mdxhealth®

# Corporate Presentation

March 2024

# 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, all of which involve certain risks and uncertainties. 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. 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 the coronavirus (COVID-19) pandemic, including its possible effects on our operations, and the demand for our products; our ability to successfully and profitably market our products; the acceptance of our products and services by healthcare providers; our ability to achieve and maintain adequate levels of coverage or reimbursement for our current and future solutions we commercialize or may seek to commercialize; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; our ability to obtain and maintain regulatory approvals and comply with applicable regulations; timing, progress and results of our research and development programs; the period over which we estimate our existing cash will be sufficient to fund our future operating expenses and capital expenditure requirements; 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. MDxHealth expressly disclaims any obligation to update any such forward-looking statements in this 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. This 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.*

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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

Nasdaq

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/DiaSornin)
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
Lab `Corp

**Jason Poole**

Chief Scientific Officer

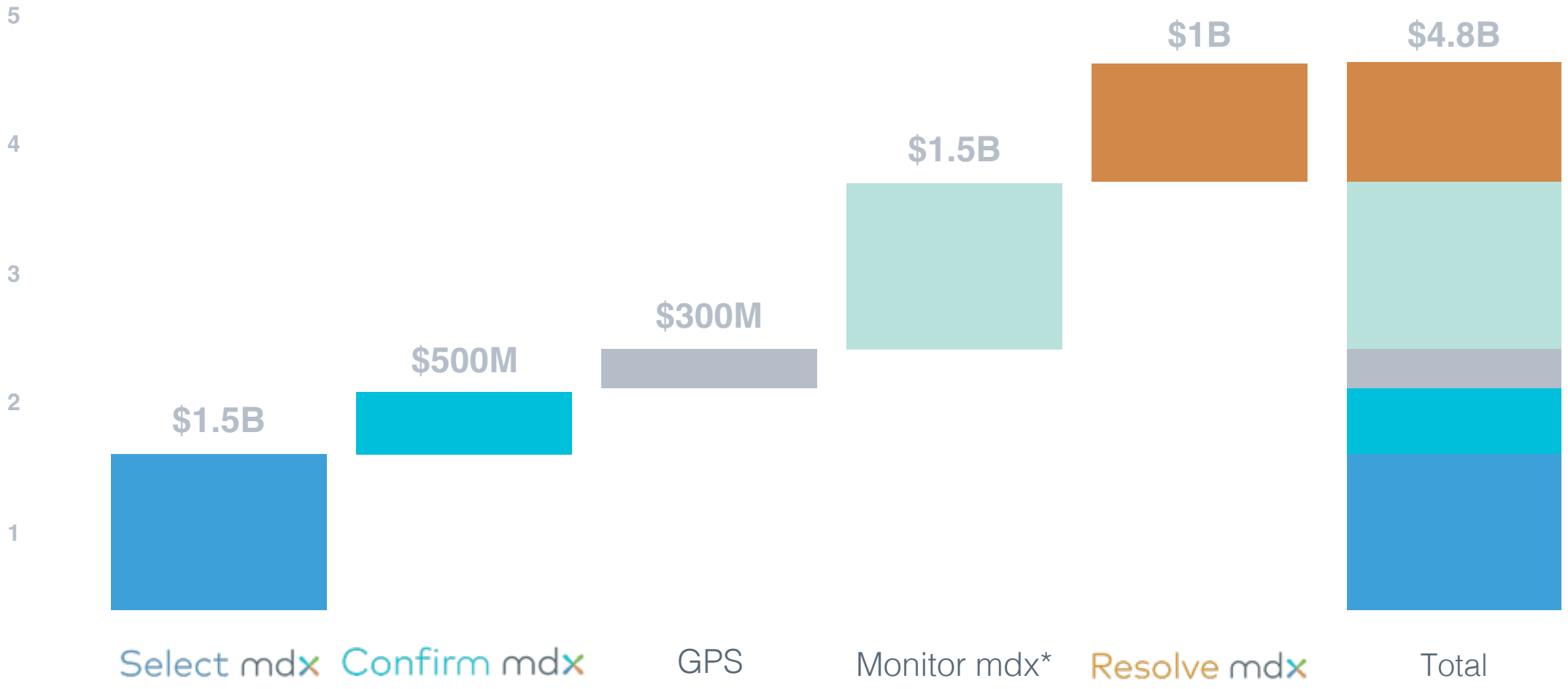
**Joined Mdxhealth in 2023**
Active Motif
Biocept
Trovagene



