



mdxhealth®

Corporate Presentation
January 2025

Forward looking statement

This presentation contains forward-looking statements and estimates with respect to the anticipated future performance of mdxhealth and the market in which it operates. These statements are often, but are not always, made through the use of words or phrases such as “potential,” “expect,” “will,” “goal,” “next,” “potential,” “aim,” “explore,” “forward,” “future,” and “believes” as well as similar expressions. Forward-looking statements contained in this presentation include, but are not limited to, statements regarding the acquisition of Oncotype DX® GPS prostate cancer business from Exact Sciences including statements regarding the anticipated benefits of the acquisition; statements regarding expected future operating results; statements regarding product development efforts; and statements regarding our strategies, positioning, resources, capabilities and expectations for future events or performance. Such statements and estimates are based on assumptions and assessments of known and unknown risks, uncertainties and other factors, which were deemed reasonable but may not prove to be correct. Actual events are difficult to predict, may depend upon factors that are beyond the company’s control, and may turn out to be materially different. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results; product development efforts, our strategies, positioning, resources, capabilities and expectations for future events or performance. Important factors that could cause actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with global macroeconomic conditions; our ability to successfully and profitably market our products; the acceptance and reimbursement of our products and services by healthcare providers and payors; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; the possibility that the anticipated benefits from our business acquisitions like our acquisition of the Oncotype DX® GPS prostate cancer business will not be realized in full or at all or may take longer to realize than expected; and the amount and nature of competition for our products and services. Other important risks and uncertainties are described in the Risk Factors sections of our most recent Annual Report on Form 20-F and in our other reports filed with the Securities and Exchange Commission. The Company expressly disclaims any obligation to update any such forward-looking statements in this presentation to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based unless required by law or regulation. The Company obtained the industry, statistical and market data, including its general expectations, market position and market opportunity, in this presentation from its own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. The market data used in this presentation involves a number of assumptions and limitations. While the Company believes that the information from these industry publications, surveys and studies is reliable, the industry in which it operates is subject to a high degree of uncertainty and risk due to a variety of important factors. These and other factors could cause results to differ materially from those expressed in the estimates made by third parties and by the Company. This presentation does not constitute an offer or invitation for the sale or purchase of securities or assets of mdxhealth in any jurisdiction. No securities of mdxhealth may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. securities laws.

NOTE: *The mdxhealth logo, mdxhealth, Confirm mdx, Select mdx, Resolve mdx, Genomic Prostate Score, GPS and Monitor mdx are trademarks or registered trademarks of MDxHealth SA. All other trademarks and service marks are the property of their respective owners. The GPS test was formerly known as and is frequently referenced in guidelines, coverage policies, reimbursement decisions, manuscripts and other literature as Oncotype DX Prostate, Oncotype DX GPS, Oncotype DX Genomic Prostate Score, and Oncotype Dx Prostate Cancer Assay, among others. The Oncotype DX trademark, and all other trademarks and service marks, are the property of their respective owners.*

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/DiaSorin)
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



