



In-Service Guide

Confirm mdx • Genomic Prostate Score • Select mdx • Resolve mdx

Client Services: 866.259.5644

Fax: 949.788.0014

Email: cs@mdxhealth.com

Order Kits: www.mdxhealth.com/testkits

Physician Portal: www.mdxhealthsecure.com

Test Menu

Prostate Cancer

Confirm mdx for Prostate Cancer (negative biopsy)

This DNA methylation test is utilized for patients who have received a cancer-negative biopsy. It assists in assessing the risk for undetected clinically significant cancer post-prostate biopsy.

- 96% NPV
- Included in the NCCN Guidelines
- No additional office visit required (performed on previous cancer-negative biopsy tissue)

Genomic Prostate Score (GPS) (positive biopsy)

Designed for patients diagnosed with localized prostate cancer, this 17-gene genomic test predicts the aggressiveness of the cancer and the likelihood of disease progression.

- Gene selection based on biopsy tissue
- Initially developed to predict adverse pathology
- Requires only 5ng/RNA

Select mdx for Prostate Cancer (pre-biopsy)

Targeting patients being considered for a prostate biopsy and/or MRI, this molecular diagnostic test aids in identifying individuals at risk for clinically significant prostate cancer prior to initial biopsy and/or MRI.

- 95% NPV
- Outperforms PCA3 gene
- Included in the NCCN Guidelines

Infectious Disease

Resolve mdx (for UTI and STI)

This advanced test identifies what is causing the infection and lists effective antibiotics to address it.

- 48-hour turnaround time (for PCR and ASTx susceptibility testing)
- Detects up to 27 pathogens, as well as 19 resistance genes
- Detects pathogens to an LOD of 10^3 (New STI panel now available)

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Negative Biopsy

Patient eligibility

Patients with cancer-negative biopsy results (benign, HGPIN, ASAP/atypia) within 30 months.

Technology: DNA RT-PCR methylation assay

Genes: GSTP1, APC, RASSF1a

Specimen type: Prostate biopsy tissue cores

Turnaround time: 10 business days

Insurance: Traditional Medicare \$0 patient responsibility. Vast majority of patients pay less than \$250.

Test requisition form checklist:

- Ordering physician name
- Copy of patient demographics and insurance information
- Copy of pathology report
- PSA and DRE results
- ICD-10 code(s)
- Authorized signature

EHR integrations available

email: info@mdxhealth.com or contact your mdxhealth sales representative



TRF Required Fields

Confirm mdx for Prostate Cancer

Confirm mdx Test Requisition Form

Ordering Physician	Patient Information	
	Name: _____ First _____ Last _____ Address: _____ City: _____ State: _____ Zip: _____ Date of Birth: _____ Month _____ Day _____ Year _____ Phone: _____ MRN/Patient ID: _____	
Account Information		
1. Test Ordered <input checked="" type="checkbox"/> Confirm mdx for Prostate Cancer		
2. Clinical Information: (Please provide a copy of pathology report, history & physical, and office/progress notes with test order)		
Specimen ID(s): _____	Collection Date: _____ Month _____ Day _____ Year _____	Date retrieved from archive: _____ Month _____ Day _____ Year _____
Last DRE Result: <input type="checkbox"/> Very Suspicious for Prostate Cancer <input type="checkbox"/> Not Very Suspicious for Prostate Cancer		
(Medicare only) If mpMRI performed, PI-RADS Score: _____ / Date: _____ Month _____ Day _____ Year _____		
Last 2 PSA Results: PSA: _____ ng/mL Date: _____ Month _____ Day _____ Year _____	PSA: _____ ng/mL Date: _____ Month _____ Day _____ Year _____	
Other Risk Factor(s): PSA level increase of greater than 0.35 ng/mL/year if PSA level less than or equal to 10 ng/mL PSA doubling time of less than 3 years, when initial PSA level greater than or equal to 4 ng/ml and other causes of rising PSA (i.e., infection, inflammation) have been ruled out for individuals whose PSA doubling occurred in less than 2 years African descent (including African American and Caribbean of African ancestry)		
3. Confirm mdx Specimen Request:		
I want mdxhealth to request the specimen. Mdxhealth will obtain the patient's prostate biopsy from the Pathology Laboratory. Fax signed requisition, pathology report, and patient's insurance to (949) 788-0014.		
4. Required Billing Information: (ICD-10 and copy of insurance card required)		
CD-10 Codes: <input type="checkbox"/> R97.20 Elevated Prostate Specific Antigen [PSA] <input type="checkbox"/> N40.2 Nodular prostate without lower urinary tract symptoms <input type="checkbox"/> D29.1 Benign neoplasm of prostate <input type="checkbox"/> N40.3 Nodular prostate with lower urinary tract symptoms <input type="checkbox"/> D40.0 Neoplasm of uncertain behavior of prostate <input type="checkbox"/> Other: _____		
Payment Type: <input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient Self-Pay <input type="checkbox"/> Client (contract required)		
Name of insurance: _____ Member ID: _____		
(Medicare only) Was procedure performed in hospital? If yes: <input type="checkbox"/> hospital outpatient <input type="checkbox"/> hospital inpatient - discharge date: _____ Month _____ Day _____ Year _____		
Include copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.		
5. Authorization and Statement of Medical Necessity:		
I hereby authorize testing and confirm that an informed consent has been obtained, if required by state law. I confirm that this is medically necessary and the results will be used in the medical management decisions for the patient. I hereby attest that the person listed in the Ordering Physician space above is authorized by law in the relevant jurisdiction to order the test requested herein. I confirm that I have on file the patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers, such as mdxhealth, Inc. I further instruct mdxhealth to retain this completed test requisition as part of the patient medical record. I authorize mdxhealth to release the information on this form, and other information provided by me, or on my behalf, necessary to process a claim for this service.		
For Medicare and Medicare Advantage Beneficiaries: Prior to ordering, I certify that the patient meets the Medicare eligibility criteria provided on the back side of this form.		
Ordering Physician Signature (No stamped signatures) _____ Date: _____ / _____ / _____		
Submitting this form constitutes a Certification of Medical Necessity and a certification that you have obtained consent for Mdxhealth Inc. to release the test results and relevant medical information to the patient's insurance carrier as part of the coverage and reimbursement process.		
PLEASE KEEP A COPY AND RETAIN IN PATIENT'S MEDICAL RECORD		
Mdxhealth Internal Use Only: Total Pages: _____ Blocks: _____ Slides: _____		
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mdxhealth		

Negative

SAMPLE

Patient Report

PATIENT

Patient Name:	Stephan Sample
Date of Birth:	03/15/1945
MRN/Patient#:	MRN 123
PATH:	Negative
PSA:	5.2 ng/mL
DRE:	Normal

SPECIMEN

Specimen#:	1776
Collection Date:	12/07/2016
Received Date:	01/11/2017
Report Date:	01/19/2017
Specimen Type:	Prostate FFPE tissue slides
MDxH Accession#:	PR-123456

ACCOUNT

Physician:	Mike Test, MD
Account:	Urology Partners of California
Address:	15279 Alton Parkway Suite 100
City/State/Zip:	Irvine, CA 92618

Patient Result: DNA Methylation Negative

The negative result for this patient indicates a low likelihood of detecting prostate cancer upon repeat biopsy.

