

GENOMIC PROSTATE SCORE ASSAY

STUDY INFORMATION /CODE

The clinical information provided below will be utilized to calculate the patient's risk group as defined in NCCN guidelines. The resulting NCCN risk group will appear on the test report.

PATIENT INFORMATION

Patient Name (Last, First, MI) _____
 Male Female
DOB (mm/dd/yyyy) _____
Medical Record / Patient # (If applicable) _____
Address _____
City _____ State _____ Zip _____ Country _____
Primary Phone _____ Alternative Phone (Optional) _____

CLINICAL INFORMATION (complete all)

Pre-Biopsy PSA _____ ng/mL Stage T1c T2a T2b T2c T3a
Prostate Volume _____ Gleason Score (Primary + Secondary) 3+3 3+4 4+3 4+4 3+5 4+5
Date of Current Biopsy _____ Patient has a Life Expectancy of ≥ 10 years? Yes No
PSA Density (PSA/Prostate Volume) <0.15 ng/mL ≥0.15 ng/mL
Prostate Biopsy Cores
a) MRI Targeted Biopsy Yes No b) # of Cores Collected _____
c) # of Positive Cores _____
d) Max % tumor involvement in any core ≤ 50% > 50%

ORDERING INFORMATION

Practice Account Name _____ Fax _____
Ordering Physician Name _____ NPI _____ Email _____
Contact Name _____ Contact Phone _____ Contact Email _____
Additional Physician / Recipient Name _____
Email _____
Phone _____ Fax _____

BILLING INFORMATION

Submitting Diagnosis Prostate Cancer Other _____ Select ICD-10 Code C61 Other _____
Select Billing Type Medicare Private Insurance Medicaid Patient Pathology Account (Restricted to contracted accounts)
(Medicare only) Was procedure performed in hospital? If yes: hospital outpatient hospital inpatient - discharge date _____
Primary Insurance Company Name _____ Member ID# _____ Prior Authorization# _____
Secondary Insurance Company Name (If applicable) _____ Member ID# _____ Prior Authorization# _____

Include a copy of the front and back of the patient's insurance card(s).

PATIENT CONTACT

Mdxhealth will serve as an advocate to patients during the billing process which may require us to contact the patient directly.
 Check the box if the patient IS AWARE OF A DIAGNOSIS OF PROSTATE CANCER and mdxhealth is authorized to contact the patient.

SPECIMEN RETRIEVAL

Mdxhealth will obtain the specimen on your behalf. Check box if location is listed on attached pathology report, or indicate location of specimen in the fields provided below.
 Reference attached pathology report. _____
Location of Specimen _____ Phone _____ Fax _____ Contact Name _____

PHYSICIAN SIGNATURE & ATTESTATION

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 mdxhealth 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 mdxhealth to release test information when necessary to obtain reimbursement.

Ordering Physician Signature _____ Print Physician Name _____ Date (mm/dd/yyyy) _____

Exception Criteria/Comments

PATHOLOGY INFORMATION | PATHOLOGY TO COMPLETE

Pathology Account _____
Submitting Pathologist Name _____
Phone _____ Fax _____

SUBMIT SPECIMEN WITHIN 24 HOURS

Specimen ID _____ Specimen Barcode _____
Date of Collection (mm/dd/yyyy) _____
Date Block Pulled From Archive (Medicare only) _____

Pathology Comments:

No substitutions for this assay

REQUISITION FORM INSTRUCTIONS

For assistance in setting up a Portal Account for online ordering, please contact Customer Service. Assay results will be delivered to the Ordering Physician and additional recipients via the secure online portal and/or by fax based on the physicians' report delivery preferences.

The result report is based upon mdxhealth's analysis of the submitted specimen and information provided on the Requisition Form. Additional materials or information that may have been submitted with the specimen are not considered in analyzing the specimen or preparing the report.

CLINICAL INFORMATION

Enter the clinical information for your patient. This information will be utilized to calculate the patient's risk group as defined in NCCN guidelines. The resulting NCCN risk group will appear on the test report.

ORDERING INFORMATION

Additional physician/recipient information is optional. If another physician is responsible for the care of this patient and has requested a copy of the result, enter the applicable information in the spaces provided under this section.

BILLING INFORMATION

- A. Indicate the party responsible for payment.
- B. Billing Type:
 - » All Medicare patients will have an eligibility check and may be contacted during the process. If Patient is selected, a representative will contact the ordering physician's office to collect payment information.
 - » If inpatient's insurance is Medicare, enter the date of discharge from the hospital
 - » Before selecting Bill Pathology Account, verify with mdxhealth that you have a contracted account on file.
- C. Complete the Primary and Secondary Insurance Information fields.
- D. Include a copy of the front and back of both the primary and secondary insurance cards.