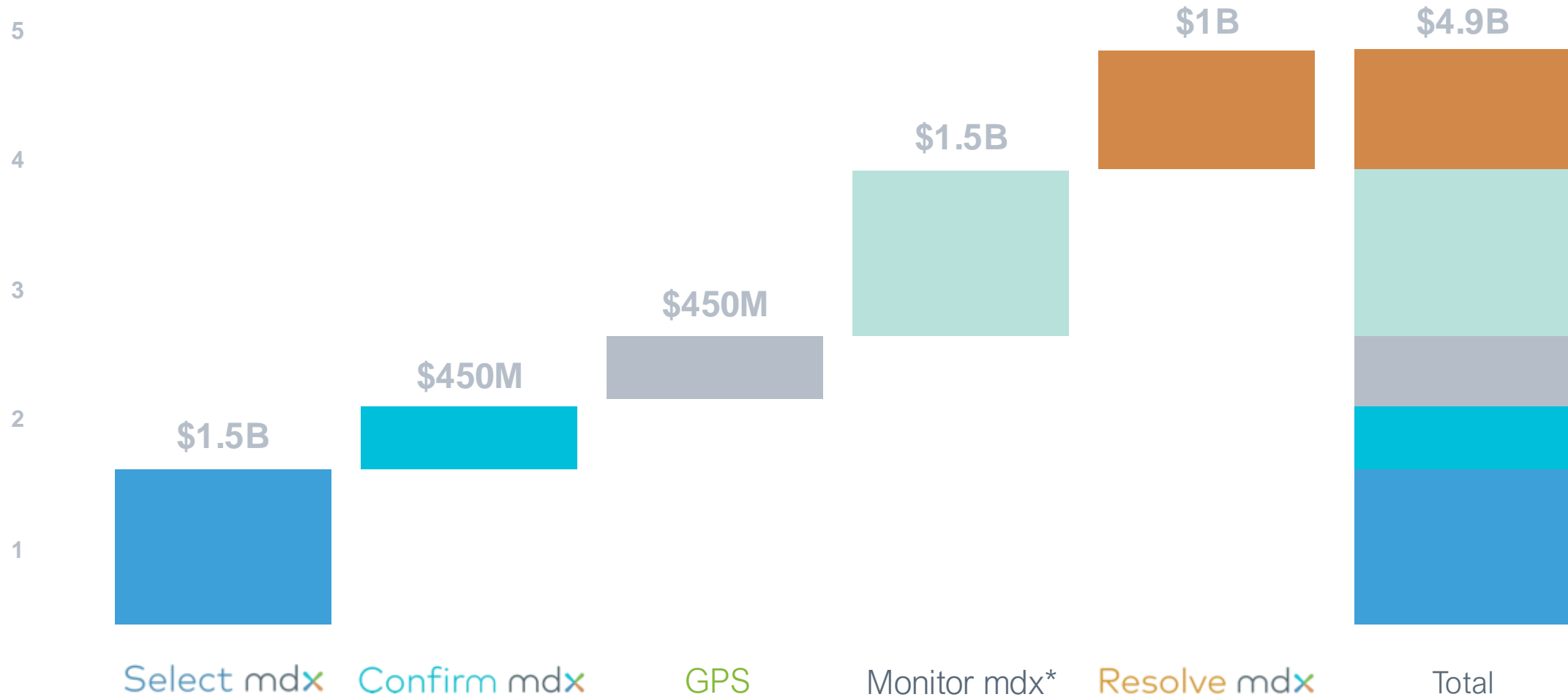
**Miriam
Reyes**

Executive Vice President
Laboratory Operations

Joined Mdxhealth in 2011
CombiMatrix
Agendia
Labcorp

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

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

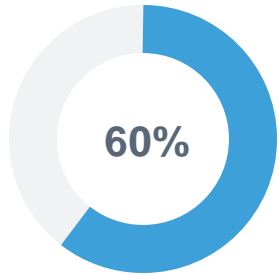
Genomic Prostate Score

Acquired August 2022

Resolve mdx
for Urinary Tract Infection

UTI test launched 2021

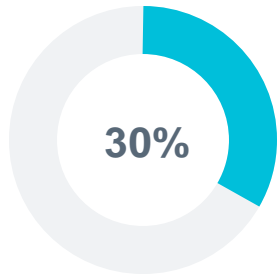
Current challenges with diagnosing prostate cancer



Prostate cancer screening

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

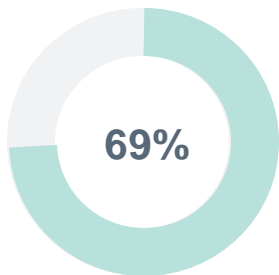
~60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization ⁽³⁻⁶⁾



