



mdxhealth®

Corporate Presentation
November 2024

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Analyst Coverage

Any opinions, estimates or forecasts made by analysts are theirs alone and do not represent opinions, forecasts or predictions of mdxhealth or its management. Requests for copies of analyst reports should be directed at the respective analyst and institution.

mdxhealth provides highly accurate and clinically actionable urologic solutions to inform patient diagnosis and treatment while improving healthcare economics for payers and providers



Ticker: **MDXH**

mdxhealth fundamentals for growth



Fundamentals in place

- Compelling and comprehensive menu in prostate cancer
- Robust clinical data
- Established reimbursement and guidelines inclusion



Levers for growth

- Expansion of mdxhealth clinical pathway for prostate cancer (acquisition of Genomic Prostate Score)
- Expanding coverage of current menu (Select mdx LCD published)
- Expanding US commercial footprint



Established focus & execution

- World-class CLIA certified multi-state lab operations
- Experienced and expanded channel into urology
- Urinary Tract Infection opportunity validated



Potential opportunities

- Opportunistic decentralization of menu as appropriate
- Expanded channel outside of urology
- Menu Expansion: Monitor mdx and business development opportunities

Experienced leadership team

Track record of success



**Michael K.
McGarrity**

Chief Executive Officer

Joined mdxhealth in 2019
Nanosphere
(Luminex/DiaSormin)
Stryker



**Ron
Kalfus**

Chief Financial Officer

Joined mdxhealth in 2019
Rosetta Genomics
Mabcure



**John
Bellano**

Chief Commercial Officer

Joined mdxhealth in 2019
Assurex Health (Myriad
Genetics)
Third Wave Technologies
(Hologic)
Roche Diagnostics Molecular
Diagnostics



