

The Patient Pack contains:

Patient Brochure
ClarityDX Prostate Payment Authorization Form
ClarityDX Prostate® Requisition Form
APL Third Party Requisition Form

PATIENT INSTRUCTIONS

1. Print the ClarityDX Prostate® Requisition Form and the APL Third Party Requisition Form.
2. Bring both printed requisition forms to your doctor for them to complete.
3. Book an appointment at an Alberta Precision Laboratories (APL) sample collection site by phoning the Customer Call Centre at 780-702-4486, or 1-877-702-4486.

IF PAYING BY CREDIT CARD ONLINE

Complete your online payment for the ClarityDX Prostate test for the **discounted price* of \$100** and either print your receipt or write down your order number (found on your receipt) on a printed copy of the ClarityDX Prostate Payment Authorization form.

IF PAYING BY CHEQUE OR CREDIT CARD OFFLINE

Print and fill in the ClarityDX Prostate Payment Authorization Form. If you are paying by cheque, make it payable to Nanostics Inc. for the **discounted price* of \$100**.

4. Take the completed requisition forms and the payment receipt or cheque with you to your appointment at the APL sample collection site.
5. The test results will be sent to your doctor within five (5) business days.
6. Reach out to your doctor to discuss the results of your test.

***The total cost of the ClarityDX Prostate test is \$300. Effective up to Jan 31, 2024, we are pleased to provide ClarityDX Prostate at an introductory discount of \$200 making the final cost \$100.**

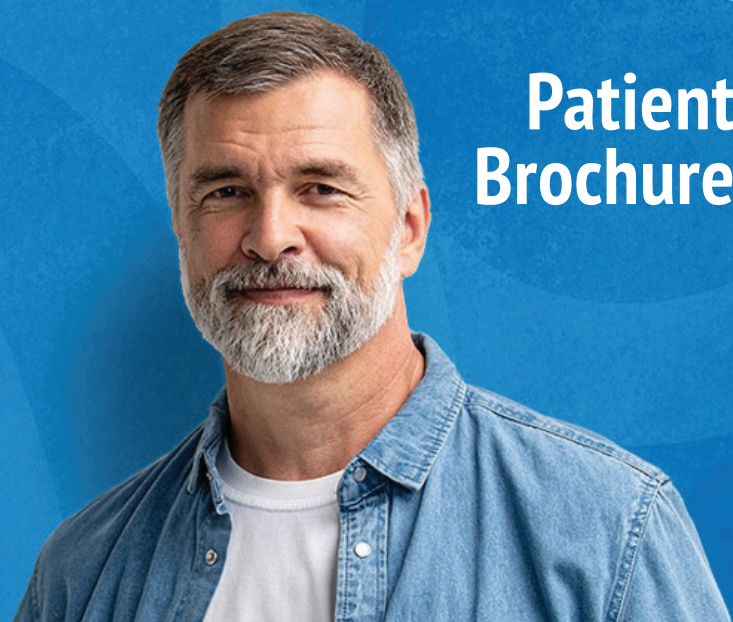
NOTE: You may be eligible for reimbursement through your employer's health spending account.



Patient Brochure

There's a lot riding on your prostate test...

KNOW THE SCORE.



Want to know your risk for aggressive prostate cancer?

ClarityDX Prostate can help!

What is ClarityDX Prostate?

ClarityDX Prostate is a blood test that gives you and your doctor more information about whether to have a prostate biopsy done or not. ClarityDX Prostate is up to 3X more accurate than PSA for predicting aggressive prostate cancer ^(1,2).



The result of the ClarityDX Prostate test indicates your relative risk of finding aggressive prostate cancer if an invasive biopsy is performed.



For more information about the benefits of the ClarityDX Prostate test please go to

www.nanosticsdx.com

or email

info@nanosticsdx.com

A Simple Test Bringing Clarity to

Prostate Cancer Screening

How Much Does the ClarityDX Prostate Test Cost?

ClarityDX Prostate is currently available as a private pay test and is not covered by Alberta Health. It may be eligible for reimbursement through your employer's health spending account.

For cost information please email info@nanosticsdx.com.



What Can PSA Tell You?

The PSA test measures the level of prostate specific antigen in your blood. High levels of blood PSA can indicate the presence of cancer in the prostate. However, there are many reasons why you might have a high PSA level that have no relation to cancer. In fact, only 1 in 4 men with high PSA levels have prostate cancer. PSA testing also finds indolent prostate cancer that may not need treatment leading to men opting for unnecessary treatments with potential harmful side effects ^(3,4).

ClarityDX Prostate is designed for men with elevated PSA levels to help identify men with aggressive prostate cancer.