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⁾

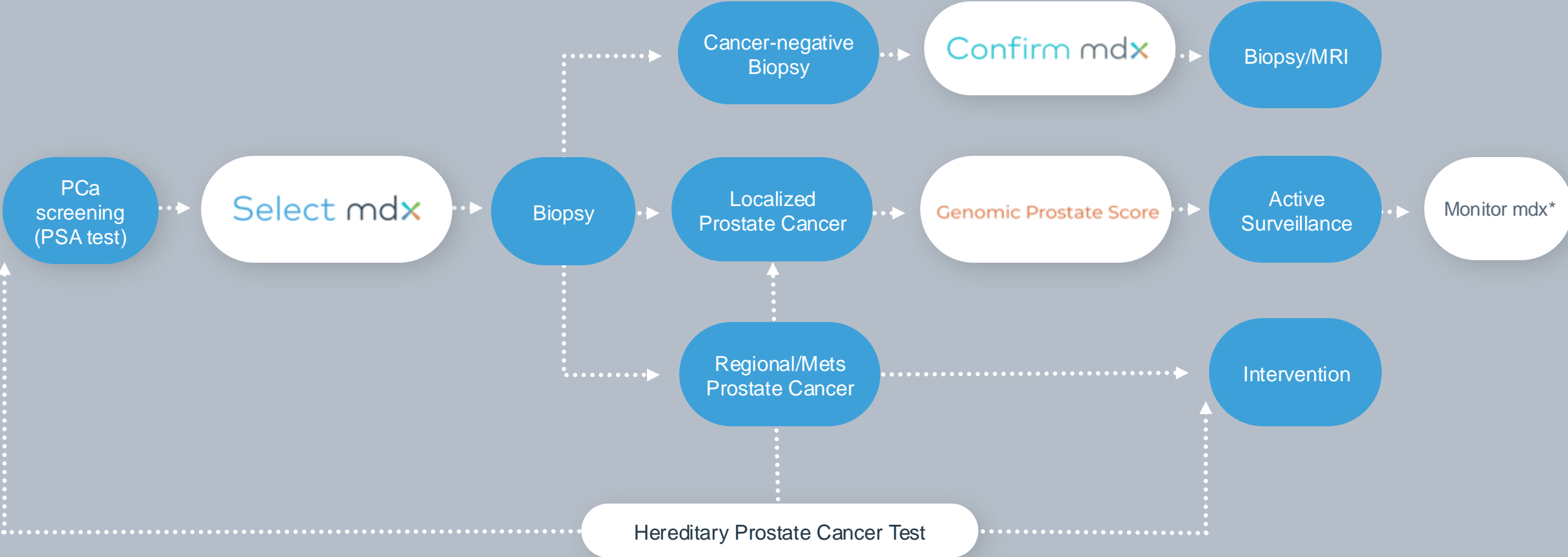
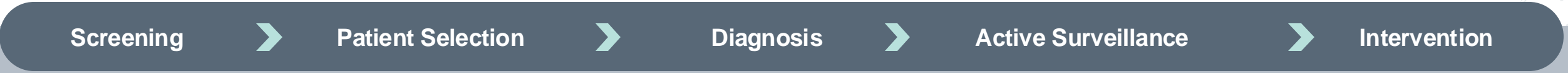
~69% of new prostate cancer diagnosis are localized; Active Surveillance or treatment decision ⁽⁸⁾