Result Description:

Clinical validation study results indicate a negative predictive value (NPV) of 96% for high-grade disease (Gleason score ≥ 7), and a 90% NPV for all grades of prostate cancer. Cancer association with DNA methylation of ConfirmMDx gene markers has been reported on ~4,500 patients.¹⁻⁵⁵

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Base:	Negative	Negative	Negative
Left Lateral Mid:	Negative	Negative	Negative
Left Lateral Apex:	Negative	Negative	Negative
Left Base:	Negative	Negative	Negative
Left Mid:	Negative	Negative	Negative
Left Apex:	Negative	Negative	Negative
Left Transition Zone:	Negative	Negative	Negative
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Negative	Negative	Negative
Right Lateral Mid:	Negative	Negative	Negative
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram

Sample Reports

Positive

ConfirmMDx[®]

for Prostate Cancer

SAMPLE

Patient Report



PATIENT

Patient Name:	John Sample
Date of Birth:	01/01/1942
MRN/Patient#:	MRN 123
PATH:	Negative
PSA:	9.4 ng/mL
DRE:	Normal

SPECIMEN

Specimen#:	5641305
Collection Date:	12/20/2016
Received Date:	01/11/2017
Report Date:	01/18/2017
Specimen Type:	Prostate FFPE tissue slides
MDxH Accession#:	PR-123456

ACCOUNT

Physician:	Mike Test, MD
Account:	Urology Partners of California
Address:	15279 Alton Parkway Suite 100
City/State/Zip:	Irvine, CA 92618

Patient Result: DNA Methylation Positive

The DNA methylation positive test result for this patient indicates a 32% likelihood of detecting prostate cancer, with a 20% probability for low-grade disease (GS \leq 6) versus a 12% probability of high-grade disease (GS \geq 7), on repeat biopsy.

Likelihood of prostate cancer upon repeat biopsy



0% 32% 20% 12% 100%

Likelihood of detecting Gleason score \leq 6 cancer

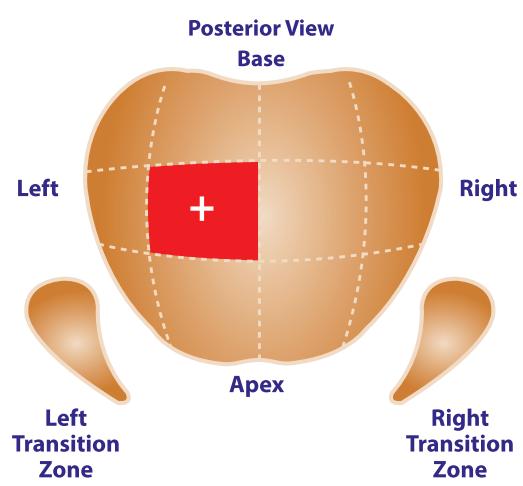
Likelihood of detecting Gleason score \geq 7 cancer

The ConfirmMDx test result indicating the likelihood of GS \leq 6 and GS \geq 7 prostate cancer being detected on repeat biopsy is calculated by incorporating DNA methylation intensity with clinical risk factors, including PSA, DRE, age, and histopathology of the previous biopsy, based on a clinical model that yields an area under the curve (AUC) of 0.762 (95% CI: 0.679-0.844). Performance is based on the presence of all relevant data elements; if all data are not available, or 5 α -reductase inhibitors (5ARI) have been administered to decrease serum PSA values, results should be interpreted with caution since the AUC of the test may vary. Cancer association with DNA methylation of the ConfirmMDx gene markers has been reported on ~4,500 patients.¹⁻⁵⁵

DNA Methylation Status Table

Biopsy Site	GSTP1 Methylation	APC Methylation	RASSF1 Methylation
Left Lateral Base:	Negative	Negative	Negative
Left Lateral Mid:	Negative	Negative	Negative
Left Lateral Apex:	Negative	Negative	Negative
Left Base:	Negative	Negative	Negative
Left Mid:	Positive	Positive	Positive
Left Apex:	Negative	Negative	Negative
Left Transition Zone:	Negative	Negative	Negative
Right Base:	Negative	Negative	Negative
Right Mid:	Negative	Negative	Negative
Right Apex:	Negative	Negative	Negative
Right Lateral Base:	Negative	Negative	Negative
Right Lateral Mid:	Negative	Negative	Negative
Right Lateral Apex:	Negative	Negative	Negative
Right Transition Zone:	Negative	Negative	Negative

Distribution of DNA Methylation Diagram



Posterior View

Base

Left Right

Left Apex Right

Left Transition Zone Right Transition Zone

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Genomic Prostate Score®

for Localized Prostate Cancer

Positive Biopsy

Patient eligibility

Patients diagnosed with NCCN very low- to high-risk prostate cancer within 36 months.

Technology: RT-PCR genomic assay

Genes: AZGP1, FAM13C, KLK2, SRD5A2, FLNC, GSN, GSTM2, TPM2, BGN, COL1A1, SFRP4, TPX2, ARF1, ATP5E, CLTC, GPS1, PGK1

Specimen type: Prostate biopsy tumor tissue

Turnaround time: 10 business days

Insurance: Traditional Medicare \$0 patient responsibility.
Vast majority of patients pay less than \$250.

Test requisition form checklist:

- Ordering physician name
- Print copy of patient demographics and insurance information
- PSA, prostate volume, biopsy date, # of cores, stage, gleason score, patient life expectancy
- ICD-10 code(s)
- Authorized signature

EHR integrations available

email: info@mdxhealth.com or
contact your mdxhealth sales
representative



TRF Required Fields

Order Form and Statement of Medical Necessity Complete and Fax to 949.788.0014

Genomic Prostate Score® (formerly Oncotype DX GPS)