What is Indolent vs. Aggressive Prostate Cancer?

Indolent prostate cancer is low-risk because the cancer stays in the prostate. The 5 year survival rate for indolent prostate cancer is 98-100%. Aggressive prostate cancer is high-risk because it spreads from the prostate and forms cancerous tumors at distant site(s) in the body.

The 5 year survival rate drops to 32% for men with aggressive prostate cancer ^(3,4).



Prostate Cancer screening

The Canadian Urology Association (CUA) suggests having a discussion with your doctor about whether PSA screening and alternative tests are right for you ⁽³⁾.



Get Clarity on Your Prostate Health

ClarityDX Prostate gives you and your doctor more information about what your elevated PSA levels mean and whether to have a prostate biopsy done or to continue monitoring PSA levels instead.

To be eligible for the ClarityDX Prostate test patients must be between 40-75 years of age with total PSA of 3 ng/ml or higher and without a prior diagnosis of prostate cancer.

References:

- (1) Paproski et al. 2023. Eur Urol. 83. Suppl 1.
- (2) Wallis et al. 2023. JCO. 41. 5023-5023.
- (3) Mason et al. 2022. Can Urol Assoc J. 16(4).
- (4) Brenner et al. 2022. CMAJ. 194 (17).

Test performed by Nanostics Clinical Lab
CPSA Accreditation Facility No. L0526000
10133-103 Street NW, DynaLIFE Medical
Labs, Suite 4 TRC, Edmonton, AB, T5J 5E2
(C) 2024 Nanostics, Inc.



ClarityDX Prostate® Payment Authorization Form

ClarityDX Prostate Test Price: \$300

Introductory Discount: - \$200

You Pay \$100

PATIENT INFORMATION

Legal Last Name	_____	Street Address	_____																				
Legal First Name	_____	City/Town	_____																				
Date of Birth (e.g., 1960-Jan-01)	<table border="0"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> <tr> <td>Y</td><td>Y</td><td>Y</td><td>Y</td><td>M</td><td>M</td><td>M</td><td>D</td><td>D</td><td></td> </tr> </table>											Y	Y	Y	Y	M	M	M	D	D		Province	_____
Y	Y	Y	Y	M	M	M	D	D															
Referring Doctor	_____	Postal Code	_____																				
Doctor's Phone No.	_____	Phone Number	_____																				

PAYMENT INFORMATION

Credit card ☐ Cheque

- ☐ MasterCard
☐ VISA
☐ Other: _____

Complete the fields below if a credit card is used for payment offline.

Credit card number _____ / _____ / _____

Expiry date _____ / _____ Security code _____

M M Y Y

Cardholder name _____

Cardholder signature _____

Date _____

☐ Online Credit Card Payment

Order Number (found on your ClarityDX Prostate test ordering receipt): _____



ClarityDX Prostate® Requisition Form

Scanning Label or Accession # (lab only)

Nanostics 1-800-672-2027

**** 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		PHYSICIAN INFORMATION	
Legal last name		Legal last name	
Legal first name		Legal first name	
Patient ID (e.g., PHN)		Physician ID	
Date of birth (e.g., 1960-Jan-01)	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>Y Y Y Y M M M D D</div>	Street address	
Gender	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Prefer not to Disclose	City/Town	
Postal Code		Province	
Phone number		Postal Code	
		Phone number	
		Fax	
		Ordering Date (e.g., 2023-Jan-01)	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div> <div>Y Y Y Y M M M D D</div>
CLINICAL INFORMATION		ClarityDX Prostate patient reports are only sent to the ordering physician. Forwarding patient reports to other physicians is the responsibility of the ordering physician.	
Digital rectal exam within 6 months	<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal (asymmetry, induration, nodules)		
Prior negative prostate biopsy	<input type="checkbox"/> No <input type="checkbox"/> 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		Complete the section below at the diagnostic laboratory performing the ClarityDX Prostate test.	
SERUM COLLECTION INFORMATION		LABORATORY COLLECTION INFORMATION	
Collection date (e.g., 2023-Jan-01)		Received date (e.g., 2023-Jan-01)	
Collection time (24-hr)		Received time (24-hr)	

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.



APL THIRD PARTY REQUISITION

Scanning Label or Accession # (lab only)

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

Non-Participating Submitter - Use 'Req Entry'

Patient	PHN / Healthcare Number		Date of Birth (dd-Mon-yyyy)	
	Expiry:			
	Legal Last Name		Legal First Name	Middle Name
	Alternate Identifier	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Non-Binary <input type="checkbox"/> 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 bag 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°C freezer until delivery to Nanostics lab.

Collections available at APL Community Patient Service Centres only