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

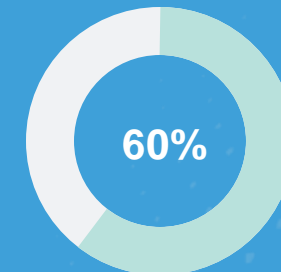


Negative



Routinely Monitor

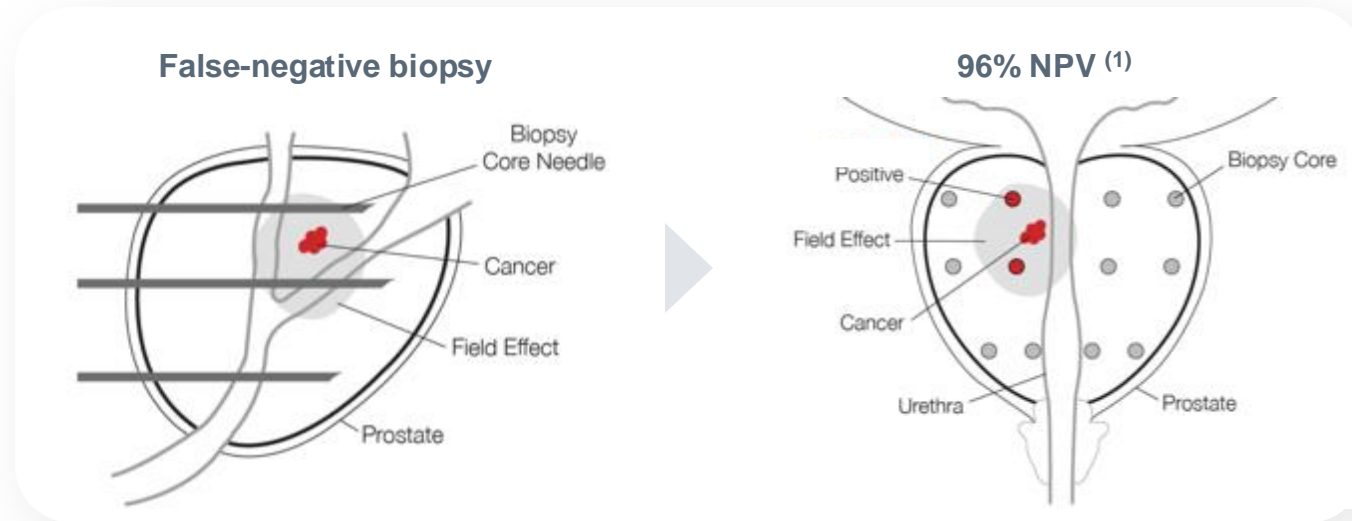
- **Non-invasive:** Urine-based “rule-out” test improves the diagnostic disposition of patients by avoiding unnecessary prostate biopsies
- **Accurate:** 95% negative predictive value ⁽¹⁾
- **Validated:** 12 published studies on genes and technology
- **Cost effective:** Potential to avoid invasive and 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⁾



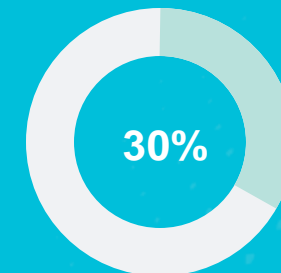
60% of initial biopsies do not reveal cancer ⁽⁵⁻⁸⁾

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)

- **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

How the test can help you



Low risk patients			High risk patients	
When to treat			How to treat	
Very low	Low	Favorable intermediate	Unfavorable intermediate	High
Provides additional information to help when deciding on whether to pursue active surveillance or more aggressive treatment options.			Provides information to help select 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

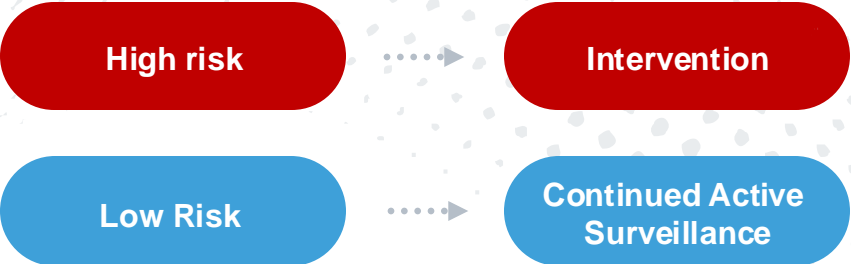
Est. market size
(men annually)

