

PATIENT INFORMATION - ALL REQUIRED

Date of Collection: _____ Time of Collection: _____
 Last Name: _____ First Name: _____ MI: _____
 Cell #: _____ Email: _____
 Home #: _____ Street Address: _____
 Apt: _____ City: _____ State: _____ Zip: _____
 DOB: (MM/DD/YYYY): _____ / _____ / _____ SSN #: _____
(SSN # required for uninsured patients only)

Gender Identity and Sexual Orientation

- | | | |
|---|---|---|
| <input type="checkbox"/> Male | <input type="checkbox"/> Transgender Male | <input type="checkbox"/> Straight or Heterosexual |
| <input type="checkbox"/> Female | <input type="checkbox"/> Transgender Female | <input type="checkbox"/> Lesbian, Gay or Homosexual |
| <input type="checkbox"/> Non-Binary/Genderqueer | <input type="checkbox"/> Choose not to disclose | <input type="checkbox"/> Bisexual |
| | | <input type="checkbox"/> Other: _____ |

Race and Ethnicity - Select all that apply

- | | | |
|--|---|---|
| <input type="checkbox"/> American Indian or Alaska Native | <input type="checkbox"/> Asian | <input type="checkbox"/> Hispanic or Latino |
| <input type="checkbox"/> Black or African American | <input type="checkbox"/> White | <input type="checkbox"/> Non-Hispanic or Latino |
| <input type="checkbox"/> Native Hawaiian or Other Pacific Islander | <input type="checkbox"/> Choose not to disclose | <input type="checkbox"/> Other: _____ |

Guidelines for patient demographics are provided by NIDOH/CLIS (NISA 45:9-42.46 to -42.49)



SPECIMEN ID: _____

T128353

LAB ACCESSION #: _____

REFERRING PHYSICIAN INFO. (Required)

INSURANCE INFO. (Required)

Policyholder Name: _____
 Insurance Name: _____
 Policy #: _____
 Group #: _____

- Bill Insurance
 Bill Client
 Self Pay

Please provide a copy of the front & back of insurance card(s).

HISTOPATHOLOGY

Prostate # of Jars: _____
 Bladder Biopsy Location(s): _____
 Vas Deferens- L Vas Deferens- R Other: _____
 Previous Biopsy: Benign Suspicious/ASAP HGPIN Malignant None
 Procedure: TURBT Cold Cup Biopsy Needle Core Biopsy TURP Other: _____
 Clinical Findings: DRE Normal Abnormal
 Last PSA: _____ ng/ml Free PSA Level: _____ % Date: _____ / _____ / _____

For Saturation Biopsy: Must check off at least one Primary Code (in red) to support medical necessity.

Primary Codes:

- C61** Malignant neoplasm of prostate.
 R97.20 Elevated prostate specific antigen (PSA).
 R97.21 Rising PSA following treatment for malignant neoplasm of prostate.

Secondary Codes:

- N40.2 Nodular prostate without lower urinary tract symptoms.
 N40.3 Nodular prostate with lower urinary tract symptoms.
 R89.7 Abnormal histological findings in specimens from other organs/tissues.

GENOMIC TESTING

Clinical Information Requires for Genomic Testing:

Pre-Biopsy PSA (ng/mL): _____
 Prior Radiation or Hormone Therapy: No Yes (Patient ineligible for testing)
 Clinical Stage: T1c T2a T2b T2c T3a
 Prostate Volume: _____ Medical Notes: _____

TEST REQUESTED

- Prostate Histology
 Reflex Options: You may select up to two reflex options
(one pos/one neg):
 Confirm MDx on benign or HGPIN
 Decipher® Biopsy on Gleason 6&7
 Oncotype Dx® GPS on Grade Group 1-4*
*For Gleason 3+3, 3+4, 4+3, 4+4, 3+5, or 4+5

URINE CYTOLOGY & FISH

- Urine Cytology Cytology & FISH FISH Only Cytology with Reflex FISH (Atypical/Suspicious Cytology)
Source: Voided Catheterized Bladder Wash Cystoscopy
Previous Therapy: BCG TURB Radiation Chemotherapy Other: _____
Medical Necessity for FISH REQUIRED: History of Bladder Cancer Persistent Hematuria
Time Urine Specimen Collected: _____
Time Fixative Added to Urine Specimen REQUIRED: _____ (if not added at time of collection)
 Semen Analysis (Post-vasectomy)

