

December 2021

# Corporate Presentation

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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 is dedicated to providing highly accurate and clinically actionable urologic solutions to inform patient diagnosis and treatment while improving healthcare economics for payers and providers

**MDxHealth<sup>®</sup>**



Ticker: MDXH



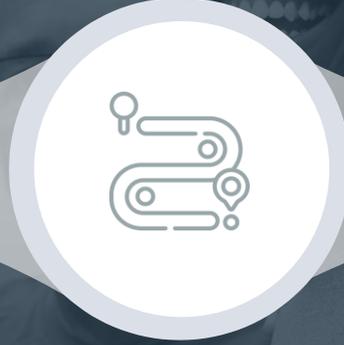
Ticker: MDXH.BR

# • Strategy and focus



## Commercial execution

- Experienced leadership based in focus and execution
- Operating discipline instituted through new leadership and all drivers of the P&L



## Payer coverage & guidelines

- ConfirmMDx covered by Medicare & commercial payers
- SelectMDx draft Medicare LCD published in 2021
- SelectMDx & ConfirmMDx included in National Comprehensive Cancer Network (NCCN) Guidelines



## Established commercial channel

- Leveraging direct US urology sales force
- Expanding urologic menu into:
  - Active surveillance for prostate cancer
  - Urinary Tract Infection testing
- Capable of driving additional opportunities into urology