**Joseph
Sollee**

Executive Vice President
Corp. Dev. General Counsel

Joined mdxhealth in 2008
Triangle Pharmaceuticals
TherapyEdge



**Miriam
Reyes**

Executive Vice President
Laboratory Operations

Joined Mdxhealth in 2011
CombiMatrix
Agendia
Labcorp



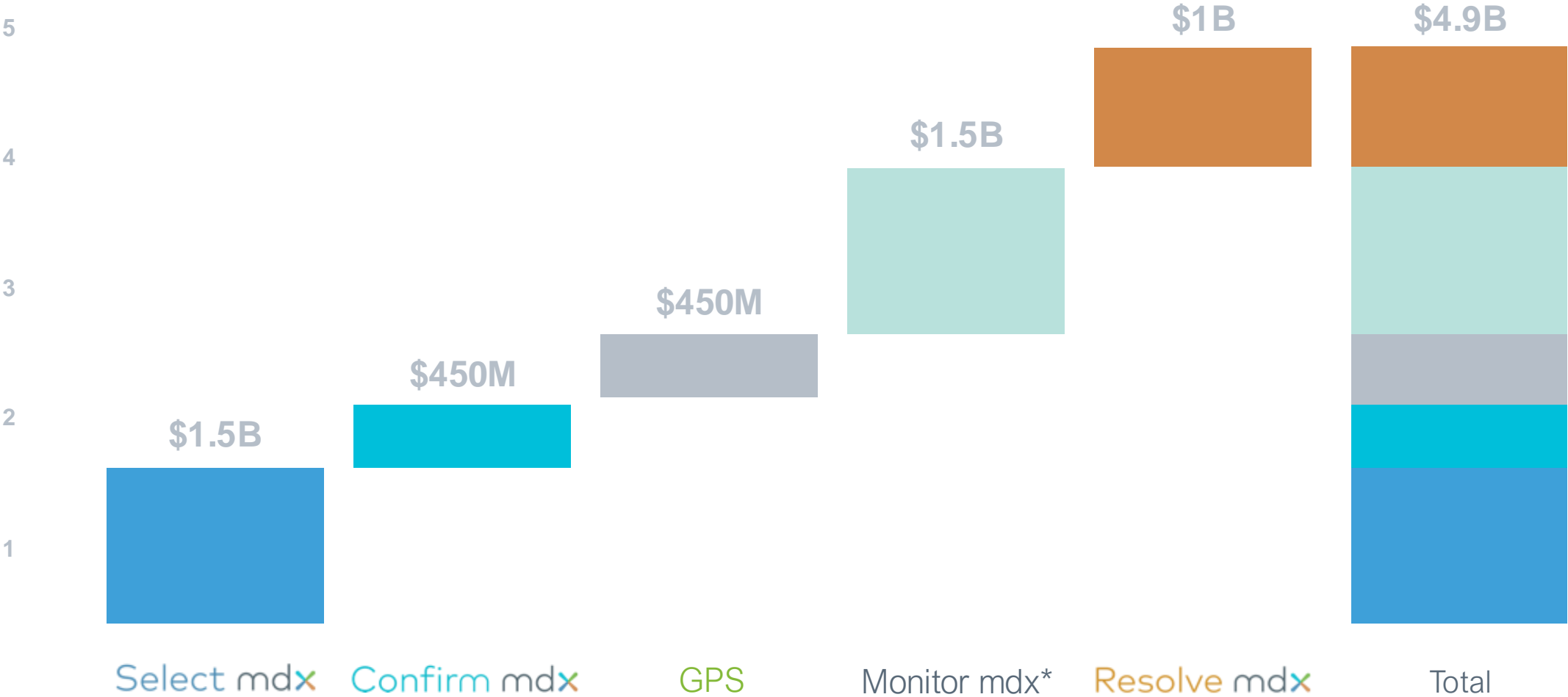
**Jason
Poole**

Chief Scientific Officer

Joined Mdxhealth in 2023
Active Motif
Biocept
Trovagene

Our menu addresses a \$4.9B U.S. market opportunity ⁽¹⁻⁵⁾

Comprehensive Urology Menu



Commercial levers to drive growth

One of the most compelling, comprehensive and accurate menus in urology

Standardized laboratory partner for urology group practice

- **One** rep
- **One** laboratory
- **One** patient support program
- **ONE PARTNER** in the diagnosis and treatment of prostate cancer

Acquired Exact Sciences' Genomic Prostate Score (GPS) test

- Established brand with broad customer base
- Covered by Medicare and included in NCCN guidelines

Validated advanced Urinary Tract Infection (UTI) opportunity

- Launched in second half of 2021

Experienced distribution channel and broad KOL network

- Expanded commercial team to >70 people

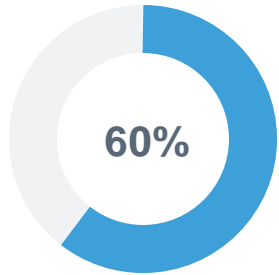
Genomic Prostate Score

Acquired August 2022

Resolve mdx
for Urinary Tract Infection

UTI test launched 2021

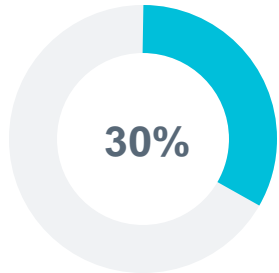
Current challenges with diagnosing prostate cancer



Prostate cancer screening

~3 million elevated PSA results annually ⁽¹⁻²⁾

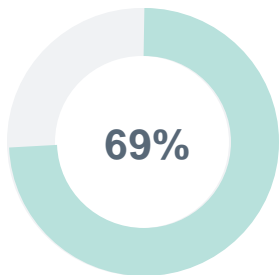
~60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization ⁽³⁻⁶⁾



Prostate cancer diagnosis

~ 500,000 men undergo biopsies annually ⁽²⁾

~30% of cancer-negative biopsies are false negatives, meaning these patients actually have cancer ⁽⁷⁾



