

The Patient Pack contains:

Patient Brochure
Clarity DX Prostate® Requisition Form
DynaLIFE Third Party Requisition Form
ClarityDX Prostate Payment Authorization Form

PATIENT INSTRUCTIONS

1. Print the Clarity DX Prostate® Requisition Form and the DynaLIFE Third Party Requisition Form.
2. Bring both printed requisition forms to your doctor for them to complete.
3. Go to <https://qme.dynalife.ca/> to reach DynaLIFE/Alberta Precision Laboratories online booking system. Book an appointment at your preferred sample collection site, located across Alberta. Or book an appointment by phone at either 1-800-661-9876 or (780) 451-3702.

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 a DynaLIFE/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.

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

KNOW THE SCORE.



**Patient
Brochure**

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. ClarityDX Prostate is up to 3X more accurate than PSA for predicting aggressive prostate cancer (1,2).

PSA
Screening
Test



ClarityDX[®]
prostate
Risk Score



**informed
Decision**



**MRI / Biopsy /
Intervention**



**Continue
monitoring**

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



More information about the
benefits of the ClarityDX
Prostate test can be found at
www.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 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 \geq 3 ng/mL and without a prior diagnosis of prostate cancer.

References:

- (1) Paproski et al. 2023. MP 9.8 CUA 17. 6S2 pS117-S118.
- (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
10150-102 Street NW, Edmonton, AB, T5J 5E2
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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

Legal last name _____

Legal first name _____

Patient ID (e.g., PHN) _____

Date of birth (e.g., 1960-Jan-01)
Y Y Y Y M M M D D

Gender Male Female Prefer not to Disclose

Postal Code _____

Phone number _____

PHYSICIAN INFORMATION

Legal last name _____

Legal first name _____

Physician ID _____

Street address _____

City/Town _____

Province _____

Postal Code _____

Phone number _____

CLINICAL INFORMATION

Digital rectal exam within 6 months Normal Abnormal (asymmetry, induration, nodules)

Prior negative prostate biopsy No Yes

Fax _____

Ordering Date (e.g., 2023-Jan-01)
Y Y Y Y M M M D D

ClarityDX Prostate patient reports are only sent to the ordering physician. Forwarding patient reports to other physicians is the responsibility of the ordering physician.

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

SERUM COLLECTION INFORMATION

Collection date (e.g., 2023-Jan-01) _____

Collection time (24-hr) _____

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

LABORATORY COLLECTION INFORMATION

Received date (e.g., 2023-Jan-01) _____

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 \geq 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 \geq 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 \geq 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.



THIRD PARTY REQUISITION

DynaLIFE Medical Labs 1 (800) 661-9876 or (780) 451-3702

Appointment Booking & Locations: www.dynalife.ca

Scanning Label or Accession # (lab only)

Patient	PHN / Healthcare Number		Requisition Date (dd-Mon-yyyy)		
	Expiry:				
	Legal Last Name		Legal First Name		Middle Name
	Date of Birth (dd-Mon-yyyy)				
Provider	Gender <input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> X (Non-Binary/Prefer not to Disclose)		Phone		Address
	City / Town		Province	Postal Code	Chart Number– Record in corresponding field in Beaker ClarityDx Prostate Kit
	Submitter ID 19967	Client Number DL-37541	Submitter Nanostics Inc.		Phone 1-800-672-2027
Provider ID 267580	Authorizing Provider Name Physician Not Applicable			Bill Type Client Bill	
Collection	Date (dd-Mon-yyyy)	Time (24 hr)	Location	Collector ID / Initials	

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 the 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 **DynaLIFE** Third Party Requisition, the ClarityDX Prostate Requisition and Payment Authorization form to your laboratory appointment – 3 documents.

DL LAB STAFF INSTRUCTIONS

SPECIAL NOTES

- Collect patient sample only if they have a Nanostics Payment Authorization form, Proof of Payment and/or Certified Cheque - Use your site's supplies for collection

DATA ENTRY

Number	Procedure Description
LAB71878	Third Party Collection Fee
LAB71885	DL Third Party Processing Fee

COLLECTION / PROCESSING

1. Do not proceed with collection unless the patient has a 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. Place vials in the freezer.

SHIPPING

1. Place the **two transport vials** into a specimen back with both the **ClarityDX Prostate Requisition Form and Payment Authorization Form/Proof of Payment/Certified Cheque** in the front pouch.
2. Store sample UPRIGHT in your freezer until the next scheduled courier run to Base Lab. Ship under frozen conditions.
3. Send the **DynaLIFE** 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 DynaLIFE Patient Care Centres only



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): _____