GENOMIC PROSTATE SCORE ASSAY 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.		STUDY INFORMATION /CODE	
PATIENT INFORMATION		CLINICAL INFORMATION (complete all)	
Patient Name (Last, First, MI) <input type="radio"/> Male <input type="radio"/> Female DOB (mm/dd/yyyy)		ng/mL Pre-Biopsy PSA Prostate Volume Date of Current Biopsy PSA Density (PSA/Prostate Volume) <input type="radio"/> <0.15 ng/mL <input type="radio"/> ≥0.15 ng/mL	
Medical Record / Patient # (If applicable) Address City State Zip Country		Stage <input type="radio"/> T1c <input type="radio"/> T2a <input type="radio"/> T2b <input type="radio"/> T2c <input type="radio"/> T3a Gleason Score (Primary + Secondary) <input type="radio"/> 3+3 <input type="radio"/> 3+4 <input type="radio"/> 4+3 <input type="radio"/> 4+4 <input type="radio"/> 3+5 <input type="radio"/> 4+5	
Primary Phone Alternative Phone (Optional)		Patient has a Life Expectancy of ≥ 10 years? <input type="radio"/> Yes <input type="radio"/> No	
ORDERING INFORMATION			
Practice Account Name <input type="radio"/>	Fax		
Ordering Physician Name <input type="radio"/>	NPI	Email	Additional Physician / Recipient Name <input type="radio"/>
Contact Name	Contact Phone	Contact Email	Email <input type="radio"/> Phone Fax
BILLING INFORMATION			
Submitting Diagnosis <input type="radio"/> Prostate Cancer <input type="radio"/> Other		Select ICD-10 Code <input type="radio"/> C61 <input type="radio"/> Other	
Select Billing Type <input type="radio"/> Medicare <input type="radio"/> Private Insurance <input type="radio"/> Medicaid <input type="radio"/> Patient <input type="radio"/> Pathology Account (Restricted to contracted accounts)			
(Medicare only) Was procedure performed in hospital? If yes: <input type="radio"/> hospital outpatient <input type="radio"/> 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. <input type="checkbox"/> 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.			
<input type="checkbox"/> Reference attached pathology report	Location of Specimen	Phone	Fax
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)	
PATHOLOGY INFORMATION PATHOLOGY TO COMPLETE		SUBMIT SPECIMEN WITHIN 24 HOURS	
Pathology Account		Specimen ID	
Submitting Pathologist Name		Specimen Barcode Affix Specimen barcode here	
Phone	Fax	Date of Collection (mm/dd/yyyy)	
Pathology Comments:		No substitutions for this assay	
Include a pathology report with specimen submission.			

Genomic Prostate Score®

for Localized Prostate Cancer

Low Risk - Front Page

Genomic Prostate Score® (GPS™) Report

Genomic Prostate Score

(Formerly Oncotype DX GPS)

For NCCN Very Low, Low, and Favorable Intermediate Risk Groups

FIRSTNAME, LASTNAME MI.

mdx #: A123456

Date of Birth: 01-Jan-1950 Gender: Male

Report Number: 0000000000-0000 Report Date: 01-DEC-2021

Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Submitted NCCN Risk Group^{(a),1}: Low

Physician-Provided Information^(b):

Gleason Score: **3+3**

Prostate Volume (cc): **20**

PSA (ng/mL): **5.0**

PSA Density (ng/mL/cc): **0.30**

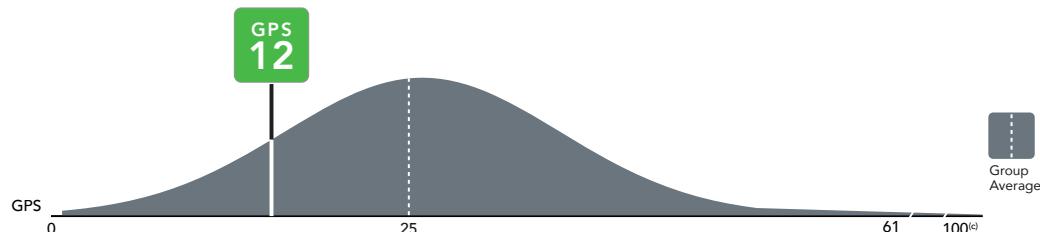
Clinical Stage: **T2a**

Number of Cores Positive: **1**

Max. % of tumor involvement in any core: **≤ 50%**

Number of Cores Collected: **12**

Patient's GPS Result is 12



This graph above shows the range of GPS results with estimates of likelihood of adverse pathology for NCCN Low risk. ^{2,3}

Likelihood of Adverse Pathology at Radical Prostatectomy ^(d)

16%

LOW LIKELIHOOD ≤25%

MODERATE LIKELIHOOD 26-59%

HIGH LIKELIHOOD ≥60%

Clinical Interpretation^(e)

- This patient's likelihood of adverse pathology (higher Gleason Score and/or extra prostatic disease^(f)) at radical prostatectomy is **16%** (95% CI: 12%-21%) based on the combined GPS result and NCCN risk group.
- Data from the clinical validation studies suggest this patient has a **low likelihood** of adverse pathology, compared to other patients in the clinical validation studies. ^{2,3}
- In our clinical validation studies, 29% of patients with NCCN Low risk prostate cancer had adverse pathology at radical prostatectomy. ^{2,3}

(a) Calculated or reported from physician-provided clinical information. (b) N/A (not available) indicates data has not been provided to Genomic Health. (c) Distribution curve for illustrative purposes only. (d) Based on GPS result & submitted NCCN risk group. (e) All Patients in the clinical validation studies have been treated with radical prostatectomy. (f) Gleason Score ≥ 4+3 and/or pT3+.

IR-BROC-014

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Sample Reports

Low Risk - Back Page

Genomic Prostate Score® (GPS™) Report

Genomic Prostate Score

(Formerly Oncotype DX GPS)

For NCCN Very Low, Low, and Favorable Intermediate Risk Groups

FIRSTNAME, LASTNAME MI.

mdx #: A123456

Date of Birth: 01-Jan-1950 Gender: Male

Report Number: 0000000000-0000 Report Date: 01-DEC-2021

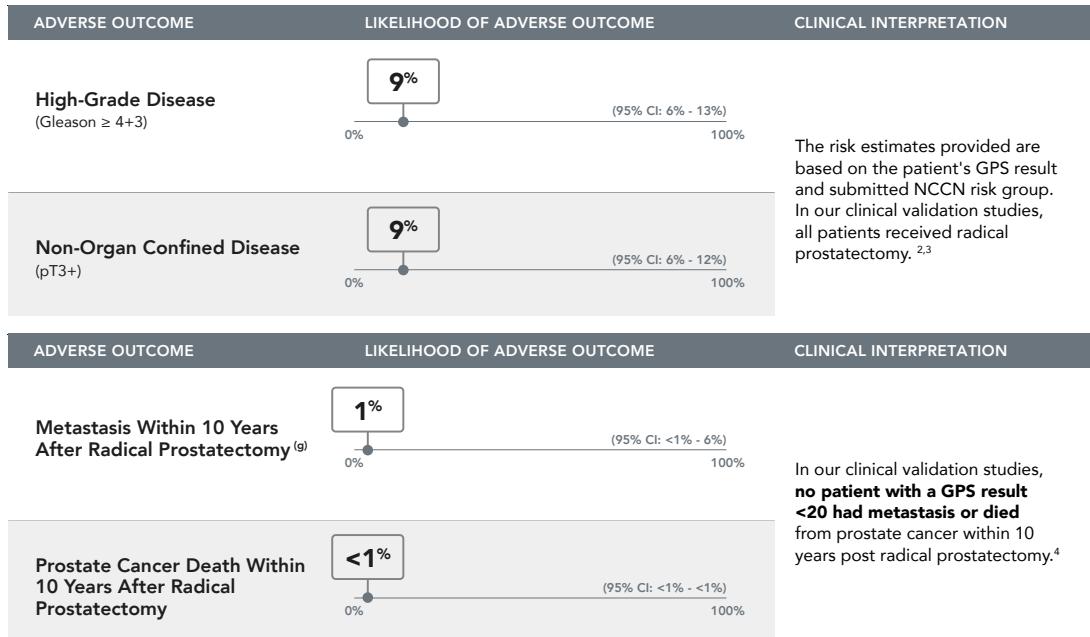
Ordering Physician: Dr. First-Name I. Ordering-Physician-Last-Name