Prostate cancer risk stratification

~300,000 prostate cancers diagnosed annually ⁽⁸⁾

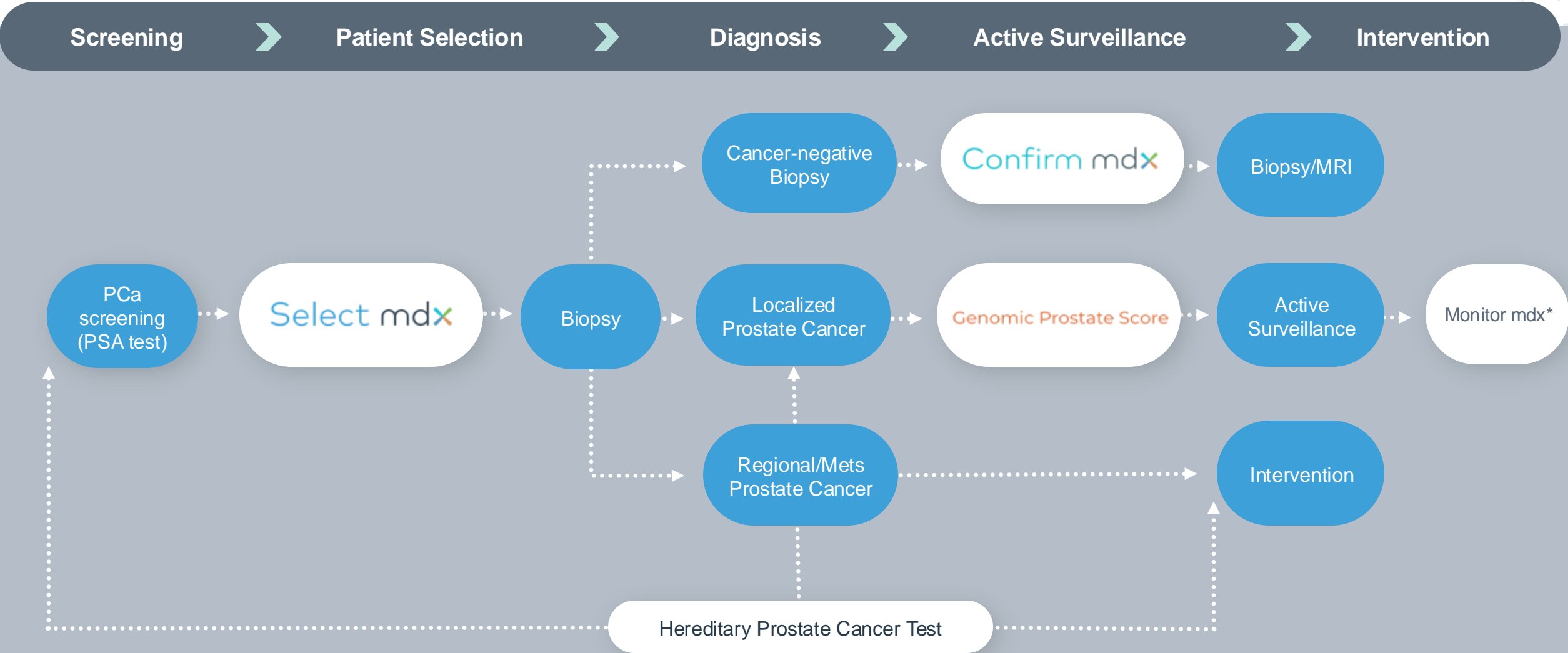
~69% of new prostate cancer diagnosis are localized; Active Surveillance or treatment decision ⁽⁸⁾

Prostate cancer is the most common cancer and the 2nd deadliest cancer in U.S. men ⁽¹⁾



Expanding menu in the prostate cancer diagnostic pathway

One of the most comprehensive menus in prostate cancer



Select mdx improves patient selection prior to prostate biopsy

A highly predictive test to identify men at low risk for aggressive prostate cancer

Abnormal PSA/DRE

At risk for aggressive cancer?

95% NPV

Select mdx[®]