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY (SUMMARY OF LOCAL COVERAGE DETERMINATION)

- A. **The test is considered reasonable and necessary to help identify men with localized Prostate Cancer and a life expectancy of at least 10 years who are good candidates for active surveillance according to the most recent National Comprehensive Cancer Network (NCCN) guidelines.**

GPS is covered for men with prostate cancer:

- **With localized adenocarcinoma of the prostate (i.e., no clinical evidence of metastasis) who have a life expectancy of greater than or equal to 10 years if they are a candidate for and are considering (or being considered for) at least 1 of the following:**
- **Conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or;**
- **Radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or;**
- **Radiation therapy and yet would be eligible for the addition of short-term androgen deprivation therapy (ADT), or;**
- **Radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, or;**
- **Radiation with standard ADT yet would be eligible for systemic therapy intensifying next generation androgen signaling inhibitors or chemotherapy, or;**

The following criteria must also be met for coverage

- **The assay is performed on formalin-fixed paraffin embedded (FFPE) prostate biopsy tissue with at least 0.5 mm of linear tumor diameter;**
 - **Result will be used to determine treatment according to established practice guidelines, and;**
 - **Patient has not received pelvic radiation or ADT prior to the biopsy or prostate resection specimen, and;**
 - **Patient is monitored for disease progression according to established standards of care.**
- B. **In some cases, additional assessment methods may be used to verify that the specimen meets the criteria for the assay.**

PATIENT CONTACT

- A. **Select the box if the patient is aware of his prostate cancer diagnosis and the Ordering Physician is authorizing mdxhealth to contact the patient directly regarding his financial responsibility.**

NOTE: Third-party reimbursement is affected by many factors. Mdxhealth makes no representation or guarantee that full or partial insurance reimbursement or any other payment will be available. While mdxhealth tries to provide correct information, we make no representations or warranties, expressed or implied, as to the accuracy of the information. These support services have no independent value to providers and are included within the cost of the Genomic Prostate Score testing services.

SPECIMEN RETRIEVAL

If indicated, mdxhealth will request the retrieval of the appropriate specimen for the ordered assay on your behalf.

NOTE: If the specimen retrieval section is not completed and the specimen is not submitted with the Order Form and Statement of Medical Necessity, mdxhealth assumes you will initiate the retrieval of the specimen.

PHYSICIAN SIGNATURE & ATTESTATION

Sign and date the Order Form and Statement of Medical Necessity and print your name. The signature must be of an Ordering Physician (treating physician or pathologist) or his/her representative. If this order form is completed by the Physician's representative, the patient's medical record must contain the signed order from the Ordering Physician.

PATHOLOGY INFORMATION

- A. **Enter the identification number for the most representative specimen (i.e. the longest linear length of the highest grade tumor) on the appropriate line.**
- B. **While the mdxhealth laboratory can accept tumor blocks and unstained slides, blocks are preferred.**
- C. **Include a copy of the pathology report with the Specimen Kit submission box. The pathology report may be used for reimbursement and/or administrative purposes.**

SUBMIT REQUISITION FORM TO MDXHEALTH

- A. Fax the completed, signed Requisition Form to the fax number indicated on the reverse side.
- B. If submitting a specimen, include the Requisition Form with the specimen collection kit. See specimen preparation and shipment instructions.

SPECIMEN INSTRUCTIONS

Specimen Preparation Instructions

- A. For specimen criteria and specimen preparation instructions, visit mdxhealth.com.
 - B. Please send either:
 - » One fixed paraffin embedded tumor block.
 - » Eight 5 µm serial unstained slides.
- IMPORTANT:** Hand number the serially sectioned slides to indicate the order in which they were cut. Unnumbered slides will be returned.
- C. Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.
 - D. Label all specimens with barcode labels from the Specimen Collection and Transportation Kit. Affix a coinciding barcode in the designated area on the Order Form. (Discard any remaining barcodes; do not use for future submissions.)
 - E. Label the specimens with an additional patient-specific identifier (e.g. patient name, date of birth, hospital number, order number, accession number). All specimens require two patient-specific identifiers for processing.
 - F. If you have any questions, please contact customer service at the phone number listed on the front side of this form.

DOMESTIC SHIPPING INSTRUCTIONS

- A. Before shipping, make a copy of the Order Form and Statement of Medical Necessity and retain it for your records.
- B. Place the Specimen Kit into the FedEx® Clinical Pak.
- C. Complete the FedEx® US Airbill. The airbill is pre-printed with shipping information.
- D. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
- E. Place the package in the designated FedEx® pickup location at your site.
- F. If your site does not have standard FedEx® pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.

NOTE: To order additional kits, email Customer Service at client.services@mdxhealth.com Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed April 1, 2022. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. ©2022 Mdxhealth, Inc. All rights reserved. Genomic Prostate Score and GPS are trademarks of Mdxhealth, Inc. Oncotype DX is a trademark of Genomic Health Inc., a wholly owned subsidiary of Exact Sciences Corporation. Exact Sciences is a registered trademark of Exact Sciences Corporation.