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

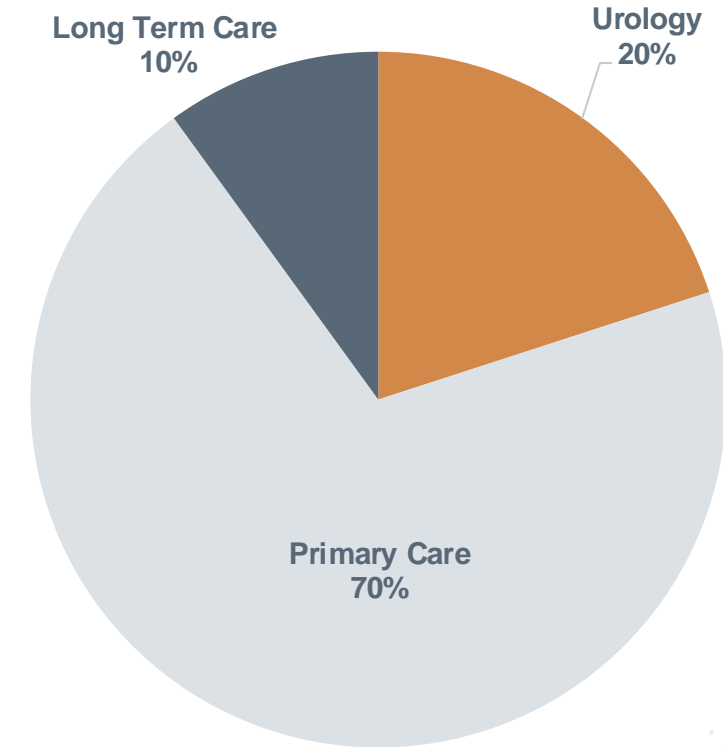
UTIs are the most common outpatient infection⁽¹⁾

- 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)

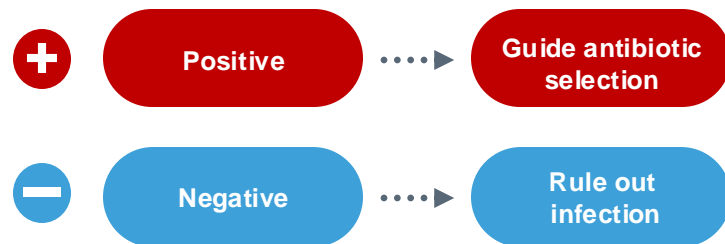
The addressable market for UTI testing in the urology segment is 2M tests⁽²⁾ annually, or \$1B⁽³⁾



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

Investor relations contact

LifeSci Advisors, LLC
US +1 949 271 9223
ir@mdxhealth.com

Global operations

US headquarters & laboratory
15279 Alton Parkway, Ste 100
Irvine, CA 92618
United States

EU headquarters
CAP Business Center
Rue d'Abhooz, 31
4040 Herstal, Belgium

References

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

1. MDxHealth management estimates
2. Welch. et. Al., Prostate-Specific Antigen Levels in the United States: Implications of Various Definitions for Abnormal. JNCI 2005.
3. NIH Cancer Trends Progress Report. July 2021. https://progressreport.cancer.gov/detection/prostate_cancer
4. NIH Surveillance, Epidemiology and end Results Program. July 2021. <https://seer.cancer.gov/statfacts/html/prost.html>.
5. Paul et. al. State of the Globe: Rising Antimicrobial Resistance of Pathogens in Urinary Tract Infection. J Glob Infect Dis. 2018.