Binary actionable results for patient and HCP



Positive



Biopsy

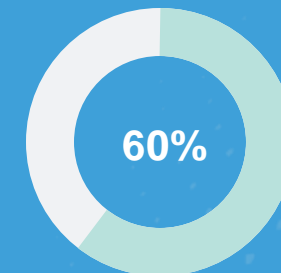


Negative



Routinely Monitor

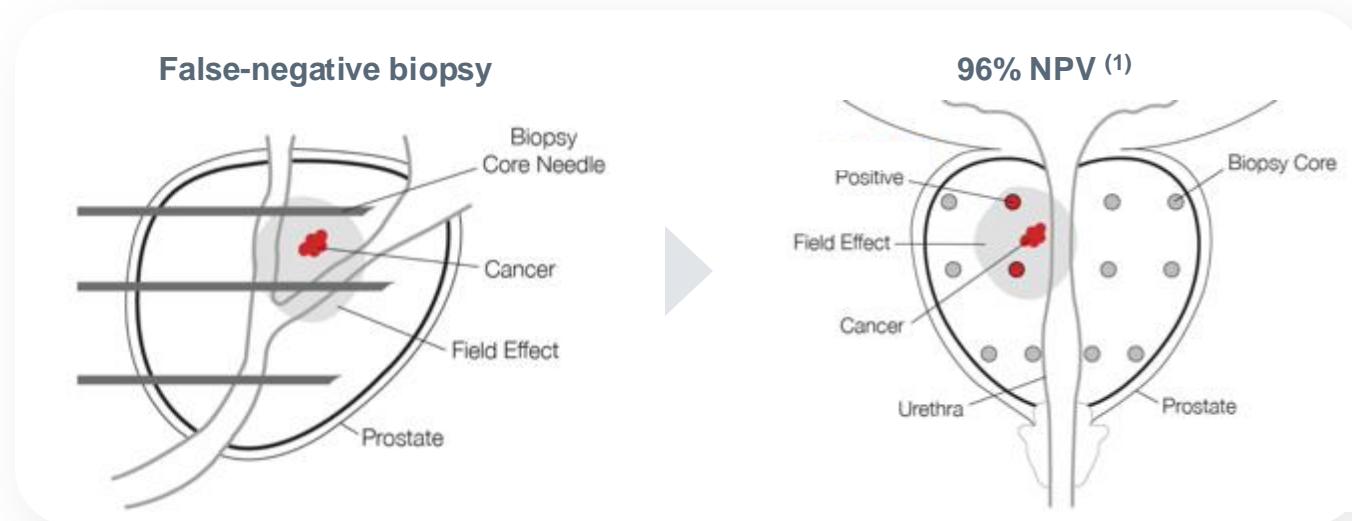
- **Non-invasive:** Urine-based “rule-out” test improves the diagnostic disposition of patients by avoiding unnecessary prostate biopsies
- **Accurate:** 95% negative predictive value ⁽¹⁾
- **Validated:** 12 published studies on genes and technology
- **Cost effective:** Potential to avoid invasive and unnecessary prostate biopsies and save the U.S. healthcare system >\$500 million ⁽²⁾ each year
- **National guidelines:** Included in EAU and NCCN guidelines ⁽³⁻⁴⁾



60% of initial biopsies do not reveal cancer ⁽⁵⁻⁸⁾

Confirm mdx improves diagnostic confidence of biopsy result

The only epigenetic test to identify men at risk for aggressive prostate cancer



- **Non-invasive:** “Rule-out” test performed on previous biopsy tissue
- **Accurate:** 96% Negative Predictive Value for aggressive prostate cancer ⁽¹⁾
- **Validated:** Over 55 published studies on genes and technology
- **Cost effective:** Potential annual U.S. health system savings of \$500K per 1M covered patients ⁽²⁾
- **National guidelines:** Included in EAU and NCCN guidelines ⁽³⁻⁴⁾



30% of men with a cancer-negative biopsy result actually have cancer ⁽⁵⁾

Genomic Prostate Score (GPS) guides treatment decisions for localized prostate cancer

The test analyzes prostate cancer gene activity to predict disease aggressiveness and provide clinically meaningful endpoints ⁽¹⁻²³⁾

How the test can help you



- **Non-invasive:** test performed on previous biopsy tissue
- **Accurate:** Predicts adverse pathology, distant metastasis, prostate cancer mortality and pT3/Extra prostatic extension
- **Validated:** Predicts adverse pathology in AS candidate cohorts in 7 studies >2,000 patients
- **National guidelines:** Included in NCCN guidelines ⁽²⁴⁾

Low risk patients

When to treat

Very low	Low	Favorable intermediate
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Provides additional information to help when deciding on whether to pursue active surveillance or more aggressive treatment options.

High risk patients

How to treat

Unfavorable intermediate	High
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Provides information to help select treatment intensity.

