

mdxhealth®



**Corporate Presentation**  
September 2022

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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**



Ticker: **MDXH.BR**

# mdxhealth fundamentals for growth



## Fundamentals in place

- The most 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 Oncotype DX)
- Expanding coverage of current menu (Select mdx LCD published)
- Expanding US commercial footprint



## Established focus & execution

- World-class CLIA certified lab operation
- Best-in-class commercial channel into urology
- Urinary Tract Infection opportunity validated



## Potential opportunities

- Select mdx point of care testing
- Expanded channel outside of urology
- Pipeline: 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  
Mabcare



**John  
Bellano**

Chief Commercial Officer

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



**Miriam  
Reyes**

Executive Vice President  
Laboratory Operations

**Joined Mdxhealth in 2011**  
CombiMatrix  
Agendia  
LabCorp



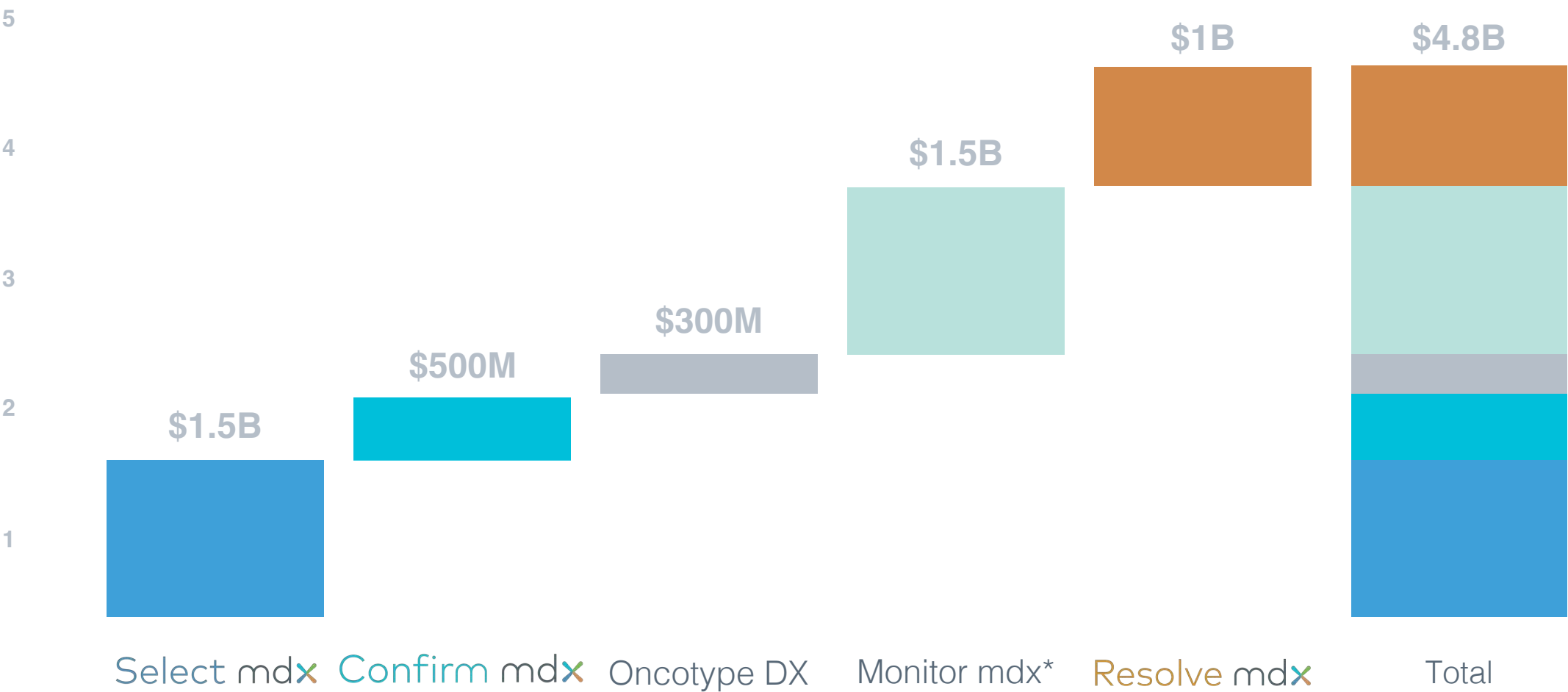
**Joseph  
Sollee**

Executive Vice President  
Corp. Dev. General Counsel

**Joined mdxhealth in 2008**  
Triangle Pharmaceuticals  
TherapyEdge

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

Comprehensive Urology Menu



# 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' Oncotype DX 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

**oncotype dx<sup>®</sup>**  
**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 <sup>(1)</sup>

A circular progress indicator with a blue arc representing 60% completion.