# Our menu addresses a $4.8B U.S. market opportunity

Comprehensive Urology Menu

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*In development (Based on management estimates)

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# Commercial levers to drive growth

Best-in-class offering into urology with menu of the most accurate clinically-actionable tests for patients and urologists

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 and other urologic diseases

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

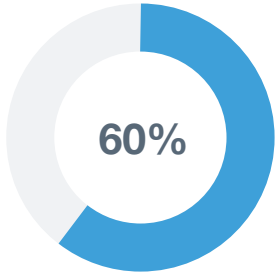
UTI test launched 2021



# Current challenges with diagnosing prostate cancer

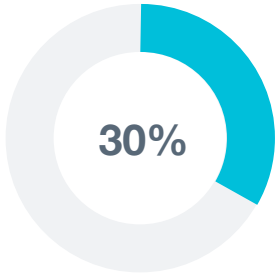
**Prostate cancer is the most common cancer and the 2nd deadliest cancer in U.S. men [1]**




## Prostate cancer screening

3 million elevated PSA results annually [1-2]

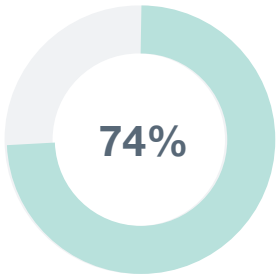
60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization [3-6]




## 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

268,000 prostate cancers diagnosed annually [8]

74% of new prostate cancer diagnosis are localized; Active Surveillance or treatment decision [8]

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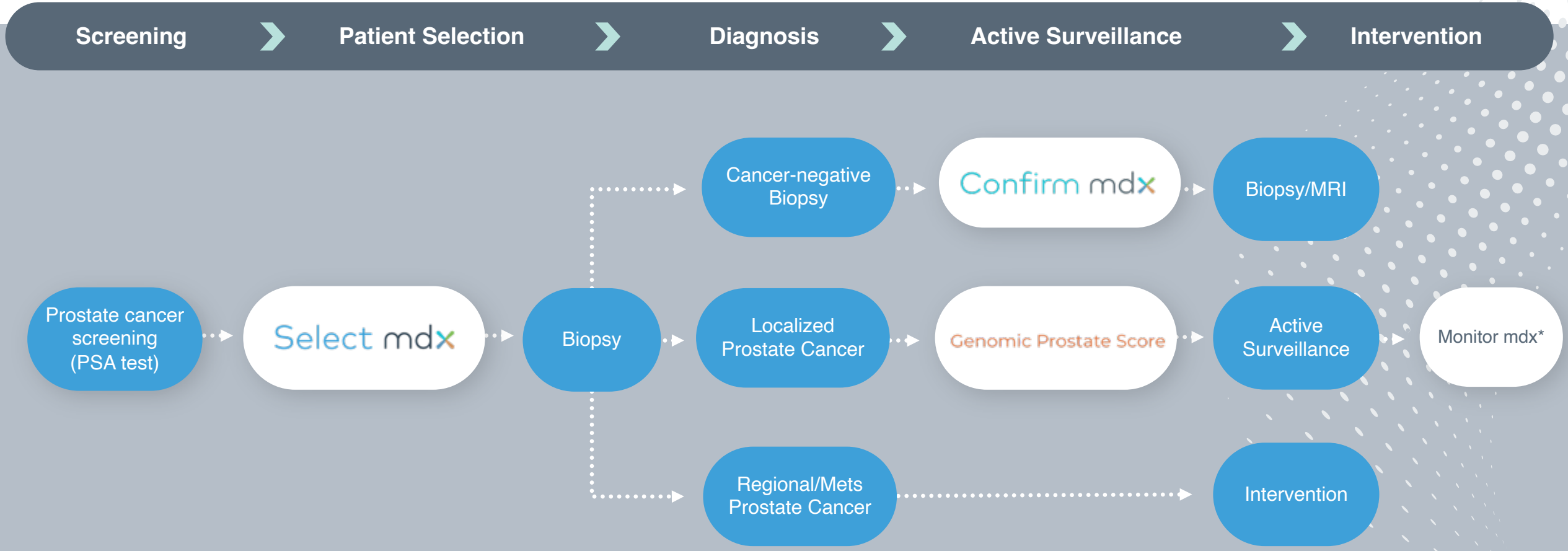
# Expanding menu in the prostate cancer diagnostic pathway