Low Risk



Active Surveillance

High Risk



Treatment Intensity

Hereditary Prostate Cancer Testing

Prostate cancer remains a leading cause of cancer-related death among men, with an estimated 300,000 new diagnoses and 35,000 deaths annually. Decades of research indicate that prostate cancer has a strong genetic component with implications to ancestry.

- Prostate cancer has the highest heritability of any major cancer in men
- Hereditary Prostate Cancer Testing:
 - is recommended in the National Comprehensive Cancer Network (NCCN) guidelines
 - is critical to identify patients eligible for novel therapies (e.g., PARP inhibitors, immunotherapies, and targeted agents for inherited prostate cancers)
 - is covered by Medicare and many commercial insurance plans, for eligible patients

Hereditary prostate cancer accounts for

5-10%

of newly diagnosed patients

Prostate cancer pipeline

Active surveillance monitoring
(Localized prostate cancer)

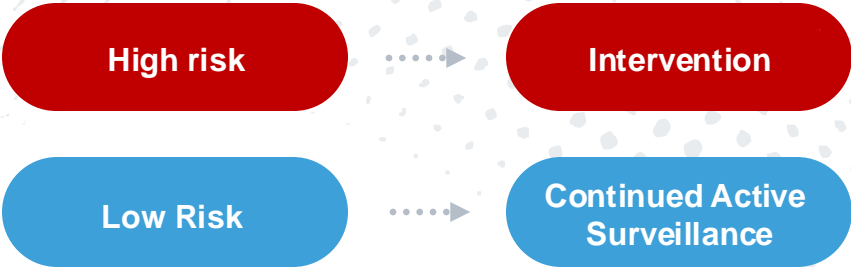
1.5M
Est. market size
(men annually)

Monitor mdx

Patients under active surveillance are currently monitored by invasive and costly prostate biopsies

Monitor mdx will be a non-invasive alternative that risk-stratifies patients for continued active surveillance vs. intervention, which may also improve patient compliance

Monitor mdx*



Urinary Tract Infection (UTI) annual market opportunity

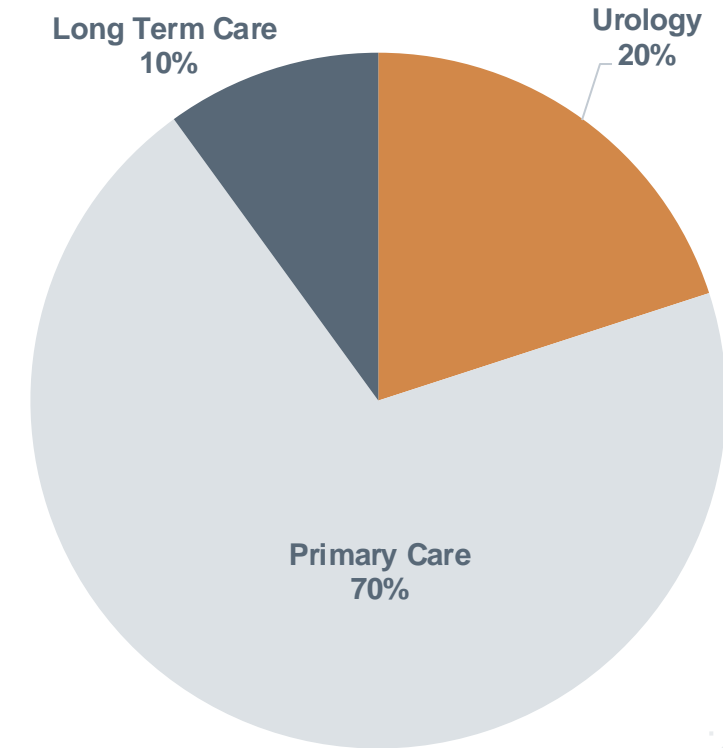
UTIs are the most common outpatient infection⁽¹⁾

- 10 million suspected UTI cases present annually⁽²⁾
- 20% of volume presents to urology⁽³⁾

The current UTI testing market is underserved

- Current standard is based on dated culture methodologies
- Complex molecular methods target both organism and susceptibility markers
- Market conversion comps: Virology and infectious disease
- Reimbursement well characterized (Medicare/commercial)