Medical Record/Patient #: 1234567-01

Specimen Source/ID: Prostate/SP-16_0123456

Date of Collection: 10-Apr-2023

Specimen Received: 12-Apr-2023



The Oncotype DX Genomics Prostate Score (GPS) test is a continuous scale (0-100) that quantifies expression of 17 genes in tumor tissue as assessed by RT-PCR. The GPS Test has been validated in three prospectively designed studies (N=1056) of biopsy tissue from patients with localized prostate cancer.^{2,3,4}

(g) In the clinical validation study, metastasis was determined by imaging or biopsy.

References: 1. 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 guidelines, go online to NCCN.org. 2 Klein E, et al. Eur Urol. 2014. 3 Cullen J et al, Eur Urol. 2015. 4 Van Den Eeden S, et al. Eur Urol. 2017.

Laboratory Director(s): William P. Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. It has not been cleared or approved by the FDA, nor is it currently required to be. The laboratory is regulated under CLIA and qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

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IR-BROC-0164

mdxhealth
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Test performed at:
Genomic Health, Inc.
301 Penobscot Drive
Redwood City, CA 94063 USA
CLIA Number 05D1018272

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Genomic Prostate Score®

for Localized Prostate Cancer

High Risk - Front Page

GPS Report

For NCCN Unfavorable Intermediate & High Risk Groups

Genomic Prostate Score®

(Formerly Oncotype DX GPS)

LASTNAME, FIRSTNAME MI.

Date of Birth: 01-Jan-1960

mdx #: A123456

Physician:

Report Date: 30-APR-2023

Account:

Submitted NCCN Risk Group^{(a),1}: Unfavorable Intermediate

Physician-Provided Information^(b):

Gleason Score: **3+4**

Prostate Volume (cc): **95.00**

PSA (ng/mL): **6.3**

PSA Density (ng/mL/cc): **0.07**

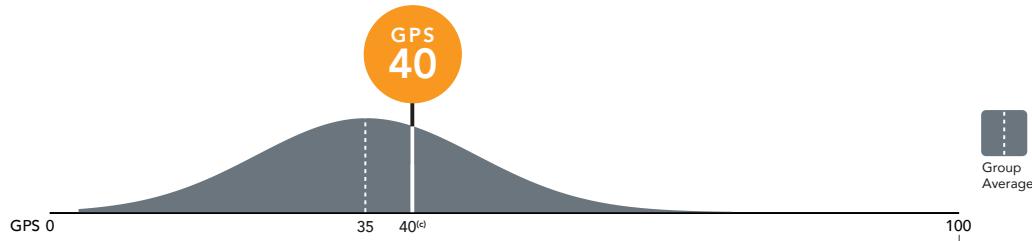
Clinical Stage: **T2a**

Number of Cores Positive: **8**

Max. % of tumor involvement in any core: **> 50%**

Number of Cores Collected: **12**

Normalized GPS Distribution Curve in NCCN Unfavorable Intermediate Risk Patients²⁻⁴



Likelihood of Disease Progression



POST THERAPY OUTCOMES*

LIKELIHOOD OF DISEASE PROGRESSION

Metastasis Within 10 Years^(d)



Prostate Cancer Death Within 10 Years



Clinical Interpretation

- Based on this patient's GPS result of 50 and their submitted NCCN risk group, their likelihood of distant metastasis within 10 years is 13% and their likelihood of death due to prostate cancer within 10 years is 2%, if treated with radical prostatectomy or radiation therapy.
- In clinical validation studies, the 10-year likelihood of distant metastasis for the mean GPS result in NCCN Unfavorable Intermediate Risk patient is 10% (95% CI: 6%-15%).^{3,4}
- In clinical validation studies, patients with a GPS result 40 and below had lower likelihood of disease progression (distant metastasis and death due to prostate cancer) than those with a GPS result above 40, after being treated with either radical prostatectomy or radiation therapy.^{4,5}

Footnotes and references are at the bottom of page 2

IR-BROC-0181-R03

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Sample Reports

High Risk - Back Page

GPS Report

For NCCN Unfavorable Intermediate & High Risk Groups

Genomic Prostate Score[®]

(Formerly Oncotype DX GPS)

LASTNAME, FIRSTNAME MI.

Date of Birth: 01-Jan-1960 mdx #: A123456

Physician:

Report Date: 30-APR-2023

Account:

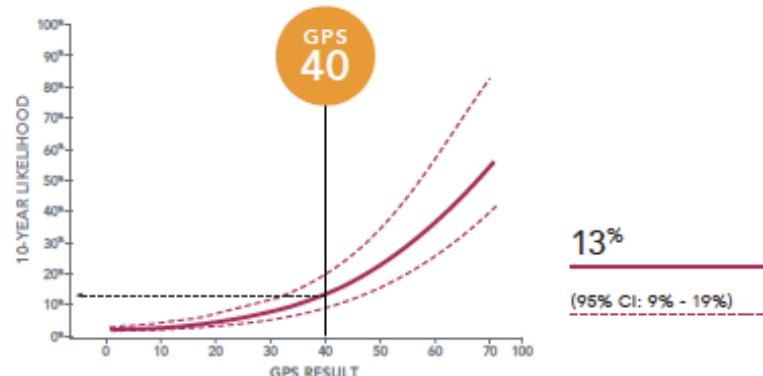
Medical Record/Patient #: 1234567-01

Specimen Type/ID: Slides/SP-16_0123456

Date of Collection: 10-Apr-2023

Specimen Received: 12-Apr-2023

10-Year Likelihood of Distant Metastasis in NCCN Unfavorable Intermediate Risk Group



