

The Requisition Pack contains:

Patient and Healthcare Provider Instructions
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 healthcare provider 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 **\$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 **\$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 healthcare provider within five (5) 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 (including the results from DRE).
2. Fill out the Patient and Provider sections of the APL Third Party Requisition Form.

NOTE: Patient fasting is not required before the ClarityDX Prostate test.



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.





APL THIRD PARTY REQUISITION

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

Scanning Label or Accession # (lab only)

Non-Participating Submitter - Use 'Req Entry'

Patient	PHN / Healthcare Number		Date of Birth (dd-Mon-yyyy)			
	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 back 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