The Requisition Pack contains:
Patient and Healthcare Provider Instructions
ClarityDX Prostate® Requisition Form
LifeLabs Laboratory Requisition Form for Saskatchewan

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. Book an appointment at any LifeLabs sample collection site by visiting www.lifelabs.com for locations, hours of operation, and appointment-only centres.
4. 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.
5. The test results will be sent to your healthcare provider within ten (10) business days.
6. 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.

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 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., 2024-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. Extensive 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 and the results are 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 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 phone at 1-800-672-2027 at extension 1 or by email at info@nanosticsdx.com during Clinical Laboratory hours of operation which are Monday to Friday from 9 a.m. to 5 p.m. Mountain Time.

Nanostics Inc
Issue Date: 11-Mar-2024
Revision Date:

SASKATCHEWAN CONTRACT CLIENT

CONTRACT NUMBER:	AO687	**Demographic and Billing Label (For LifeLabs Use Only)**
Ordering Physician Name and Address and phone #	Dr. _____ _____ _____ Ph #_____	
Bill Type:	Contract	**Test List Label (For LifeLabs Use Only)**
Bill to Client No:	AO687	

PHYSICIAN'S SIGNATURE REQUIRED

X_____ Date: _____

Patient Last Name	**Patient First Name**	**Sex** ☐ Male ☐ Female
Date of Birth (YYYYMMDD)	**Health Number**	**Phone Number**
Date Collected (YYYYMMDD)	**Time Collected** (HH:MM)	**Fasting** ☐ No ☐ Yes - _____ hours

TESTS REQUESTED

- ☑ Documentation Fee (105)
- ☑ Collection Fee (G56)
- ☑ Dry Ice Fee (G58)

Patient Instructions:

Please take this requisition **Monday – Thursday before 1pm** to the designated collection sites listed below.

LifeLabs (Midtown PSC)
5-39 23rd St. E., Saskatoon

LifeLabs (Towers PSC)
2723 Avonhurst Drive, Regina

SK LifeLabs Staff

Processing must be completed within 2 hours of collection. Use LifeLabs Tubes

- Collect 1 x 5.0ml SST – mix, clot and spin
  Aliquot into 2 aliquot tubes
  Freeze samples
  Record Date and Time of blood collection on **ClarityDX Requisition** and LL account requisition.
  Ship samples with **ClarityDX Requisition** and payment authorization form.

SK LifeLabs Staff

- **Ship Frozen samples on Dry Ice to Nanostics Inc. using Client's FedEx waybill,** Include a copy of ClarityDX requisition and payment authorization form.
  Attention: Argo Basu
  Nanostics Inc. TR
  Suite# 4 10133 103 St NW Edmonton Alberta T5J 5E2
  Attn: Argo Basu
  Phone: 780.908.9012

- FEDEX tracking # _____

THIS REQUISITION IS VALID IN SASKATCHEWAN ONLY