60%

## Prostate cancer screening

3 million elevated PSA results annually <sup>(1-2)</sup>

60% of biopsies DO NOT reveal cancer and may lead to increased complications and hospitalization <sup>(3-6)</sup>

A circular progress indicator with a teal arc representing 30% completion.

30%

## Prostate cancer diagnosis

500,000 men undergo biopsies annually <sup>(2)</sup>

30% of cancer-negative biopsies are false negatives, meaning these patients actually have cancer <sup>(7)</sup>

A circular progress indicator with a teal arc representing 74% completion.

74%

## Prostate cancer risk stratification

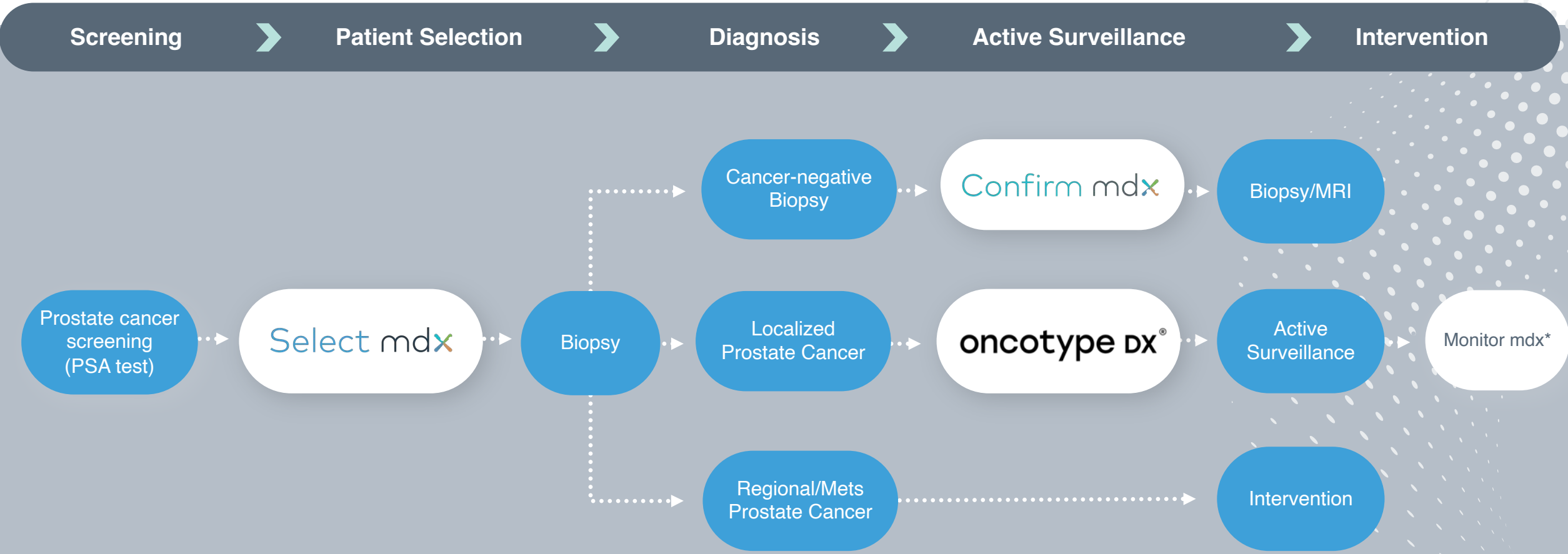
268,000 prostate cancers diagnosed annually <sup>(8)</sup>

74% of new prostate cancer diagnosis are localized; Active Surveillance or treatment decision <sup>(8)</sup>



# Expanding menu in the prostate cancer diagnostic pathway

The most comprehensive menu 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<sup>®</sup>

