Ontario Requisition Pack contains:

1. Patient and Healthcare Provider Instructions
2. ClarityDX Prostate® Requisition Form
3. LifeLabs Laboratory Requisition Form for Ontario

PATIENT INSTRUCTIONS

1. Print the ClarityDX Prostate Requisition Form and the LifeLabs 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 any LifeLabs sample collection site by visiting www.lifelabs.com for locations, hours of operation, and appointment-only centres.
5. Take the completed requisition forms and either the online payment receipt or the completed Payment Authorization form (if purchasing offline) with you to your sample collection appointment.
6. The test results will be sent to your healthcare provider within ten (10) 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 the patient information, physician information, and clinical information sections of the ClarityDX Prostate Requisition Form.
2. Fill out the Patient and Provider sections of the LifeLabs 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.

Nanostics Inc.
Issue Date: 5-Mar-2024
Revision Date: 1-Feb-2025

CONTRACT NUMBER:	AO681	**Demographic and Billing Label (For LifeLabs Use Only)**
Ordering Physician Name, Address and Phone #	_____ _____ _____ Tel #:	
Bill Type	Contract	**Test List Label (For LifeLabs Use Only)**
Bill to Client No.:	AO681	

Patient Last Name	**Patient First Name**	
Date of Birth (YYYYMMDD)	**Sex** ☐ Male ☐ Female	**Phone Number**
Date Collected (YYYYMMDD)	**Time Collected** (HH:MM)	

TESTS REQUESTED

- ☑ Documentation Fee (code 105)
- ☑ Collection Fee (codes 11F & 10F)
- ☑ Dry Ice Fee (code 5686)

Samples can be collected any day of the week.

Patient will not present with a kit. Use LifeLabs supplies.

Process sample WITHIN 2 HOURS of collection.

Collect one (1) SST. Allow blood to clot and then centrifuge.

Complete date and time of collection on the ClarityDX Prostate Requisition.

Aliquot serum into 2 aliquot tubes and freeze samples.

Label tubes with patient's name and DOB.

Forward frozen samples to IRL with contract requisition, ClarityDX requisition and payment authorization. DO NOT PROCEED with collection if these documents are not provided.

Instructions for IRL Specimen Management

Ship samples on dry ice using 3rd Party FedEx account # 207536345. Provide Contract Services with the FedEx tracking number.

Nanostics Inc.
A108, 2011 94 Street NW
Edmonton, AB T6N 1H1
Attn: Clinical Laboratory
Manager, 1-780-249-2210

THIS REQUISITION IS VALID IN ONTARIO ONLY