IMPORTANT INFORMATION

- The results in this report reflect a meta-analysis of five clinical validation studies with 597 patients, treated by either radical prostatectomy or radiotherapy and incorporating NCCN risk group and the GPS result to estimate 10-year likelihood of disease progression.⁴ Patients were treated within 12 months of the biopsy used to generate the GPS result.
- Based on clinical data and clinical guidelines, patients with localized prostate cancer in the unfavorable intermediate and higher risk groups have a high likelihood of disease progression and are candidates for intensification of therapy (see NCCN Guidelines Version 1.2023, PROS-6 and PROS-7)¹.
- The GPS test is a continuous scale (0-100) that quantifies expression of 17 genes in tumor tissue as assessed by RT-PCR.⁴
- The GPS test has been validated in six prospectively designed studies (N=1,885) of biopsy tissue from patients with localized prostate cancer.^{2,4}

Footnotes: (a) Calculated or reported from physician-provided clinical information. (b) N/A (not available) indicates data has not been provided to mdxhealth.⁴ (d) The dichotomous GPS cut-point of 40 was validated in four studies and demonstrated significantly higher likelihood of post-treatment recurrence, metastasis, and prostate cancer death for patients falling above the cut-point.^{4,5} (d) In the clinical validation studies, metastasis was determined by Imaging or biopsy and disease progression is defined by prostate cancer death and metastasis. ⁴ In the clinical validation studies, all patients received radical prostatectomy or radiation therapy as their primary intervention. Risk estimates provided are based on the GPS result and submitted NCCN risk group.

References: 1. From the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V1.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org. 2. Cullen J, et al. Eur Urol. 2015. 3. Van Den Eeden S, et al., Eur Urol. 2017. 4. Data on file. 5. Cullen J, et al., Urology. 2020. 6. Klein E, et al., Eur Urol. 2014.

Disclaimer: Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Genomic Prostate Score for localized prostate cancer was developed, and its performance characteristics determined by mdxhealth. It has not been reviewed by the U.S. Food and Drug Administration (FDA). The FDA has determined such clearance or approval is not necessary. The test is intended for use as an aid to clinicians for patient management decisions about treatment decisions for men with localized prostate cancer. Use outside this indication has not been validated by mdxhealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for treatment.

CLIA# 05D2033858; CAP# 8015399

General information about Genomic Prostate Score can be found at www.mdxhealth.com. If you have any questions regarding this report, please contact mdxhealth Client Services at 866.259.5644 or cs@mdxhealth.com.



Ruben Gamez, MD, Laboratory Director



mdxhealth

IR-BROC-0181-R03

P: 866.259.5644 | F: 949.788.0014
E: cs@mdxhealth.com | www.mdxhealth.com

Test performed at:
Mdxhealth, Inc. 15279 Alton Parkway, Suite 100
Irvine, CA 92618 USA

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Pre-Biopsy

Patient eligibility

For patients being considered for a prostate biopsy (elevated PSA or suspicious DRE).

Technology: RT-PCR genomic assay

Genes: HOXC6 and DLX1

Specimen type: First void urine

Turnaround time: 5 business days

Insurance: Traditional Medicare \$0 patient responsibility. Vast majority of patients pay less than \$100.

Test requisition form checklist:

- Ordering physician name
- Print copy of patient demographics and insurance information
- Specimen collection date
- PSA and DRE result
- ICD-10 code(s)
- Authorized signature

Shipment instructions

- Insert test requisition form, patient demographics, and a copy of the patient's insurance information into the Select mdx transport kit.
- Scheduled same-day pick up
 - FedEx 800.463.3339

EHR integrations available

email: info@mdxhealth.com or contact your mdxhealth sales representative



View and download our collection instruction:



TRF Required Fields

Select mdx
for Prostate Cancer

Test Requisition Form

Ordering Physician	Patient Information
Account Information	Name: <input type="text"/> First <input type="text"/> Last Address: <input type="text"/> City: <input type="text"/> State: <input type="text"/> Zip: <input type="text"/> Date of Birth: <input type="text"/> Month <input type="text"/> Day <input type="text"/> Year Phone: <input type="text"/> MRN/Patient ID: <input type="text"/>
1. Test Ordered <input checked="" type="checkbox"/> Select mdx for Prostate Cancer	
2. Clinical Information: Collection Date: <input type="text"/> Specimen ID: <input type="text"/> Last DRE Result: <input type="checkbox"/> Very Suspicious for Prostate Cancer <input type="checkbox"/> Not Very Suspicious for Prostate Cancer Last PSA Results: PSA: <input type="text"/> ng/mL Date: <input type="text"/> Month <input type="text"/> Day <input type="text"/> Year Prostate volume: <input type="text"/> (only if obtained by MRI or ultrasound)	
3. Required Billing Information: (ICD-10 and copy of insurance card required) ICD-10 Codes: <input type="text"/> <input type="checkbox"/> R97.20 Elevated Prostate Specific Antigen [PSA] <input type="checkbox"/> N40.2 Nodular prostate without lower urinary tract symptoms <input type="checkbox"/> D29.1 Benign neoplasm of prostate <input type="checkbox"/> N40.3 Nodular prostate with lower urinary tract symptoms <input type="checkbox"/> D40.0 Neoplasm of uncertain behavior of prostate <input type="checkbox"/> Other: <input type="text"/> Payment Type: <input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient Self-Pay <input type="checkbox"/> Client (contract required) Name of insurance: <input type="text"/> Member ID: <input type="text"/> (Medicare only) Was procedure performed in hospital? If yes: <input type="checkbox"/> hospital outpatient <input type="checkbox"/> hospital inpatient - discharge date: <input type="text"/> Month <input type="text"/> Day <input type="text"/> Year Include copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.	
4. Authorization and Statement of Medical Necessity: I hereby authorize testing and attest that the person listed in the Physician Signature space below is authorized by law in the relevant jurisdiction to order the test requested herein. I confirm that I have on file the patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers, such as mdxhealth. I further instruct mdxhealth to retain this completed test requisition as part of the patient medical record. I authorize mdxhealth to release the information on this form, and other information provided by me or on my behalf, necessary to process a claim for this service. For Medicare and Medicare Advantage Beneficiaries: Prior to ordering, I certify that the patient meets the Medicare eligibility criteria provided on the back side of this form.	
Ordering Physician Signature (No stamped signatures) <input type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/>
Submitting this form constitutes a Certification of Medical Necessity and a certification that I have obtained consent for Mdxhealth Inc. to release the test results and relevant medical information to the patient's insurance carrier as part of the coverage and reimbursement process.	
Place Patient Label Here	Place Provided Barcode Here
Mdxhealth Internal Use Only: Total Pages: <input type="text"/> Tubes: <input type="text"/>	