ADDITIONAL TESTING/NOTES

CLINICAL HISTORY

- | | | | |
|--|---|--|---|
| <input type="checkbox"/> Bladder Cancer (C67.9) | <input type="checkbox"/> Microscopic Hematuria (R31.1) | <input type="checkbox"/> Personal History Prostate Cancer (Z85.46) | <input type="checkbox"/> Other/ Known Drug Allergy: _____ |
| <input type="checkbox"/> Gross Hematuria (R31.0) | <input type="checkbox"/> Family History Bladder Cancer (Z80.52) | <input type="checkbox"/> Renal Calculus (N20.0) | _____ |
| <input type="checkbox"/> Voluntary Sterilization (Z30.2) | <input type="checkbox"/> Uncertain Neoplasm of Bladder (D41.4) | <input type="checkbox"/> Elevated PSA (R97.2) | _____ |
| <input type="checkbox"/> Prostate Cancer (C61) | <input type="checkbox"/> Hematuria (R31.9) | <input type="checkbox"/> Personal History Bladder Cancer (Z85.51) | _____ |

BOTH PATIENT AND PHYSICIAN MUST SIGN to approve testing

By signing below, I confirm I have read the ABN on the reverse side.

Patient Signature: _____

I authorize the release of medical information related to services provided herein to my health plan/ insurance carrier and authorize payment directly to QDx Pathology Services and/or lab services provider. I assume responsibility for payment of charges not covered by my healthcare insurer.

Physician Signature: _____

CMS requires physician signature on all requisitions. QDx Pathology Services is responsible for verifying signature prior to performing testing.

300 Columbus Circle, Suite A, Edison, NJ 08837 | Tel: (866) 909-PATH | Fax: (908) 272-1478 | www.qdxpath.com

- | | | | | |
|---|-------------------------------------|--------------------------------------|--|--|
| Left Lateral Apex
Name: _____
T128353 | Left Apex
Name: _____
T128353 | Right Apex
Name: _____
T128353 | Right Lateral Apex
Name: _____
T128353 | Urine Cytology
Name: _____
T128353 |
| Left Lateral Mid
Name: _____
T128353 | Left Mid
Name: _____
T128353 | Right Mid
Name: _____
T128353 | Right Lateral Mid
Name: _____
T128353 | Urine C&S
Name: _____
T128353 |
| Left Lateral Base
Name: _____
T128353 | Left Base
Name: _____
T128353 | Right Base
Name: _____
T128353 | Right Lateral Base
Name: _____
T128353 | Biopsy Site
Name: _____
T128353 |
| Left Lateral Zone
Name: _____
T128353 | Other
Name: _____
T128353 | Other
Name: _____
T128353 | Right Lateral Zone
Name: _____
T128353 | Urinalysis
Name: _____
T128353 |

Explanation of Reflex Test Offerings

Below are the description of the test panels and shown on the front of the requisition. By requesting any of the below test panels on the requisition, you are acknowledging that all components of the panel are medically necessary for the diagnosis and treatment of the patient.

Prostate Histology Reflex Order Options (See test panel components below)	Urine Cytology Reflex Order Options (See test panel components below)
ConfirmMDx on benign or HGPIN: Prostate histology will reflex to ConfirmMDx on a benign or HGPIN diagnosis (Not performed on ASAP).	Cytology w/reflex FISH: Cytology will reflex to fluorescence in situ hybridization (FISH) on an atypical/suspicious diagnosis.
*Genomic Health® Oncotype DX® Genomic Prostate Score: Prostate histology will reflex to Oncotype DX® GPS with a Gleason 6 (3+3) or 7 (3+4 or 4+3 w/ only 1 positive core) diagnosis.	
Decipher Biopsy on Gleason 6&7: Prostate histology will reflex to Decipher Biopsy with a Gleason 6 or 7 diagnosis.	Cytology w/FISH: FISH will be performed with Cytology regardless of diagnosis.

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for items checked or listed in the box below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the items listed or checked in the box below.

Laboratory Tests	Reason Medicare May Not Pay	Estimated Costs

What you need to do now:

- Read this notice, so you can make an informed decision about your care
- Ask us any questions that you may have after you finish reading
- Choose an option below about whether to receive the checked items listed in the first box above

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

OPTION 1: I want the Laboratory Test(s) listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

OPTION 2: I want the Laboratory Test(s) listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

OPTION 3: I do not want the Laboratory Test(s) listed above, I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

Additional information:

This notice gives our opinion, not an official Medicare decision.

If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

Signature:	Date:
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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

MEDICAL NECESSITY ATTESTATION

***Genomic Health® Oncotype DX® Genomic Prostate Score**

Your signature constitutes a Statement of Medical Necessity (SOMN) and your attestation of the following: 1) accurate clinical information has been entered above, as this information will be used by Exact Sciences to automatically calculate the patient's risk group and inaccurate information could impact the test results; 2) if the diagnosis or exception criteria sections of the form do not indicate otherwise, the patient meets the assay criteria (see reverse); 3) the test is medically necessary and test results will be used with other clinical data to help determine the appropriate treatment plan for the patient; and 4) the patient has consented for this test to be performed, and for Exact Sciences to release test information when necessary to obtain reimbursement.