

mdxhealth®

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

☒ 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: Date retrieved from archive:

Last DRE Result: ☐ Very Suspicious for Prostate Cancer ☐ Not Very Suspicious for Prostate Cancer

(Medicare only) If mpMRI performed, PI-RADS Score: / Date:

Last 2 PSA Results: PSA: ng/mL Date: PSA: ng/mL Date:

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:

R97.20 Elevated Prostate Specific Antigen [PSA] ☐ N40.2 Nodular prostate without lower urinary tract symptoms

D29.1 Benign neoplasm of prostate ☐ N40.3 Nodular prostate with lower urinary tract symptoms

D40.0 Neoplasm of uncertain behavior of prostate ☐ Other:

Payment Type: ☐ Private Insurance ☐ Medicare ☐ Medicaid ☐ Patient Self-Pay ☐ Client (contract required)

Name of insurance: Member ID:

(Medicare only) Was procedure performed in hospital? If yes: ☐ hospital outpatient ☐ hospital inpatient - discharge date:

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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IR-FORM-0055-R09

mdxhealth

Negative

SAMPLE

Patient Report

ConfirmMDx
for Prostate Cancer

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

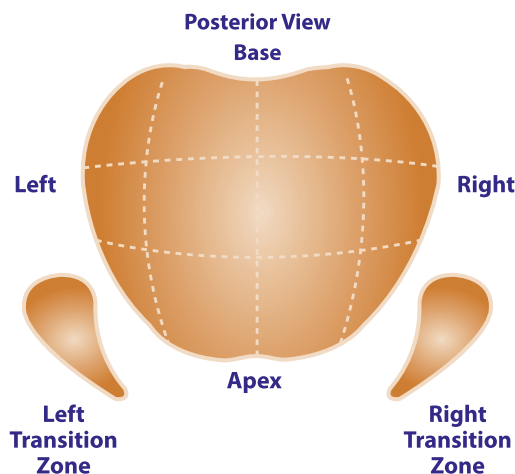
Result Description:

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



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				Distribution of DNA Methylation Diagram	
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		

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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

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)

ng/mL

Pre-Biopsy PSA

Prostate Volume

Date of Current Biopsy

PSA Density (PSA/Prostate Volume)

☐ <0.15 ng/mL ☐ ≥0.15 ng/mL

Prostate Biopsy Cores

a) MRI Targeted Biopsy ☐ Yes ☐ No

c) # of Positive Cores

d) Max % tumor involvement in any core ☐ ≤ 50% ☐ > 50%

Stage

☐ T1c ☐ T2a ☐ T2b ☐ T2c ☐ T3a

Gleason Score (Primary + Secondary)

☐ 3+3 ☐ 3+4 ☐ 4+3 ☐ 4+4 ☐ 3+5 ☐ 4+5

Patient has a Life Expectancy of ≥ 10 years?

☐ Yes ☐ No

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

Affix Specimen barcode here

Date of Collection (mm/dd/yyyy)

Date Block Pulled From Archive (Medicare only)

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

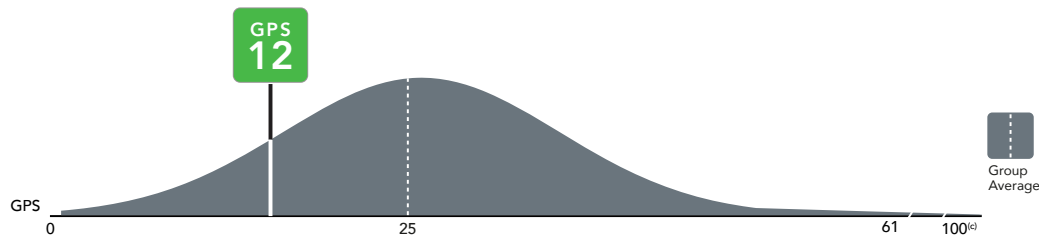
Clinical Stage: T2a

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)



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-0164

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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.

mdxhealth

mdxhealth
P: 866.259.5644
F: 949.788.0014
E: client.services@mdxhealth.com
www.mdxhealth.com

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

IR-BROC-0164

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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