Binary actionable results for patient and HCP



Positive



Biopsy



Negative



Routinely Monitor

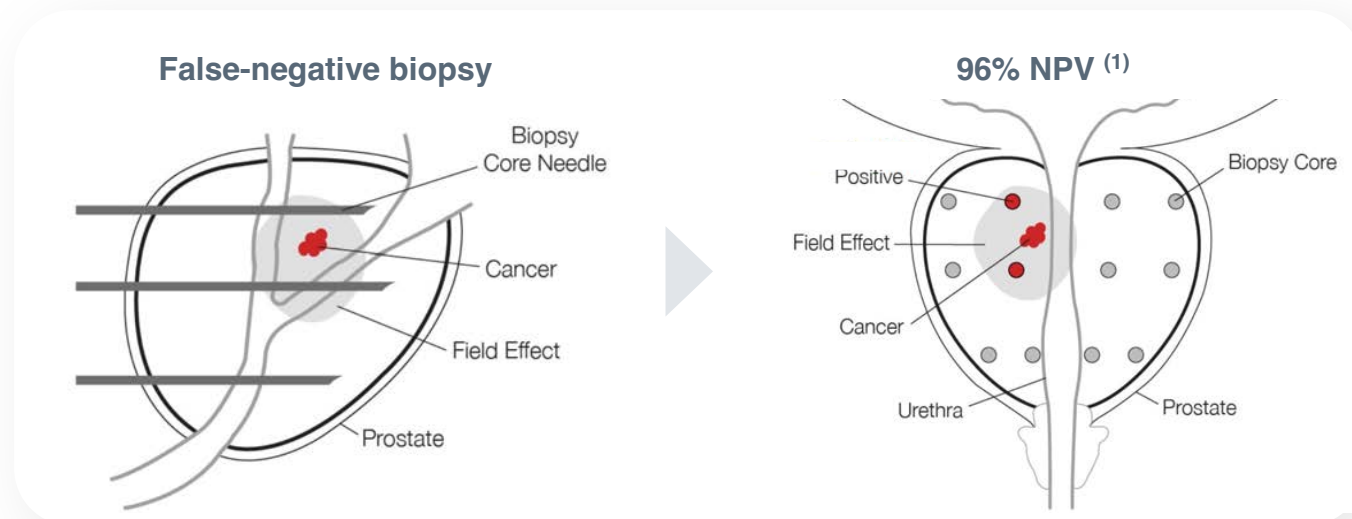
- **Non-invasive:** Urine-based “rule-out” test improves the diagnostic disposition of patients by avoiding unnecessary prostate biopsies
- **Accurate:** 95% negative predictive value <sup>(1)</sup>
- **Validated:** 12 published studies on genes and technology
- **Cost effective:** Potential to avoid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

60%

**60% of initial biopsies do not reveal cancer** <sup>(5-8)</sup>

# 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 <sup>(1)</sup>
- **Validated:** Over 55 published studies on genes and technology
- **Cost effective:** Potential annual U.S. health system savings of \$500K per 1M covered patients <sup>(2)</sup>
- **National guidelines:** Included in EAU and NCCN guidelines <sup>(3-4)</sup>

30%

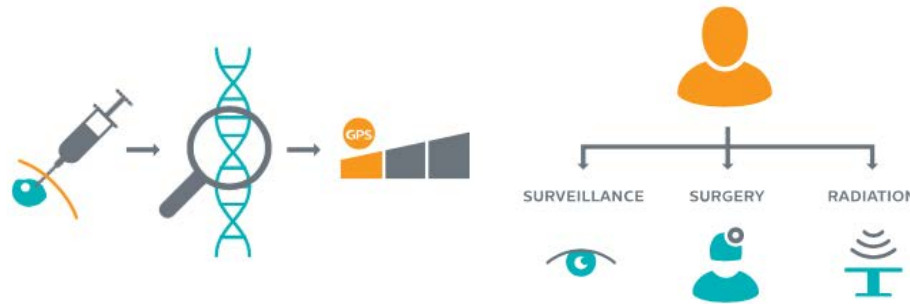
30% of men with a cancer-negative biopsy result actually have cancer <sup>(5)</sup>

# Oncotype DX 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 <sup>(1-23)</sup>

- **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 <sup>(24)</sup>

How the test can help you



## 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
--------------------------	------

Provides information to help select treatment intensity.