Mdxhealth Inc. P: 866.259.5644 • F: 949.788.0014 • E: cs@mdxhealth.com • www.mdxhealth.com
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IR-FORM-0145-R07

mdxhealth

Select mdx

for Prostate Cancer

Low Risk

Select mdx
for Prostate Cancer

SAMPLE Patient Report

Patient

Patient Name: David Sample
Date of Birth: 12/27/1959
MRN/Patient #: 8979821
Prostate Volume: 30cc
PSA: 6.7 ng/mL
DRE: Normal

Specimen

Specimen #: 72389
Collection Date: 01/28/2023
Received Date: 02/01/2023
Report Date: 02/04/2023
Specimen Type: Post DRE Urine
Mdx Accession #: SL-91322

Account

Physician: Dr. Smith
Account: Urology Associates
Address: 15279 Alton Parkway,
Suite 100
City/State/Zip: Irvine, CA 92618

PATIENT RESULT: LOW RISK

Low Risk: This patient's test result indicates a low risk for the detection of Gleason Score (GS)≥7 prostate cancer on biopsy. In the Select mdx pivotal study, for Low Risk patients, Select mdx yield:

- Negative Predictive Value of 95% for detection of GS≥7 prostate cancer, and
- Negative Predictive Value of > 99% for detection of GS≥8 prostate cancer.¹

Test should be interpreted in conjunction with other available laboratory and clinical data and relevant guidelines to augment the patient physician shared decision making process, including the decision for biopsy. Select mdx does not replace other clinical and genetic risk factors, which should be considered as independent risk factors for prostate cancer.

In the Select mdx pivotal study¹, a clinical model combining urinary biomarkers and clinical factors was applied to generate a risk score that increases with the probability of detecting GS≥7 cancer on biopsy. This raw score has been converted to a personalized positive predictive value that ranges from 0 - 100%. For patients with Low Risk test results, the personalized positive predictive value should be interpreted in conjunction with other available laboratory and clinical data (published performance characteristics reported in the pivotal study exclude all patients with Low Risk Select mdx test results from the calculation of positive predictive value):

- Personalized positive predictive value of 8% for detection of GS≥7 prostate cancer, and
- Personalized positive predictive value of 22% for detection of GS 6 prostate cancer.¹

Questions about these results? Contact Client Services at 866.259.5644 or go to www.mdxhealth.com/selectreport

Test Description:

Select mdx for Prostate Cancer is a reverse-transcription PCR (RT-PCR) assay performed on urine specimens collected immediately following DRE from patients who are being considered for prostate biopsy. The test measures the urinary mRNA levels of DLX1 and HOXC6 biomarkers to aid in patient selection for prostate biopsy. Higher levels of DLX1 and HOXC6 mRNA are associated with an increased probability for GS≥7 prostate cancer.² A clinical model combining DLX1 and HOXC6 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE findings and age, is used to estimate the likelihood of detecting GS≥7 prostate cancer upon biopsy, with an area under the curve (AUC) of 0.85 (95% CI: 0.83-0.88), in addition to the likelihood of no cancer or GS 6 disease.¹ Performance is based on the presence of all relevant data elements; if all data are not available, results should be interpreted with caution and AUC of the test will vary. Performance characteristics were established in a clinical validation study of 1,955 men from Germany, France, and The Netherlands undergoing initial prostate biopsy due to suspected prostate cancer.¹ Due to EU privacy regulations, patient racial and ethnic data were unavailable and may not reflect the diversity of a US population. Select mdx is not indicated for use in patients receiving treatment known to directly affect PSA levels (including 5α-reductase inhibitors such as finasteride or dutasteride). These medications are known to affect components of the Select mdx clinical model, and patients on such medications were excluded from Select mdx clinical validation studies.

Comments:

References:

¹ Haesse A, et al. J Urol 2019.
² Haesse A, et al. J Urol 2019; Hendriks RJ, et al. Prostate 2017; Hessels D, et al. Trans Med Communications 2017; Dijkstra S, et al. BJU Int 2017; Van Neste L, et al. Eur Urol 2017; Alinezhad S, et al. PLoS ONE 2016; Leyten GH, et al. Clin Cancer Res 2015; Vinarskaja A, et al. Cancers 2011.

Disclaimer:

Mdxhealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The Select mdx for Prostate Cancer test was developed, and its performance characteristics determined by mdxhealth. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined such clearance or approval is not necessary.

CLIA# 05D2033858; CAP# 8015399.

Ruben Gamez, MD, Laboratory Director



mdxhealth[®]

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Sample Reports

Elevated Risk

Select mdx
for Prostate Cancer

**SAMPLE
Patient Report**

Patient	Specimen	Account
Patient Name: David Sample	Specimen #: 72389	Physician: Dr. Smith
Date of Birth: 12/27/1959	Collection Date: 01/28/2023	Account: Urology Associates
MRN/Patient #: 8979821	Received Date: 02/01/2023	Address: 15279 Alton Parkway, Suite 100
Prostate Volume: 30cc	Report Date: 02/04/2023	City/State/Zip: Irvine, CA 92618
PSA: 6.7 ng/mL	Specimen Type: Post DRE Urine	
DRE: Normal	Mdx Accession #: SL-91322	

PATIENT RESULT: ELEVATED RISK

Elevated Risk: This patient's test result indicates an elevated risk for the detection of Gleason Score (GS)≥7 prostate cancer on biopsy.

In the Select mdx pivotal study¹, a clinical model combining urinary biomarkers and clinical factors was applied to generate a risk score that increases with the probability of detecting GS≥7 cancer on biopsy. This raw score has been converted to a personalized positive predictive value that ranges from 0 - 100%:

- Personalized positive predictive value of 29% for detection of GS≥7 prostate cancer, and
- Personalized positive predictive value of 27% for detection of GS 6 prostate cancer.

Test results should be interpreted in conjunction with other available laboratory and clinical data and relevant guidelines to augment the patient-physician shared decision-making process, including the decision for biopsy. Select mdx does not replace other clinical and genetic risk factors, which should be considered as independent risk factors for prostate cancer.