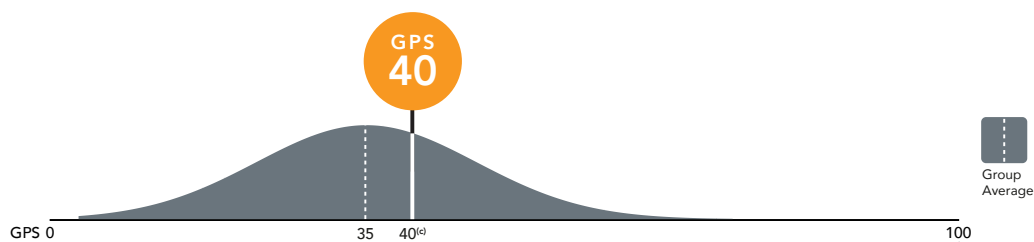
Clinical Stage: T2a

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



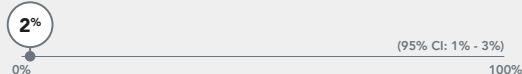
POST THERAPY OUTCOMES*

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



The 10-year likelihood of distant metastasis is based on the combination of this patient's GPS result and NCCN risk group, after treatment with radical prostatectomy or radiation therapy.

In the clinical validation studies, for the mean GPS result of 35, the 10-year likelihood of distant metastasis is 10% (95% CI: 6% - 15%).^{3,4}

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}

Footnote: (a) Calculated or reported from physician-provided clinical information. (b) N/A (not available) indicates data has not been provided to mdxhealth. (c) 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.^{4,1} (d) In the clinical validation studies, metastasis was determined by imaging or biopsy and disease progression is defined by prostate cancer death and metastasis. * 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 V.1.2023. © 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# 0502033858, 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

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

Account Information

Patient Information

Name:
First Last
Address:
City: State: Zip:
Date of Birth: Phone:
Month Day Year
MRN/Patient ID:

1. Test Ordered

☒ Select mdx for Prostate Cancer

2. Clinical Information:

Collection Date: Specimen ID:
Month Day Year
Last DRE Result: ☐ Very Suspicious for Prostate Cancer ☐ Not Very Suspicious for Prostate Cancer
Last PSA Results: PSA: ng/mL Date: Prostate volume: (only if obtained by MRI or ultrasound)
Month Day Year

3. Required Billing Information: (ICD-10 and copy of insurance card required)

ICD-10 Codes:
☐ R97.20 Elevated Prostate Specific Antigen [PSA] ☐ N40.2 Nodular prostate without lower urinary tract symptoms
☐ D29.1 Benign neoplasm of prostate ☐ N40.3 Nodular prostate with lower urinary tract symptoms
☐ D40.0 Neoplasm of uncertain behavior of prostate ☐ Other:
Payment Type: ☐ Private Insurance ☐ Medicare ☐ Medicaid ☐ Patient Self-Pay ☐ Client (contract required)
Name of insurance: Member ID:
(Medicare only) Was procedure performed in hospital? If yes: ☐ hospital outpatient ☐ 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.

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)

Date

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: Tubes:

Select mdx

for Prostate Cancer

Low Risk



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: 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 5 α -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 Haese A, et al. J Urol 2019.

² Haese 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



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.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 5 α -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 Haese A, et al. J Urol 2019.

² Haese 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.

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CLIA# 05D2033858; CAP# 8015399.

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

Resolve mdx

UTI and STI Test Requisition Form

Ordering Physician

Account Information

Patient Information

Name:
First Last

Address:

City: State: Zip:

Date of Birth: Sex: Phone:
Month Day Year M F

1. Select Test(s)

Checking box(es) required for testing.

☐ **Resolve mdx UTI Panel**
PCR detection, ABR genes, ASTX susceptibility testing
Test details on back

☐ **Resolve mdx STI Panel**
(ADDITIONAL SPECIMEN TUBE REQUIRED)
PCR Identification, ABR genes
Test details on back

2. Specimen Information

Collection Date: Collection Type: ☐ Clean catch urine ☐ Catheter urine Is patient currently on antibiotic? ☐ Yes ☐ No
Month Day Year