The most comprehensive menu in prostate cancer




mdxhealth *in development

# 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?

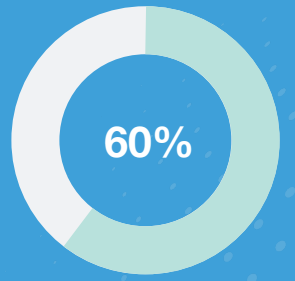
**95% NPV**

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)**

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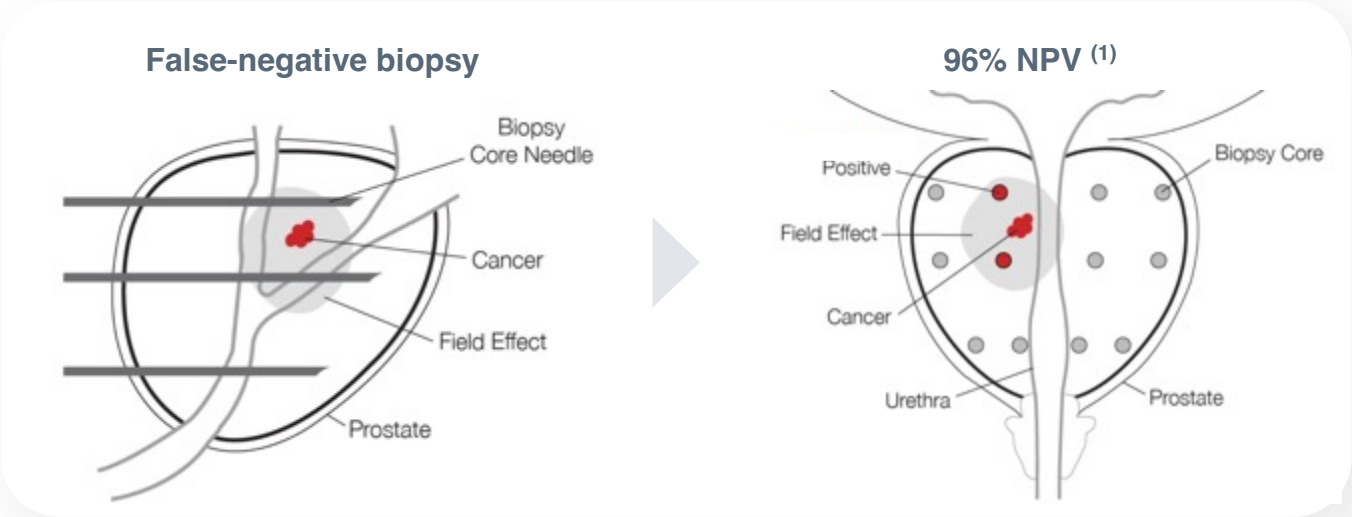
# Confirm mdx improves diagnostic confidence of biopsy result

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




**Positive** → **Biopsy/MRI**

**Negative** → **Avoid Biopsy/MRI**

- **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)**

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# 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
- **National guidelines:** Included in NCCN guidelines [24]

**How the test can help you**


**Low Risk** ····▶ **Active Surveillance**

**High Risk** ····▶ **Treatment Intensity**

| 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 agressive treatment options. | | | Provides information to help select treatment intensity. | |

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# Prostate cancer pipeline

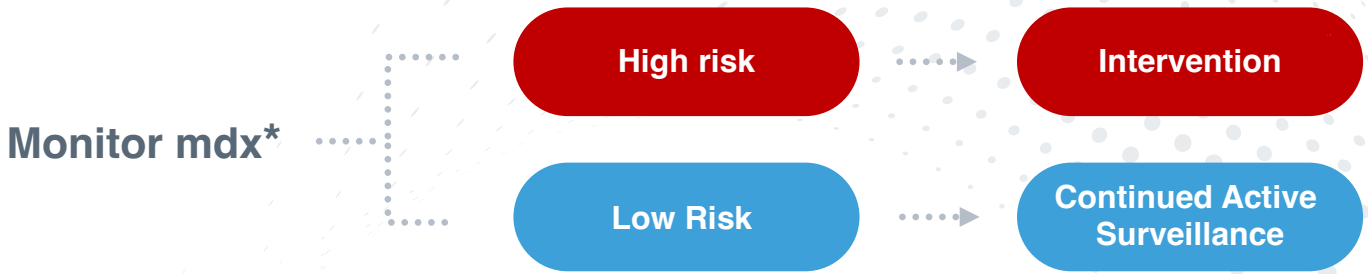
Active surveillance monitoring
(Localized prostate cancer)