In the Select mdx pivotal study, for patients with low-risk test results, Select mdx yielded a negative predictive value of 95% for detection of GS≥7 prostate cancer, and a negative predictive value of >99% for detection of GS≥8 prostate cancer.¹

Questions about these results? Contact Client Services at 866.259.5644 or go to www.mdxhealth.com/selectreport

Test Description:

Select mdx for Prostate Cancer is a reverse-transcription PCR (RT-PCR) assay performed on urine specimens collected immediately following DRE from patients who are being considered for prostate biopsy. The test measures the urinary mRNA levels of DLX1 and HOXC6 biomarkers to aid in patient selection for prostate biopsy. Higher levels of DLX1 and HOXC6 mRNA are associated with an increased probability for GS≥7 prostate cancer.² A clinical model combining DLX1 and HOXC6 mRNA levels with established clinical risk factors, including PSA, prostate volume, DRE findings and age, is used to estimate the likelihood of detecting GS≥7 prostate cancer upon biopsy, with an area under the curve (AUC) of 0.85 (95% CI: 0.83-0.88), in addition to the likelihood of no cancer or GS 6 disease.³ Performance is based on the presence of all relevant data elements; if all data are not available, results should be interpreted with caution and AUC of the test will vary. Performance characteristics were established in a clinical validation study of 1,955 men from Germany, France, and The Netherlands undergoing initial prostate biopsy due to suspected prostate cancer.¹ Due to EU privacy regulations, patient racial and ethnic data were unavailable and may not reflect the diversity of a US population. Select mdx is not indicated for use in patients receiving treatment known to directly affect PSA levels (including 5α-reductase inhibitors such as finasteride or dutasteride). These medications are known to affect components of the Select mdx clinical model, and patients on such medications were excluded from Select mdx clinical validation studies.

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Ruben Gamez, MD, Laboratory Director


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Direct UTI treatment quickly with Resolve mdx

Patient eligibility

For patients presenting with urinary tract infection symptoms.

Technology: RT-PCR & ASTX

Specimen type: Clean catch, mid-stream urine; catheter urine

Turnaround time: Within 48 hours from receipt at lab

Insurance: Traditional Medicare \$0 patient responsibility.

Vast majority of patients pay less than \$100.

Test requisition form checklist:

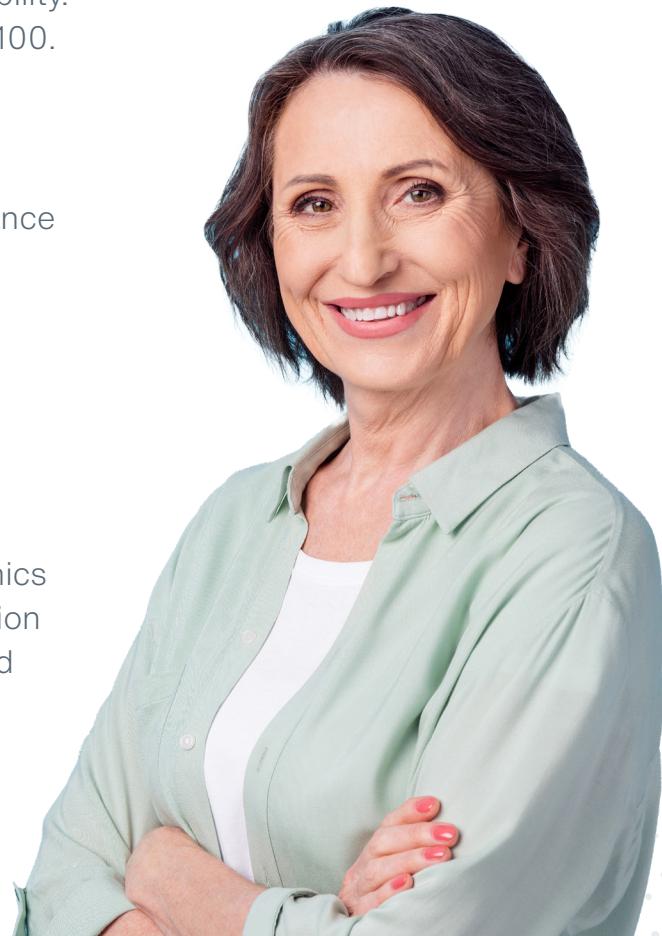
- Ordering physician name
- Print copy of patient demographics and insurance information
- Patient sex, DOB
- Specimen collection date
- ICD-10 code(s)
- Authorized signature

Shipment instructions

- Insert test requisition form, patient demographics and a copy of the patient's insurance information into the Resolve mdx transport kit or biohazard bag.
- Scheduled same-day pick up
 - FedEx 800.463.3339

EHR integrations available

email: info@mdxhealth.com or
contact your mdxhealth sales
representative



View and download our collection instruction:



TRF Required Fields



UTI and STI Test Requisition Form

Ordering Physician	Patient Information	
Account Information		
1. Select Test(s)		
<input type="checkbox"/> Checking box(es) required for testing.		
<input type="checkbox"/> Resolve mdx UTI Panel PCR detection, ABR genes, ASTX susceptibility testing <small>Test details on back</small>	<input type="checkbox"/> Resolve mdx STI Panel <small>(ADDITIONAL SPECIMEN TUBE REQUIRED)</small> PCR Identification, ABR genes <small>Test details on back</small>	
2. Specimen Information		
Collection Date: <input type="text"/> Month <input type="text"/> Day <input type="text"/> Year	Collection Type: <input type="checkbox"/> Clean catch urine <input type="checkbox"/> Catheter urine	Is patient currently on antibiotic? <input type="checkbox"/> Yes <input type="checkbox"/> No
3. Required Billing Information (At least (1) ICD-10 is required per panel ordered)		
UTI codes: <small>(Physician must include ICD-10 diagnosis to document medical necessity for UTI test.)</small>	STI codes: <small>(Physician must include ICD-10 diagnosis to document medical necessity for STI test.)</small>	
N30.00 - Acute cystitis w/o hematuria N30.01 - Acute cystitis with hematuria N30.20 - Other chronic cystitis w/o hematuria N30.80 - Other cystitis w/o hematuria N30.81 - Other cystitis with hematuria N40.1 - BPH with Lower Urinary Tract Symptoms R10.30 - Lower abdominal pain, unspecified	R30.0 - Dysuria R30.9 - Painful micturition, unspecified R31.0 - Gross hematuria R31.29 - Other microscopic hematuria R35.0 - Frequency of micturition R82.71 - Bacteriuria R82.81 - Pyuria Other:	
Copy of Insurance card (front and back) required. Payment Type: <input type="checkbox"/> Private Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Patient Self-Pay <input type="checkbox"/> Client (contract required)		
Name of insurance: <input type="text"/> Member ID: <input type="text"/>		
(Medicare only) Was procedure performed in hospital? If yes: <input type="checkbox"/> hospital outpatient <input type="checkbox"/> hospital inpatient - discharge date: <input type="text"/> Month <input type="text"/> Day <input type="text"/> Year		
Include copies of both sides of insurance card(s). If two cards are submitted, indicate which is primary.		
4. Physician Signature & Attestation		
I hereby authorize testing and confirm that an informed consent has been obtained, if required by state law. I confirm that this is medically necessary and the results will be used in the medical management decisions for the patient. I hereby attest that the person listed in the Ordering Physician space above is authorized by law in the relevant jurisdiction to order the test requested herein. I confirm that I have on file the patient's assignment of benefits authorizing insurance benefits to be paid to ancillary healthcare service providers, such as mdxhealth. I further instruct mdxhealth to retain this completed test requisition as part of the patient medical record. I authorize mdxhealth to release the information on this form, and other information provided by me, or on my behalf, necessary to process a claim for this service.		
<input type="text"/> / <input type="text"/> / <input type="text"/> Ordering Physician Signature (No stamped signatures) Date		
<small>Submitting this form constitutes a Certification of Medical Necessity and a certification that you have obtained consent for mdxhealth to release the test results and relevant medical information to the patient's insurance carrier as part of the coverage and reimbursement process.</small>		
Place Patient Label Here		Place Provided Barcode Here



