Alberta Requisition Pack contains:

1. Patient and Healthcare Provider Instructions
2. ClarityDX Prostate® Requisition Form
3. APL Third Party Requisition Form

PATIENT INSTRUCTIONS

1. Print the ClarityDX Prostate Requisition Form and the Alberta Precision Laboratories (APL) Third Party Requisition Form.
2. Bring both printed requisition forms to your healthcare provider for them to complete.
3. Purchase the ClarityDX Prostate test online or print and complete the Payment Authorization form for offline purchase of the test.
4. Book an appointment at an APL sample collection site online at https://www.albertaprecisionlabs.ca/ or phone the Booking Centre at **1-877-702-4486**.
5. Take the completed requisition forms and either the online payment receipt or the completed Payment Authorization form (if purchasing offline) to your appointment at the APL sample collection site.
6. The test results will be sent to your healthcare provider within five (5) business days.
7. Reach out to your healthcare provider to discuss the results of your test.

NOTE: You may be eligible for reimbursement through your employer's health spending account.

CHECKLIST FOR HEALTHCARE PROVIDERS

1. Complete these sections of the ClarityDX Prostate Requisition Form: patient information, physician information, and clinical information.
2. Fill out the Patient and Provider sections of the APL Third Party Requisition Form.

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

www.nanosticsdx.com/clarity-dx-prostate/

Scan to access the Nanostics ClarityDX Prostate order webpage.

NANOSTICS PRECISION HEALTH

ClarityDX Prostate® Requisition Form

Scanning Label or Accession # *(lab only)*

Nanostics Toll-Free 1-800-672-2027 or Direct 780-249-2210 or FAX 1-780-249-2211

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

Complete the sections below with the healthcare provider. Choose only one check box where applicable.

PATIENT INFORMATION

Legal first name _____

Legal last name _____

Patient ID (e.g., PHN) _____

Date of birth | | | | | | | | | |

(e.g., 1970 Jan 01) Y Y Y Y M M M D D

Gender ☐ Male ☐ Female ☐ Prefer not to disclose

Postal Code _____

Phone number _____

CLINICAL INFORMATION

Did the patient have a digital rectal exam (DRE) within 6 months?

☐ Yes ☐ No

If yes, what is the result of the DRE? ☐ Normal ☐ Abnormal (asymmetry, induration, nodules)

Is prostate volume and PI-RADS known from MRI?

☐ Yes ☐ No

If yes,

a) What is the prostate volume? _____cc

b) What is the PI-RADS score? (0 to 5) _____

Did the patient ever have a prostate biopsy?

☐ Yes ☐ No

If yes, what is the result of the biopsy? ☐ Negative ☐ Positive (ineligible for ClarityDX Prostate Test)

HEALTHCARE PROVIDER INFORMATION

Legal first name _____

Legal last name _____

Physician ID _____

Street address _____

City/Town _____

Province _____

Postal Code _____

Phone Number _____

Fax Number _____

Ordering Date | | | | | | | | | |

(e.g., 2024 Jan 01) Y Y Y Y M M M D D

ClarityDX Prostate patient reports are only sent to the ordering healthcare provider. Forwarding patient reports to other healthcare providers is the responsibility of the ordering healthcare provider.

Please indicate if the healthcare provider would like to receive the report through secure email:

☐ Yes ☐ No

If yes, please provide an email address:

_____

Take this completed form, plus the completed Third (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 Clinical Laboratory, which performs the ClarityDX Prostate test.

Complete the section below at the blood collection site.

Serum collection instructions in 3rd Party ClarityDX Prostate Req. Form

SERUM COLLECTION INFORMATION

Collection date (e.g., 2024-Jan-01) _____

Collection time (24-hr) _____

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

LABORATORY COLLECTION INFORMATION

Received date (e.g., 2024-Jan-01) _____

Received time (24-hr) _____

ADDITIONAL INFORMATION

Test Overview

ClarityDX Prostate is a laboratory-developed test developed by Nanostics that combines the lab results of two biomarkers (total PSA and free PSA) and at most five clinical features (age, previous negative prostate biopsy status, digital rectal exam findings, prostate volume, and PI-RADS) 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 a Risk Score, which ranges between 0.1% to 99.9%. ClarityDX Prostate is a minimally invasive test indicated for use by healthcare providers 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 have elevated PSA levels. Patients are not on high-dose biotin therapy (i.e., > 5 mg/day). If the patient is 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

Performance characteristics and Risk Score thresholds for each of the four ClarityDX Prostate models are displayed in the following table:

Predictive Model Name	ROC AUC	Threshold	Sensitivity	Specificity
ClarityDX Prostate + MRI + DRE	0.87	≥17	95	47
ClarityDX Prostate + MRI	0.87	≥17	95	45
ClarityDX Prostate + DRE	0.82	≥25	95	35
ClarityDX Prostate	0.80	≥25	95	32

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 population primarily between 40 to 75 years of age with PSA ≥3 ng/mL. Nanostics has not performed an extensive evaluation of this test outside of these ages and PSA values. 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, and the results used for the ClarityDX Prostate test. No other tests will be performed with the patient's serum samples other than those authorized by the patient's 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 ClarityDX Prostate tests will reside within Canada. Nanostics' privacy policy may be accessed from the Nanostics website (www.nanosticsdx.com) or by contacting Nanostics at info@nanosticsdx.com.

Test Result Disclosure

ClarityDX Prostate patient reports are only sent to the ordering healthcare provider. Forwarding patient reports to other physicians or patients is the responsibility of the ordering physician. Test results will be available within 10 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 data.

Questions or Complaints?

Please contact Nanostics by telephone: Toll-free 1-800-672-2027 at extension 1, or Direct +1-780-249-2210, or FAX +1-780-249-2211 during Clinical Laboratory hours of operation, which are Monday to Friday from 9 a.m. to 5 p.m. Mountain Time. Contact us by email at info@nanosticsdx.com.

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