

**BC Requisition Pack contains:**

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

## 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](http://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/](http://www.nanosticsdx.com/clarity-dx-prostate/)

**Scan to access the Nanostics ClarityDX Prostate order webpage.**



# ClarityDX Prostate<sup>®</sup> 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 \_\_\_\_\_

**HEALTHCARE PROVIDER INFORMATION**

Legal first name \_\_\_\_\_

Legal last name \_\_\_\_\_

Physician ID \_\_\_\_\_

Street address \_\_\_\_\_

City/Town \_\_\_\_\_

Province \_\_\_\_\_

Postal Code \_\_\_\_\_

Phone Number \_\_\_\_\_

Fax 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)

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 (3<sup>rd</sup>) 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](http://www.nanosticsdx.com)) or by contacting Nanostics at [info@nanosticsdx.com](mailto: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](mailto:info@nanosticsdx.com).



<b>Test Summary Label</b>	<b>Client Summary Label</b>	<b>Demographic Label</b>
<input checked="" type="checkbox"/> <b>Bill to Account #: A7113</b>		<b>Account Name: NANOSTICS INC</b>
Patient Surname: _____ First: _____ Middle: _____		Date of Birth: _____ / _____ / _____ <small>DD MMM YYYY</small>
Address: _____		Sex: <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Unknown
Postal Code: _____	Telephone: _____	
PHN: _____		
Ordering Physician Name, MSC Number and Address <b>Must be completed by a Canadian licensed physician</b>		Copy Report to _____  Specimen Collected by: _____ <small>INITIALS</small>
Fasting <input type="checkbox"/> No <input type="checkbox"/> Yes - _____ hours		Collection Date: _____ / _____ / _____ <small>DD MMM YYYY</small> Time (24hr Clock) : _____ : _____ (HH:MM)
Diagnosis/Comments: _____		
<b>Patient must attend a LifeLabs Patient Service Centre. Visit <a href="http://www.lifelabs.com">www.lifelabs.com</a> for locations, hours of operation and appointment only centres</b>		
<b>PSC Staff Enter: *** Patient must provide ClarityDX prostate requisition and payment authorization form. DO NOT PROCEED with collection if these documents are not provided.</b>		
<input checked="" type="checkbox"/> KIT20;KIT35 <input checked="" type="checkbox"/> BOT3		
<b>PSC Specimen Collection Instructions: ***Use LifeLabs Supplies***</b> <ul style="list-style-type: none"> <li>Collect 1 x 5mL SST tube - Clot, Centrifuge and Aliquot into <b>2 ALIQUOT TUBES</b> within 2 hours of collection</li> <li>Freeze samples</li> <li>Store and ship frozen samples</li> <li>Record date and time of collection on all forms / requisitions</li> <li>Send Frozen samples with <b>ClarityDX prostate requisition, payment authorization form and a copy of account requisition to BRL/VRL Attn: Send Out Bench</b></li> </ul>		
<b>BRL Specimen Management:</b> <input type="checkbox"/> <b>Ship Frozen specimens on DRYICE to : Nanostics Inc. using Client FedEx Account 207536345</b> Nanostics Inc. Attention: Clinical Laboratory Manager A108, 2011 94 Street NW Edmonton Alberta , T6N 1H1 Ph# 780-249-2210 <b>FedEx tracking # _____</b>		
Physician Signature: _____		Date: _____
<small>We collect use and disclose your personal information in accordance with British Columbia privacy laws. We only collect and use your personal health information: to verify your identity; accurately match your specimen with your results; follow-up for testing; enable payment; use of specimen for quality assurance and book and confirm appointments. We may also use population-level, aggregate information to evaluate our performance, contribute to health system improvement and to support market research. We disclose your results information to healthcare practitioners involved in providing care. If we are asked to disclose personal health information about you for another reason, other than as required or permitted by law, we will contact you to obtain your consent. Our privacy policy is available at <a href="http://www.lifelabs.com">www.lifelabs.com</a>. Samples may be referred to a testing laboratory outside of British Columbia (to another province or Country). By agreeing to move forward with the laboratory test, you agree to the terms set out above</small>		