Sample Report: UTI

Pathogen(s) Detected

Resolve mdx
for Urinary Tract Infection

SAMPLE
Patient Report

<p>Patient</p> <p>Patient Name: Jon Doe Date of Birth: 02-22-1952 MRN/Patient #: 1234-1</p>	<p>Specimen</p> <p>Specimen #: 123-456-789 Collection Date: 03-10-2023 Received Date: 03-11-2023 Report Date: 03-13-2023 Specimen Type: Clean catch urine Mdxhealth Accession #: A00000</p>	<p>Account</p> <p>Physician: Dr. Smith Account: Urology Care Address: 12345 Alton City, State, Zip: Irvine, CA 92618</p>																																																																																																																																																
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Cefaclor	PO	R		✓																																																																																																																																														
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Antimicrobial	Formulation	Antimicrobial Phenotypic Susceptibility	Supportive Data from Sanford Guide																																																																																																																																															
			Escherichia coli	Enterococcus faecalis																																																																																																																																														
Cephalexin	PO	R		✓																																																																																																																																														
Linezolid	PO	R	✓																																																																																																																																															
Ciprofloxacin	PO/IV	R	✓	✓																																																																																																																																														
Trimethoprim-sulfamethoxazole	PO/IV	R		✓																																																																																																																																														
Cefazolin	IM/IV	R		✓																																																																																																																																														
Cefepime	IM/IV	R		✓																																																																																																																																														
Cefoxitin	IM/IV	R		✓																																																																																																																																														
Ceftriaxone	IM/IV	R		✓																																																																																																																																														
Gentamicin	IM/IV	R	✓	✓																																																																																																																																														
Aztreonam	IV	R		✓																																																																																																																																														
Vancomycin	IV	R	✓																																																																																																																																															
Ofloxacin	PO/IM/IV	N/A	✓	✓																																																																																																																																														
Meropenem	IV	N/A	✓	✓																																																																																																																																														

Sample Report: STI

Pathogen(s) Detected

Resolve mdx

Patient Report Sexually Transmitted Infection

Patient	Specimen	Account
Patient Name: Jon Doe Date of Birth: 02-22-1952 MRN/Patient #: 1234-1	Specimen #: 123-456-789 Collection Date: 03-10-2023 Received Date: 03-11-2023 Report Date: 03-13-2023 Specimen Type: Clean catch urine Mdxhealth Accession #: A00000	Physician: Dr. Smith Account: Urology Care Address: 12345 Alton City, State, Zip: Irvine, CA 92618
PATIENT RESULT: PATHOGEN(S) DETECTED		
Pathogen(s) Detected		
Pathogen(s) Detected	Result	
Mycoplasma genitalium	Detected ($\geq 10^3$)	
Neisseria gonorrhoeae	Detected ($\geq 10^3$)	
Resistance Gene(s) Detected		
Resistance Gene(s) Detected	Antimicrobial Resistance	
Vancomycin Resistance Gene (VRE)	Vancomycin	
Pathogen(s) and Resistance Gene(s) - Not Detected		
Pathogens Tested	Result	
Chlamydia trachomatis	Not detected	
Gardnerella vaginalis	Not detected	
Mycoplasma hominis	Not detected	
Trichomonas vaginalis	Not detected	
Ureaplasma parvum	Not detected	
Ureaplasma urealyticum	Not detected	
Resistance Genes Tested	Result	
Carbapenem	Not detected	
Extended Spectrum Beta-Lactamase	Not detected	
Fluoroquinolone	Not detected	
Methicillin	Not detected	
Trimethoprim/Sulfamethoxazole	Not detected	
COMMENT:		

Page 1 of 2

Mdxhealth's Guide to Insurance and Billing



Accessible, affordable testing for all patients

We understand that every patient's insurance coverage and financial situation is unique. With our Patient First Promise, we are committed to ensuring our tests are accessible and affordable for everyone. All patients are eligible for our financial assistance program.

We offer a financial assistance program

If your patient's private insurance provider determines a deductible and/or coinsurance is owed, mdxhealth offers an easy-to-enroll financial assistance program based on their current financial situation and ability to pay.

We will work to ensure we leverage all possible options to qualify.

Most patients are responsible for less than...

Medicare | Private Insurance

Confirm mdx

\$0 | <\$250

Genomic Prostate Score

\$0 | <\$250

Select mdx

\$0 | <\$100

Resolve mdx

\$0 | <\$100

Resources

Online Ordering

Use our portal to order Confirm mdx, GPS, Select mdx, and Resolve mdx



Test Requisition Forms

Download editable pdf test requisition forms



Order Supplies

Order specimen transport kits and TRFs



Mdxhealth Support

Client Services: cs@mdxhealth.com

Medical Science Liaisons: MSL@mdxhealth.com

EHR Integrations: info@mdxhealth.com or contact your local sales representative

FedEx Pickup: www.mdxhealth.com/fedex

Sign up for Glidian's Prior Authorization: my.glidian.com/provider

EHR integrations available

email: info@mdxhealth.com or contact your mdxhealth sales representative

Mdxhealth's Xpert One Support



Xpert One Support is founded on personal attention, responsiveness, and commitment to customer satisfaction. Our Xperts are truly experts on mdxhealth products and processes, from specimen requirements and shipping logistics, to clinical insights. Together with your mdxhealth Molecular Diagnostic Specialist, Xpert One Support strives to make your mdxhealth experience the best it can be.

Physicians, patients, lab technicians, and everyone in the fight against prostate cancer and urologic diseases—you can expect more from Xpert One Support.



Xpress Response Time

Our goal is to respond to your phone or e-mail inquiry within 24 hours or less.



Xtraordinary Convenience

Optimize your workflow by customizing your support with specimen shipping, automated supplies replenishment, and more.



Xpertise On Demand

Get answers to questions along with access to mdxhealth clinical resources and opportunities to connect with industry leaders.



Xceptional Compassion

Our Patient First Promise ensures mdxhealth tests are accessible and affordable for all patients. If your patient is facing financial challenges, they can contact an Xpert One Support patient advocate to find the right assistance options for you.



866.259.5644

(Monday – Friday, 5:00 AM – 5:00 PM PT)



info@mdxhealth.com