**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

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*In development

# Urinary Tract Infection (UTI) annual market opportunity

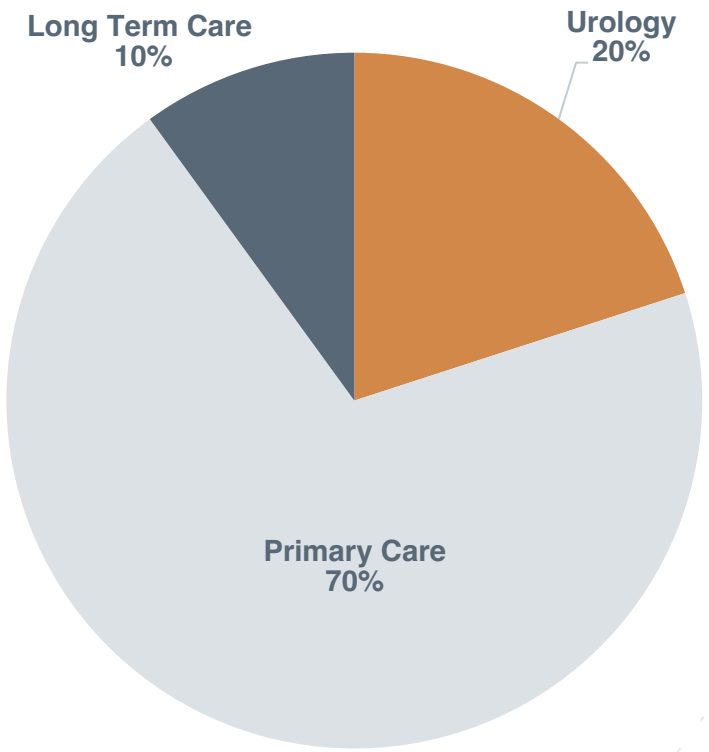
## UTIs are the most common outpatient infection[1]

- 10 million suspected UTI cases present annually[2]
- 20% of volume presents to urology*

## 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***

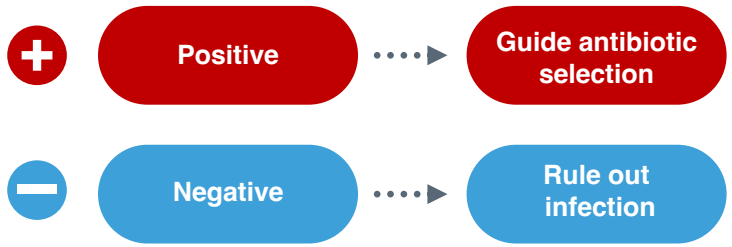



U.S. Market for UTI*

*management estimates

# 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 quantities 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

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# Selected Financial Data

| USD in thousands | Three months ended (unaudited) Dec 31, 2023 | Dec 31, 2022 | % Change | Year ended (unaudited) Dec 31, 2023 | Dec 31, 2022 | % Change |
|---|---|---|---|---|---|---|
| Total revenue | $19,398 | $12,891 | +50% | $70,193 | $37,054 | +89% |
| Total revenue (excl. GPS) | n/a | n/a | - | $39,289 | $27,720 | +42% |
| Gross profit | $12,671 | $7,224 | +75% | $43,929 | $19,219 | +129% |
| Gross profit % | 65.3% | 56.0% | +9.3pp | 62.6% | 51.9% | +10.7pp |
| Net loss | ($10,720)[1] | ($12,438) | (14%) | ($43,100)[1] | ($44,044) | (2%) |
| EPS[2] | $(0.39) | $(0.76) | (48%) | $(1.66) | $(2.78) | (40%) |

[1] Includes non-cash financial expenses of $4.0 million and $11.6 million for the three and twelve-month periods, respectively

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

## Unaudited Year-End Results and 2024 Guidance:

- 2024 revenue guidance of $79-81 million (representing year-over-year revenue growth of approximately 13-15%)

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# 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 $79-$81M

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

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6. Loeb et al. Journal of Urology 2011.
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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**

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**Slide 11 – ConfirmMDx improves diagnostic confidence of biopsy result**

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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**


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**Slide 16 – U.S. Urinary Tract Infection (UTI) annual market opportunity**

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# 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 |

BMC Urology

THE JOURNAL of UROLOGY

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 |

BMC Genomics

EUROPEAN UROLOGY

UROLOGY

American Urological Association 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.0000000000000293.
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 |
|---|---|---|
| Confirm mdx | Tissue | Post biopsy |
| Select mdx | Urine | Pre biopsy |
| GPS | Tissue | AS or treatment intensity |
| Monitor mdx | TBD | AS Monitoring |