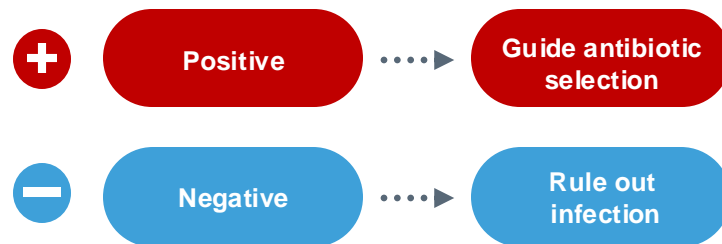
The addressable market for UTI testing in the urology segment is 2M tests⁽²⁾ annually, or \$1B⁽³⁾



U.S. Market for UTI⁽³⁾

Resolve mdx: Advance molecular urinary tract infection testing

- As many as 33% of urine cultures are polymicrobial, especially in elderly populations, and traditional urine culture may miss up to 67% of recognized uropathogens
- Resolve mdx identifies and quantifies uropathogenic bacteria and associated antibiotics susceptibility
- Resolve mdx improves antibiotic stewardship



- **Non-invasive:** Urine-based test that provides personalized antibiotics options for urinary tract infections.
- **Accurate:** 19 pathogens, 6 classes of resistance genes and susceptibility to guide antibiotic selection
- **Turnaround time:** Results within 24-48 hours

Selected Financial Data

USD in thousands	Three months ended (unaudited)			Nine months ended (unaudited)		
	Sep 30, 2024	Sep 30, 2023	% Change	Sep 30, 2024	Sep 30, 2023	% Change
Total revenue	\$23,317	\$19,350	+21%	\$65,310	\$50,795	+29%
Gross profit	\$14,275	\$12,553	+14%	\$39,624	\$31,258	+27%
Gross profit %	61.2%	64.9%	-3.7pp	60.7%	61.5%	-0.9pp
Net loss	(\$11,189)	(\$10,045)	8%	(\$31,228)	(\$32,380)	(4%)
EPS ¹	\$(0.40)	\$(0.37)	8%	\$(1.14)	\$(1.27)	(10%)

¹ EPS figures have been adjusted to reflect 10-1 reverse stock-split which occurred in November 2023

Unaudited 3Q24 results and updated 2024 guidance:

- 2024 revenue guidance of \$87-89 million (representing year-over-year revenue growth of approximately 25%)

mdxhealth is well-positioned for sustainable growth and value creation

01

Revenue growth

- Multi-billion-dollar addressable market opportunity fortified by acquisition of Oncotype DX GPS from Exact Science
- 2024 guidance of \$83-\$85M

02

Gross margin leverage

- Coverage for Select mdx indication
- Driving additional payer coverage for full menu
- Accretion of (f/k/a Oncotype DX) GPS and UTI test

03

Experienced and expanded channel into urology

- Field sales team of 70 in the US
- Urinary Tract Infection opportunity taking hold
- Additional channel opportunities as they present

04

Leadership team and operating discipline

- Focus and execution across all operating disciplines

Thank you

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Slide 6 – Our menu addresses a \$4.9B U.S. market opportunity

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Slide 8 – Current challenges with diagnosing prostate cancer in U.S.

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5. Loeb et al. European Urology 2013.
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8. NIH Cancer Stat Facts: Prostate Cancer. <https://seer.cancer.gov/statfacts/html/prost.html>

Slide 10 – SelectMDx improves patient selection prior to prostate biopsy

1. Haese, A, et al. (2019) Multicenter Optimization and Validation of a 2-Gene mRNA Urine Test for Detection of Clinically Significant Prostate Cancer Prior to Initial Prostate Biopsy. J Uro. doi: 10.1097/JU.000000000000293.
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6. Bhindi B, Mamdani M, Kulkarni GS, et al. Impact of the U.S. Preventive Services Task Force recommendations against prostate specific antigen screening on prostate biopsy and cancer detection rates. J Urol. 2015;193:1519–1524.
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Slide 11 – ConfirmMDx improves diagnostic confidence of biopsy result

1. Van Neste, et al. (2016) Risk Score Predicts High-Grade Prostate Cancer in DNA-Methylation Positive, Histopathologically Negative Biopsies. J Urology.
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Slide 12 –(f/k/a Oncotype DX) Genomic Prostate Score (GPS) to guide treatment decisions for localized prostate cancer

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Slide 15 – U.S. Urinary Tract Infection (UTI) annual market opportunity

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3. Mdxhealth management estimates are informed by the Company's knowledge of the industry.

