Take the completed ClarityDX Prostate Requisition Form, APL Third Party Requisition Form, and either their payment receipt from the online purchase of the test or a filled in copy of the ClarityDX Prostate Payment Authorization Form, to their sample collection appointment.

NOTE: Patient fasting is not required before the ClarityDX Prostate test.

ClarityDX prostate®

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** (+) or **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 ≥ 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

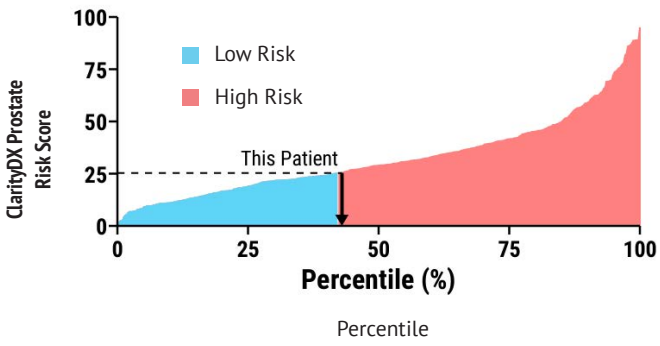
Care Path with ClarityDX Prostate

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.



Percentile

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.

NANOSTICS PRECISION HEALTH

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

10150 102 Street, Edmonton, AB,
Canada T5J 5E2

ClarityDX Prostate® Requisition Form

Nanostics 1-800-672-2027

Scanning Label or Accession # *(lab only)*

**** TEST ELIGIBILITY: Patient must not have been previously diagnosed with prostate cancer, be between 40-75 years of age and have not taken high-dose biotin therapy (>5 mg/day) within 8 hours of serum collection****

Complete the sections below at the physician's clinic. Choose only one check box where applicable.

PATIENT INFORMATION

Legal last name _____

Legal first name _____

Patient ID (e.g., PHN) _____

Date of birth (e.g., 1960-Jan-01) | | | | | | | | | |
Y Y Y Y M M M D D

Gender ☐ Male ☐ Female ☐ Prefer not to Disclose

Postal Code _____

Phone number _____

PHYSICIAN INFORMATION

Legal last name _____

Legal first name _____

Physician ID _____

Street address _____

City/Town _____

Province _____

Postal Code _____

Phone number _____

Fax _____

Ordering Date (e.g., 2023-Jan-01) | | | | | | | | | |
Y Y Y Y M M M D D

ClarityDX Prostate patient reports are only sent to the ordering physician. Forwarding patient reports to other physicians is the responsibility of the ordering physician.

CLINICAL INFORMATION

Digital rectal exam within 6 months
☐ Normal
☐ Abnormal (asymmetry, induration, nodules)

Prior negative prostate biopsy ☐ No ☐ Yes

Send this completed form with the completed 3rd Party ClarityDX Prostate requisition form to an appropriate blood collection site for the ClarityDX Prostate test. Send the collected serum sample in an SST™ tube and this completed requisition form to Nanostics' laboratory which performs the ClarityDX Prostate test. Total and free PSA, part of the ClarityDX Prostate test, may be performed by DynaLIFE (Edmonton, AB).

Complete the section below at the blood collection centre.
Serum collection instructions in 3rd Party ClarityDX Prostate Req. Form

SERUM COLLECTION INFORMATION

Collection date (e.g., 2023-Jan-01) _____

Collection time (24-hr) _____

Complete the section below at the diagnostic laboratory performing the ClarityDX Prostate test.

LABORATORY COLLECTION INFORMATION

Received date (e.g., 2023-Jan-01) _____

Received time (24-hr) _____

ADDITIONAL INFORMATION

Test Overview
ClarityDX Prostate is a laboratory-developed test by Nanostics that combines the lab results of two biomarkers (total PSA and free PSA) and three clinical features (age, previous negative prostate biopsy status, and digital rectal exam findings) to calculate the risk of having clinically significant prostate cancer, defined as Gleason Grade Group 2 or higher, on prostate biopsy. This risk probability is provided as the test Risk Score which ranges between 0.1% to 99.9%. ClarityDX Prostate is a non-invasive test indicated for use by physicians as an additional tool to aid in the decision for more advanced procedures such as diagnostic imaging or prostate biopsy.

Test Eligibility
Patients have not been previously diagnosed with prostate cancer and are between 40-75 years of age with total PSA ≥ 3 ng/mL. Patients are not on high-dose biotin therapy (i.e., > 5 mg/day). If you are taking high-dose biotin therapy, wait at least 8 hours from the last biotin administration before going to the blood collection site for this test.

Test Performance
The test demonstrated an area under the receiver operating characteristic curve (AUC) of 0.82 and a sensitivity and specificity of 0.95 and 0.35, respectively, when using a Risk Score threshold of 25%.

Test Limitations
While the ClarityDX Prostate test is more accurate compared to PCPTRC and PBCG risk calculators for predicting clinically significant prostate cancer, the test may still provide false positive and false negative test results. The instruments used to acquire total PSA and free PSA may be sensitive to high biotin concentrations in the blood (>30 ng/mL) thus patients taking large amounts of biotin supplements may have inaccurate test results. Test accuracy may be influenced by PSA-altering drugs such as 5-alpha reductase inhibitors.