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

1. NIH 6/10/2024 Website: <https://seer.cancer.gov/statfacts/html/prost.html>
2. Mdxhealth management estimates.
3. Moyer VA, U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;157:120–134.
4. 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.
5. Loeb et al. European Urology 2013.
6. Loeb et al. Journal of Urology 2011.
7. Stewart et al. Journal of Urology 2013.
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.
2. Govers TM, et al. (2018) Cost-Effectiveness of Urinary Biomarker Panel in Prostate Cancer Risk Assessment. J Urol. doi: 10.1016/j.juro.2018.07.034A.
3. 2022 National Cancer Center Network Guidelines. Early Detection for Prostate Cancer. Version 1.2022 – July 16, 2022.
4. 2021 European Association of Urology Prostate Cancer Guidelines.
5. Moyer VA, U.S. Preventive Services Task Force. Screening for prostate cancer: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2012;157:120–134.
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.
7. Loeb et al. European Urology 2013.
8. Loeb et al. Journal of Urology 2011.

References

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.
2. Aubry. Et al., Budget Impact Model: Epigenetic Assay Can Help Avoid Unnecessary Repeated Biopsies and Reduce Healthcare Spending. American Health & Drug Benefits 2013.
3. 2022 National Cancer Center Network Guidelines. Early Detection for Prostate Cancer. Version 1.2022 – July 16, 2022.
4. 2021 European Association of Urology Prostate Cancer Guidelines.
5. Stewart et al., Clinical Utility of an Epigenetic Assay to Detect Occult Prostate Cancer in Histopathologically Negative Biopsies: Results of the MATLOC Study. Journal of Urology

References

Slide 12 –(f/k/a Oncotype DX) Genomic Prostate Score (GPS) to guide treatment decisions for localized prostate cancer