Appendix

Select mdx robust clinical evidence

12 published studies on genes and technology

- **Analytical validity**
- **Clinical validity**
- **Clinical utility**
- **Health economics**

Pivotal clinical studies

Analytical validation	Hessels et al., Translational Medicine Communications 2017
Clinically validated for a 95% NPV	Haese et al., Journal of Urology 2019
Significantly impacts prostate biopsy decision making	Shore et al., Urology Practice 2019
>\$500M in savings to health care system	Govers et al., Journal of Urology 2018



Confirm mdx robust clinical evidence

Over 55 published studies on genes and technology

-  **Analytical validity**
-  **Clinical validity**
-  **Clinical utility**
-  **Health economics**

Pivotal clinical studies

Analytical validation	Van Neste et al., BMC Urology 2013
Validation of high NPV	Partin et al., Journal of Urology 2014.
Meta analysis validating high NPV	Partin et al., Trans. of the Am. Clin. and Clim. Assoc 2016
Risk score development NPV 96% CS PCa	Van Neste et al. The Prostate 2016
Validated in African American men	Waterhouse et al., Urology 2016
Validation of clinical utility/actionability	Wojno., et al 2014
Savings to health care system	Aubry et al., American Health Drug and Benefits 2013



GPS robust clinical evidence

Over 20 published clinical validation and utility studies

-  **Analytical validity**
-  **Clinical validity**
-  **Clinical utility**
-  **Health economics**

Pivotal clinical studies

Analytical validation	Knezevic et al., 2013
Clinically validated as an independent predictor of adverse pathology	Klein et al., 2014, Cullen et al., 2015, Eeden et al., 2017, Eggner et al., 2019
Clinical validated in African American men	Cullen et al., 2015, Murphy et al., 2021
Validation of clinical utility	Badani et al., 2015, D
Validation of clinical utility/actionability	Badani et al., 2015, Dall’Era et al., 2015, Eure et al., 2017, Lynch et al., 2017, Murphy et al., 2021, Moschovas et al., 2021
Cost savings by decreasing unnecessary immediate treatment	Albala et al., 2016



Select mdx, Confirm mdx and GPS technology

The most comprehensive menu in prostate cancer

	Select mdx ⁽¹⁾	Confirm mdx ⁽²⁾	GPS ⁽³⁾
Specimen	Urine	Prostate tissue	Localized PCa tissue
Science	mRNA RT-PCR assay	DNA Methylation Specific PCR assay	Multi gene expression RT-PCR Assay
Biomarkers	DLX1, HOXC6	GSTP1, APC RASSF1	17 genes (AZGP1, FAM13C, KLK2, SRD5A2, FLNC GSN, GSTM2, TPM2, BGN, COL1A1, SFRP4, TPX2, ARF1, ATP5E, CLTC, GPS1, PGK1)
Clinical Model	Clinical model combines mRNA with established clinical risk factors	Clinical model combines DNA Methylation markers with established clinical risk factors	Clinical algorithm aggregates expression of 5 reference genes to normalize the expression of the 12 cancer-related genes
Performance	95% NPV for clinically significant prostate cancer	96% NPV for clinically significant prostate cancer	Predicts adverse pathology, distant metastases, PCa mortality

1. Haese, A, et al. (2019) Multicenter Optimization and Validation of a 2-Gene mRNA Urine Test for Detection of Clinically Significant Prostate Cancer Prior to Initial Prostate Biopsy. J Uro. doi: 10.1097/JU.0000000000000293.
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3. Knezevic et al., (2013) Analytical validation of the Oncotype DX prostate cancer assay – a clinical RT-PCR assay optimized for prostate needle biopsies. BMC Genomics

Prostate cancer precision diagnostics: menu and pipeline