The performance characteristics of ClarityDX Prostate were determined by Nanostics in a primarily Albertan population 40 to 75 years of age with PSA ≥3 ng/mL. Evaluation of this test outside of these ages and PSA values has not been performed by Nanostics. Total PSA and free PSA tests are indicated for men ≥50 years of age; caution is required when interpreting individual total PSA and free PSA results in patients below 50 years of age. Patient management should be based on holistic clinical judgment. This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA) or Health Canada.

Sample Handling
Collected blood samples will be separated into serum which will be used to perform total PSA and free PSA tests which results are used for the ClarityDX Prostate test. No other tests will be performed with your serum samples other than those authorized by your healthcare provider. Nanostics may use a referral laboratory to perform the total PSA and free PSA tests. The referral laboratory will be evaluated for quality using Nanostics' supplier approval process to ensure test results can be trusted. Referral laboratories will be located in Canada to ensure that samples do not cross international borders.

Information Handling
Patient and physician information collected for the ClarityDX Prostate test will only be used to generate and evaluate ClarityDX Prostate test results. Information will not be provided to other parties without the consent of patients and physicians. All collected data for the ClarityDX Prostate test will reside within Canada to ensure identifiable health information does not cross international borders. Nanostics' privacy policy may be accessed by contacting Nanostics at info@nanosticsdx.com.

Test Result Disclosure
ClarityDX Prostate patient reports are only sent to the ordering physician. Forwarding patient reports to other physicians or patients is the responsibility of the ordering physician. Test results will be available within 5 business days.

Patient consent
By completing and submitting this ClarityDX Prostate requisition form to a blood collection site, the patient is providing implied consent that they understand the information on this requisition form and allow Nanostics to perform the ClarityDX Prostate test on their clinical information.

About Nanostics
General questions and complaints may be submitted at 1-800-672-2027 or info@nanosticsdx.com. Nanostics laboratory hours of operation are from 9 a.m. to 5 p.m. Mountain Time. All communications should be within these hours of operations.

ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

APL THIRD PARTY REQUISITION

Appointment Booking: online at www.albertaprecisionlabs.ca or 1-877-702-4486
Locations and Hours of Operation: www.albertaprecisionlabs.ca

Scanning Label or Accession # *(lab only)*

Non-Participating Submitter - Use **'Req Entry'**

Patient

PHN / Healthcare Number Expiry:		Date of Birth *(dd-Mon-yyyy)*	
Legal Last Name		Legal First Name	Middle Name
Alternate Identifier	☐ Male ☐ Female ☐ Non-Binary ☐ Prefer not to Disclose	Phone	Address
City / Town	Province	Postal Code	Chart Number **ClarityDX Prostate Kit**

Provider

Submitter ID **19967**	Submitter **Nanostics Inc.**	Phone **1-800-672-2027**
Provider ID **12300005**	Authorizing Provider Name **Lab Billing Provider**	Bill Type **Client Bill**

Collection

Date (dd-Mon-yyyy)	Time *(24 hr)*	Location	Collector ID / Initials	Fasting Hours

PHYSICIAN INFORMATION

1. Ensure patient has not been previously diagnosed with prostate cancer.
2. Complete the *Patient* section on this requisition and the *patient, physician* and *clinical information* on the Nanostics ClarityDX Prostate requisition.
3. Provide the patient with this Requisition, the ClarityDX Prostate Requisition Form and the Payment Authorization form.
4. Ensure the patient is familiar with the section below.

PATIENT INFORMATION

APPOINTMENT CRITERIA Collections are **Monday thru Friday only** (excluding statutory holidays).

1. Appointments MUST be booked by phoning the Customer Call Centre at 780-702-4486. Ensure your appointment meets the above bolded criteria.
2. Bring the APL Third requisition, the ClarityDX Prostate requisition and Payment Authorization form to your laboratory appointment – 3 documents.

APL LAB STAFF INSTRUCTIONS

SPECIAL NOTES

- Collect patient only if they have a Nanostics Payment Authorization form - Use your site's supplies for collection.

DATA ENTRY

Number	Procedure Description
LAB71878	Third Party Collection Fee
LAB71885	Third Party Processing Fee

COLLECTION / PROCESSING

1. Do not proceed with collection unless the patient has a Nanostics Payment Authorization form, proof of payment or a certified cheque.
2. Verify the expiration date on the SST tube before proceeding with collection.
3. Record the date and time of collection on both this requisition and the ClarityDX Prostate requisition.
4. Collect **1 X 5mL SST Gold Top tube** and ensure tube is filled to capacity. Centrifuge sample and pour off the serum equally into two 10mL transport vials.
5. Print the *Requisition* label x 4. Apply one label to each requisition and to each transport vial.

SHIPPING

1. Place the **two transport vials** into a specimen back with both the **ClarityDX Prostate Requisition Form** *and* **Payment Authorization Form** in the front pouch.
2. Store sample UPRIGHT in your freezer until the next scheduled courier run to Base Lab.
3. Send the APL Third Party requisition to Base Lab for scanning using your regular Company billing process.

? Questions regarding collection / handling should be directed to Nanostics at 1-800-672-2027.

PRE & POST ANALYTICS EDMONTON STAFF INSTRUCTIONS

1. Store samples in the -20^{0}C freezer until delivery to Nanostics lab.

Collections available at APL Community Patient Service Centres only