1. Brooks MA, et al. Validating the association of adverse pathology with distant metastasis and prostate cancer mortality 20-years after radical prostatectomy. *Urol Oncol*. 2022;40(3):104.e1-104.e7.
2. Mehralivand S, et al. A grading system for the assessment of risk of extraprostatic extension of prostate cancer at multiparametric MRI. *Radiology*. 2019;290(3):709-719.
3. Brooks MA et al. GPS assay association with long-term cancer outcomes: twenty-year risk of distant metastasis and prostate cancer-specific mortality. *JCO Precis Oncol*. 2021;5:PO.20.00325.
4. Cullen J, et al.,. The 17-gene genomic prostate score test as a predictor of outcomes in men with unfavorable intermediate risk prostate cancer. *Urology*. 2020;143:103-111.
5. Klein EA, et al. A 17-gene assay to predict prostate cancer aggressiveness in the context of Gleason grade heterogeneity, tumor multifocality, and biopsy undersampling. *Eur Urol*. 2014;66(3):550-560.
6. Cullen J, et al. A biopsy-based 17-gene genomic prostate score predicts recurrence after radical prostatectomy and adverse surgical pathology in a racially diverse population of men with clinically low- and intermediate-risk prostate cancer. *Eur Urol*. 2015;68(1):123-131.
7. Van Den Eeden SK, et al. A biopsy-based 17-gene genomic prostate score as a predictor of metastases and prostate cancer death in surgically treated men with clinically localized disease. *Eur Urol*. 2018;73(1):129-138.
8. Eggener S,, et al. A 17-gene panel for prediction of adverse prostate cancer pathologic features: prospective clinical validation and utility. *Urology*. 2019;126:76-82.
9. Lin DW, et al. 17-gene genomic prostate score test results in the Canary Prostate Active Surveillance Study (PASS) cohort. *J Clin Oncol*. 2020;38(14):1549-1557.
10. Badani KK,, et al. The impact of a biopsy based 17-gene genomic prostate score on treatment recommendations in men with newly diagnosed clinically prostate cancer who are candidates for active surveillance. *Urol Pract*. 2015;2(4), 181-189.
11. Dall'Era MA, et al.,. Utility of the Oncotype DX® prostate cancer assay in clinical practice for treatment selection in men newly diagnosed with prostate cancer: a retrospective chart review analysis. *Urol Pract*. 2015; 2(6), 343-348.
12. Albala D, et al. Health economic impact and prospective clinical utility of Oncotype DX® Genomic Prostate Score. *Rev Urol*. 2016;18(3):123-132.
13. Eure G, et al. Use of a 17-gene prognostic assay in contemporary urologic practice: results of an interim analysis in an observational cohort. *Urology*. 2017;107:67-75.
14. Lynch JA, et al. Improving risk stratification among veterans diagnosed with prostate cancer: impact of the 17-gene prostate score assay. *Am J Manag Care*. 2018;24(1 Suppl):S4-S10.
15. Leapman MS, et al. Association between a 17-gene genomic prostate score and multiparametric prostate MRI in men with low and intermediate risk prostate cancer (PCa). *PLoS One*. 2017;12(10):e0185535.
16. Kornberg Z, et al. Genomic Prostate Score, PI-RADS™ version 2 and progression in men with prostate cancer on active surveillance. *J Urol*. 2019;201(2):300-307.
17. Salmasi A, et al. A 17-gene genomic prostate score assay provides independent information on adverse pathology in the setting of combined multiparametric magnetic resonance imaging fusion targeted and systematic prostate biopsy. *J Urol*. 2018;200(3):564-572.
18. Magi-Galluzzi C, et al. The 17-gene genomic prostate score assay predicts outcome after radical prostatectomy independent of PTEN status. *Urology*. 2018;121:132-138.
19. Cullen J, et al. Multicenter comparison of 17-gene genomic prostate score as a predictor of outcomes in African American and Caucasian American men with clinically localized prostate cancer. *J Urol*. 2021;205(4):1047-1054.
20. Murphy AB, et al. A 17-gene panel genomic prostate score has similar predictive accuracy for adverse pathology at radical prostatectomy in African American and European American men. *Urology*. 2020;142:166-173.
21. Moschovas M, et al. Association between Oncotype DX genomic prostate score and adverse tumor pathology after radical prostatectomy. *Eur Urol Focus*. 2021;S2405-4569(21)00094-8.
22. Aboushwareb, et al. Active surveillance or watchful waiting in clinically low-risk prostate cancer patients in the SEER database with and without an Oncotype Dx genomic prostate score assay. *J Urol*. 2021;206(3S):e1094 (MP62-06).
23. Brand TC, et al. Patient-specific meta-analysis of 2 clinical validation studies to predict pathologic outcomes in prostate cancer using the 17-gene genomic prostate score *Urology*. 2016;89:69-75.

References

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

1. Medina M, Castillo-Pino E. An introduction to the epidemiology and burden of urinary tract infections. *Ther Adv Urol*. 2019;11:1756287219832172. Published 2019 May 2. doi:10.1177/1756287219832172.
2. Flores-Mireles AL, Walker JN, Caparon M, Hultgren SJ. Urinary tract infections: epidemiology, mechanisms of infection and treatment options. *Nat Rev Microbiol*. 2015;13(5):269-284. doi:10.1038/nrmicro3432.
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



Transactions of the
American Clinical and Climatological Association

The Prostate

**AMERICAN HEALTH
& DRUG BENEFITS**

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



UROLOGYPRACTICE[®]
An Official Journal of the American Urological Association

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.000000000000293.
2. Van Neste, et al. (2016) Risk Score Predicts High-Grade Prostate Cancer in DNA-Methylation Positive, Histopathologically Negative Biopsies. J Urology.
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

Product name	Sample type	Clinical decision	R&D	Validation	Launch	Expanded coverage and utilization	
Confirm mdx	Tissue	Post biopsy	Progress bar spanning R&D, Validation, and Launch phases.				
Select mdx	Urine	Pre biopsy	Progress bar spanning R&D and Validation phases.				
GPS	Tissue	AS or treatment intensity	Progress bar spanning R&D, Validation, and Launch phases.				
Monitor mdx	TBD	AS Monitoring	Progress bar spanning R&D phase.				