Low Risk



Active Surveillance

High Risk



Treatment Intensity

# Prostate cancer pipeline

Active surveillance monitoring  
(Localized prostate cancer)

1.5M

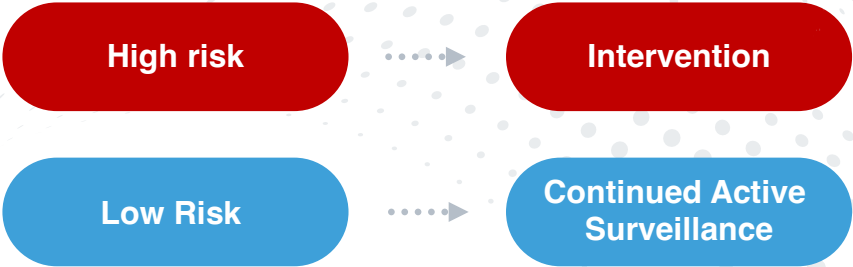
Est. market size  
(men annually)

## 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

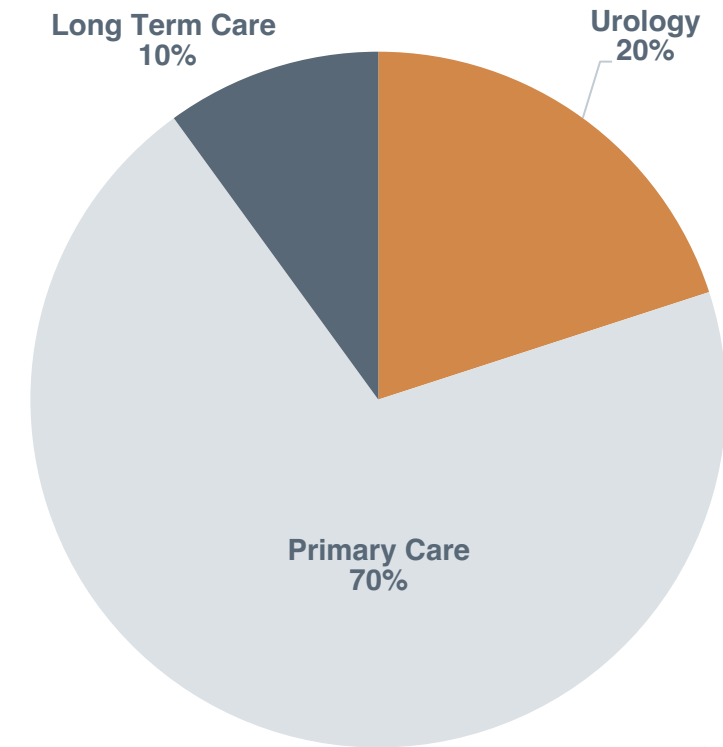
## UTIs are the most common outpatient infection<sup>(1)</sup>

- 10 million suspected UTI cases present annually<sup>(2)</sup>
- 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)

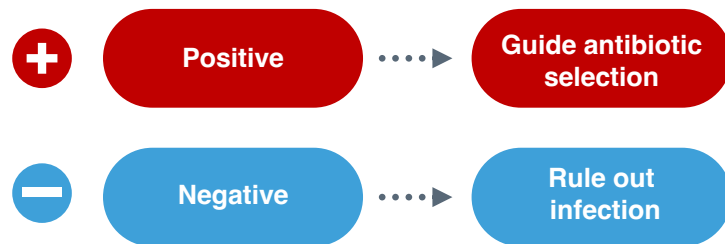
**The addressable market for UTI testing in the urology segment is 2M tests<sup>(2)</sup> annually, or \$1B\***