3. Required Billing Information (At least (1) ICD-10 is required per panel ordered)

UTI codes: (Physician must include ICD-10 diagnosis to document medical necessity for UTI test.)	STI codes: (Physician must include ICD-10 diagnosis to document medical necessity for STI test.)
<input type="checkbox"/> N30.00 - Acute cystitis w/o hematuria	<input type="checkbox"/> A54.9 - Gonococcal infection, unspecified
<input type="checkbox"/> N30.01 - Acute cystitis with hematuria	<input type="checkbox"/> A64 - Unspecified sexually transmitted disease
<input type="checkbox"/> N30.20 - Other chronic cystitis w/o hematuria	<input type="checkbox"/> A74.9 - Chlamydial infection, unspecified.
<input type="checkbox"/> N30.80 - Other cystitis w/o hematuria	<input type="checkbox"/> Z11.3 - Encounter for screening for infections with a predominantly sexual mode of transmission
<input type="checkbox"/> N30.81 - Other cystitis with hematuria	<input type="checkbox"/> Other: <input type="text"/>
<input type="checkbox"/> N40.1 - BPH with Lower Urinary Tract Symptoms	
<input type="checkbox"/> R10.30 - Lower abdominal pain, unspecified	
<input type="checkbox"/> R30.0 - Dysuria	
<input type="checkbox"/> R30.9 - Painful micturition, unspecified	
<input type="checkbox"/> R31.0 - Gross hematuria	
<input type="checkbox"/> R31.29 - Other microscopic hematuria	
<input type="checkbox"/> R35.0 - Frequency of micturition	
<input type="checkbox"/> R82.71 - Bacteriuria	
<input type="checkbox"/> R82.81 - Pyuria	
<input type="checkbox"/> Other: <input type="text"/>	

Copy of Insurance card (front and back) required.

Payment Type: ☐ Private Insurance ☐ Medicare ☐ Medicaid ☐ Patient Self-Pay ☐ Client (contract required)

Name of insurance: Member ID:

(Medicare only) Was procedure performed in hospital? If yes: ☐ hospital outpatient ☐ 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.

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.

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 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

Sample Report: UTI

Pathogen(s) Detected

Resolve mdx
for Urinary Tract Infection

SAMPLE Patient Report

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	CFU/ml
Enterococcus faecalis	4.36 x 10 ⁶
Escherichia coli	9.56 x 10 ⁵

Resistance Gene(s) Detected

Resistance Gene(s) Detected	Antimicrobial Resistance
Trimethoprim/Sulfamethoxazole	Trimethoprim-sulfamethoxazole

Patient Susceptible Antimicrobials

- Fosfomycin PO
- Nitrofurantoin PO
- Amoxicillin-clavulanate PO
- Minocycline PO/IV
- Moxifloxacin PO/IV
- Tetracycline PO/IV
- Doxycycline PO/IV
- Ampicillin PO/IM/IV
- Ampicillin-sulbactam IV
- Piperacillin-tazobactam IV

Patient Susceptibility Report

Report Key

S = Susceptible **I = Intermediate** **R = Resistant**

SDD = Susceptible-Dose Dependent ***R = Data not patient specific**

N/A = Detected organism has variable results **SNP = Susceptibility not performed**

Antimicrobial	Formulation	Antimicrobial Phenotypic Susceptibility	Supportive Data from Sanford Guide	
			Escherichia coli	Enterococcus faecalis
Amoxicillin-clavulanate	PO	S	✓	✓
Fosfomycin	PO	S	✓	✓
Nitrofurantoin	PO	S	✓	✓
Doxycycline	PO/IV	S	✓	✓
Minocycline	PO/IV	S	✓	✓
Moxifloxacin	PO/IV	S	✓	✓
Tetracycline	PO/IV	S	✓	✓
Ampicillin	PO/IM/IV	S	✓	✓
Ampicillin-sulbactam	IV	S	✓	✓
Piperacillin-tazobactam	IV	S	✓	✓
Levofloxacin	PO/IV	I	✓	✓
Cefaclor	PO	R		✓
Cefdinir	PO	R		✓
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:

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

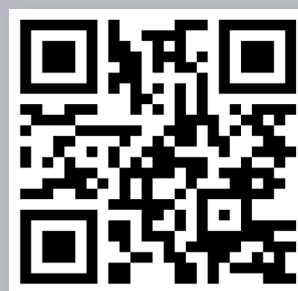
Online Ordering

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

mdxhealth®