LabGenomics

UROPATHOLOGY REQUISITION

CLIA ID# 31D2026917

PATIENT INFORMATION *(REQUIRED)*

Date of Collection: _____ Time of Collection: _____

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

- ☐ Male
- ☐ Female
- ☐ Non-Binary/Genderqueer
- ☐ Transgender Male
- ☐ Transgender Female
- ☐ Choose not to disclose
- ☐ Straight or Heterosexual
- ☐ Lesbian, Gay or Homosexual
- ☐ Bisexual
- ☐ Other: _____

Race and Ethnicity — Select all that apply

- ☐ American Indian or Alaska Native
- ☐ Black or African American
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Asian
- ☐ White
- ☐ Choose not to disclose
- ☐ Hispanic or Latino
- ☐ Non-Hispanic or Latino
- ☐ Other: _____

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

REFERRING PHYSICIAN INFORMATION *(REQUIRED)*

INSURANCE INFORMATION *(REQUIRED)*

Policyholder Name: _____

Insurance Name: _____

For patients using Medicare, please complete and sign the ABN form on the reverse side of this test requisition.

Policy #: _____

Group #: _____

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

- ☐ Bill Insurance
- ☐ Bill Client
- ☐ Self Pay

SPECIMEN ID: T128353

LAB ACCESSION #: _____

HISTOPATHOLOGY

Prostate # of Jars: ☐ TRUS # of Jars: _____ ☐ MRI Fusion # 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
- ☐ Prolaris®
- ☐ 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): ☐ (R31.0) Gross Hematuria ☐ (Z85.51) History of Bladder Cancer ☐ (R97.20) Microscopic Hematuria

Medical ntecessity "Gross Hematuria (R31.0)" must be selected if ordering FISH, in addition to any other necessity.

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

- ☐ (C67.9) Bladder Cancer
- ☐ (R31.0) Gross Hematuria
- ☐ (Z30.2) Voluntary Sterilization
- ☐ (C61) Prostate Cancer
- ☐ (R31.1) Microscopic Hematuria
- ☐ (Z80.52) Family History Bladder Cancer
- ☐ (D41.4) Uncertain Neoplasm of Bladder
- ☐ (R31.9) Hematuria
- ☐ (Z85.46) Personal History Prostate Cancer
- ☐ (N20.0) Renal Caalculus
- ☐ (97.20) Elevated PSA
- ☐ (Z85.51) Personal History Bladder Cancer
- ☐ (Z80.42) Family History of Prostate Cancer Post HIFU
- ☐ Other/ Known Drug Allergy: _____

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 LabGenomics 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. LabGenomics 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.labgusa.com

T128353 Left Lateral Apex Name: _____
T128353 Left Lateral Mid Name: _____
T128353 Left Lateral Base Name: _____
T128353 Left Lateral Zone Name: _____

T128353 Left Apex Name: _____
T128353 Left Mid Name: _____
T128353 Left Base Name: _____
T128353 Other Name: _____

T128353 Right Apex Name: _____
T128353 Right Mid Name: _____
T128353 Right Base Name: _____
T128353 Other Name: _____

T128353 Right Lateral Apex Name: _____
T128353 Right Lateral Mid Name: _____
T128353 Right Lateral Base Name: _____
T128353 Right Lateral Zone Name: _____

T128353 Urine Cytology Name: _____
T128353 Urine C&S Name: _____
T128353 Biopsy Site Name: _____
T128353 Urinalysis Name: _____

LabGenomics

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 CytologyReflex 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.	**Cytology w/FISH:** FISH will be performed with Cytology regardless of diagnosis.
Decipher Biopsy on Gleason 6&7: Prostate histology will reflex to Decipher Biopsy with a Gleason 6 or 7 diagnosis.	

The below ABN form must only be submitted by patients using Medicare

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 tha ou 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:**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid 0MB control number. The valid 0MB 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.

Form CMS-R-131 (03/11)