**U.S. Market for UTI\***

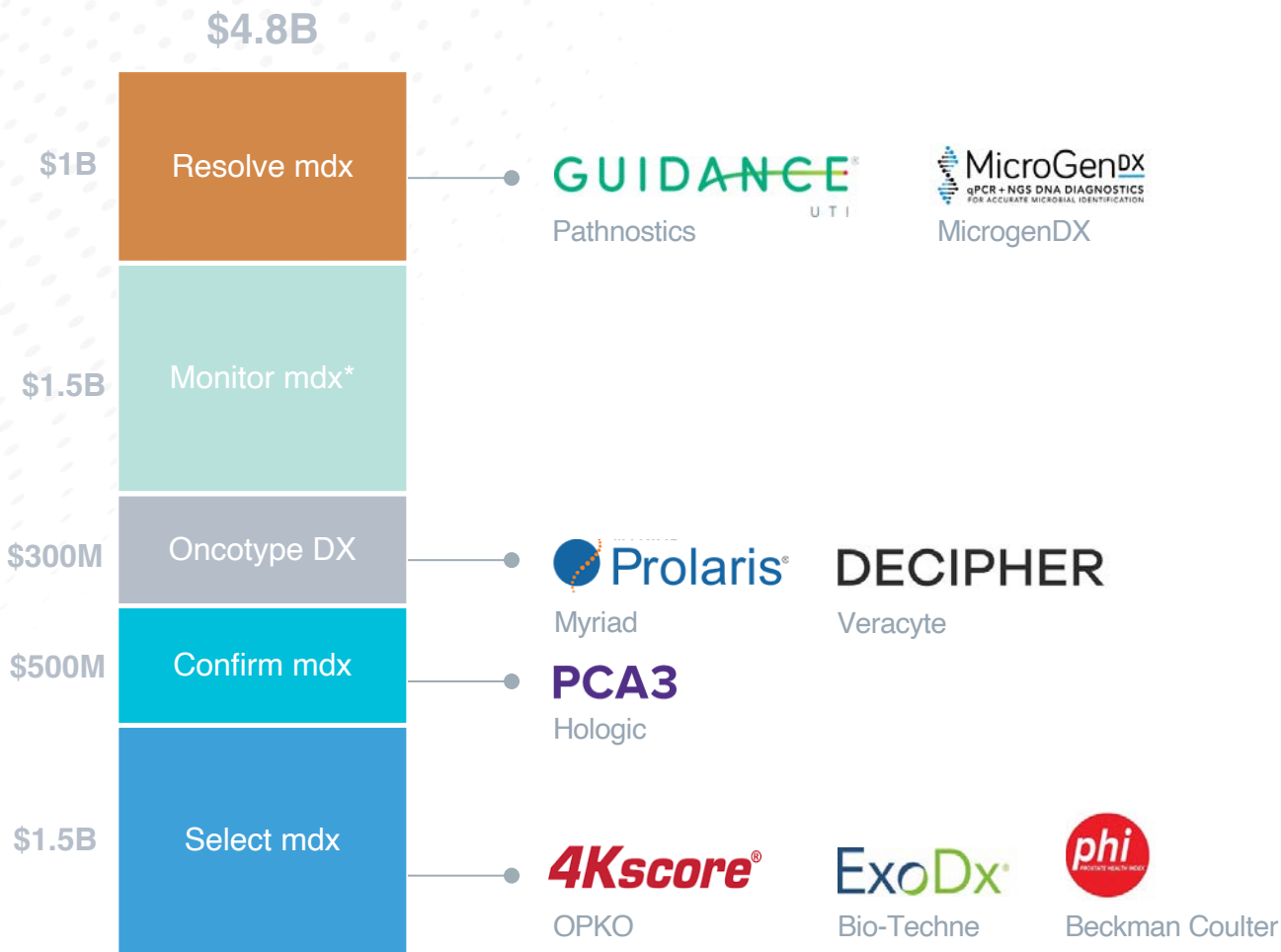
# Resolve mdx: Advance molecular urinary tract infection testing

- 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

# Broad urology-focused menu provides opportunity for growth



# mdxhealth is well-positioned for sustainable growth and value creation

01

## **Large total addressable market**

Selling clinically-actionable diagnostic tests to urologists represents a multi-billion-dollar addressable market opportunity

02

## **Broad menu provides sustainable growth potential**

Generating revenue from clinically-proven commercial products; growth to occur via commercial execution, expanded menu and improved channel access

03

## **Proprietary position into urology call point enables additional growth via menu expansion**

Continuing to pursue growth opportunities through R&D and business development

04

## **Leadership team with commercial focus**

Implementing proven strategies to support growth while maintaining operating cost discipline

# Thank you

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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.
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.0000000000000293.
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7. Loeb et al. *European Urology* 2013.
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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.*
2. Aubry. Et al., Budget Impact Model: Epigenetic Assay Can Help Avoid Unnecessary Repeated Biopsies and Reduce Healthcare Spending. *American Health & Drug Benefits* 2013.
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4. 2021 European Association of Urology Prostate Cancer Guidelines.
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## Slide 12 – Oncotype DX Genomic Prostate Score (GPS) to guide treatment decisions for localized prostate cancer

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# References

## **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



## 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



# Oncotype DX robust clinical evidence

Over 20 published clinical validation and utility studies



## 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 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
Validation of clinical utility/actionability	
Cost savings by decreasing unnecessary immediate treatment	Albala et al., 2016



# Select mdx, Confirm mdx and Oncotype DX technology

The most comprehensive menu in prostate cancer

	Select mdx <sup>(1)</sup>	Confirm mdx <sup>(2)</sup>	Oncotype DX <sup>(3)</sup>
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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# 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				
Select mdx	Urine	Pre biopsy				
Oncotype DX	Tissue	AS or treatment intensity				
Monitor mdx	TBD	AS Monitoring				