**MDxHealth is well-positioned for sustainable growth & value creation**

# Experienced leadership team

Track record of success



**Michael K.  
McGarrity**

Chief Executive Officer

**Joined MDxHealth in 2019**  
Nanosphere  
Stryker



**Ron  
Kalfus**

Chief Financial Officer

**Joined MDxHealth in 2019**  
Rosetta Genomics  
Mabcure



**John  
Bellano**

Chief Commercial Officer

**Joined MDxHealth in 2019**  
Assurex Health  
Roche Diagnostics



**Miriam  
Reyes**

Executive Vice President  
Laboratory Operations

**Joined MDxHealth in 2011**  
CombiMatrix  
Agendia  
LabCorp

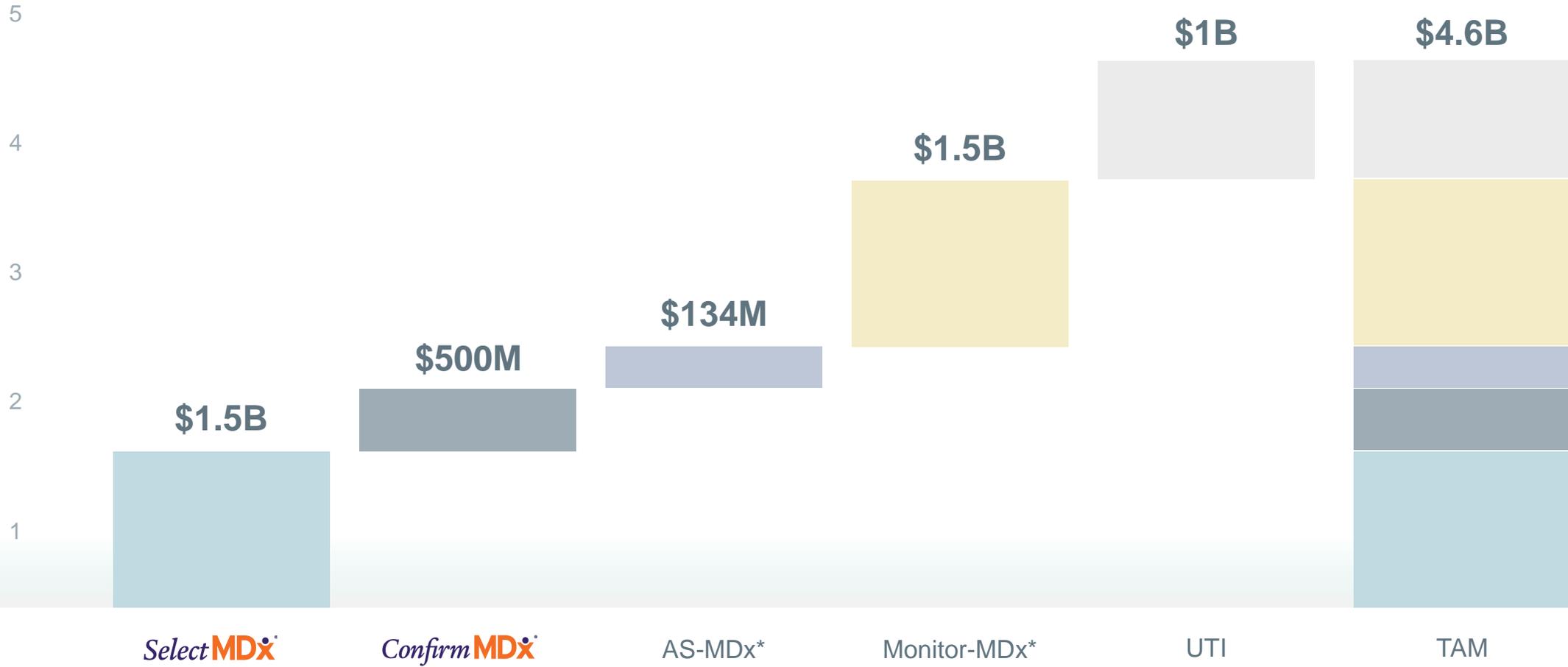


**Joseph  
Sollee**

Executive Vice President  
Corp. Dev. & General Counsel

**Joined MDxHealth in 2008**  
Triangle Pharmaceuticals  
TherapyEdge

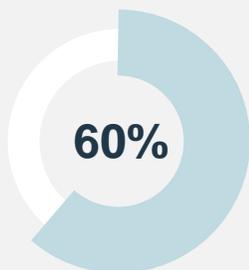
# Our menu addresses a \$4.6B U.S. market opportunity



# Current challenges with diagnosing prostate cancer in the U.S.

## Prostate cancer screening

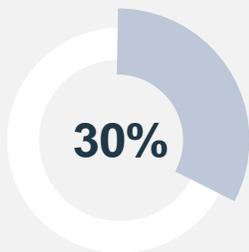
3 million elevated PSA results annually <sup>(1-2)</sup>



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

## Prostate cancer diagnosis

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

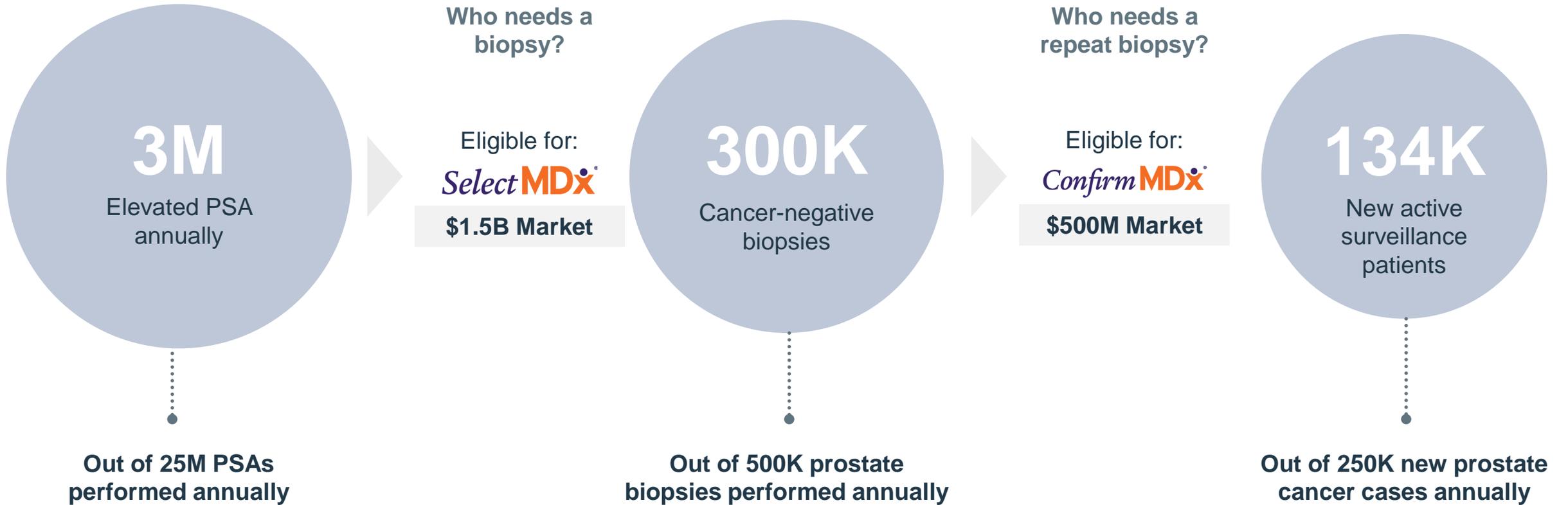


30% of cancer-negative biopsies are false negatives, meaning these patients actually have cancer <sup>(7)</sup>

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



# \$2B current U.S. prostate cancer market opportunity



# MDxHealth's proprietary prostate cancer menu

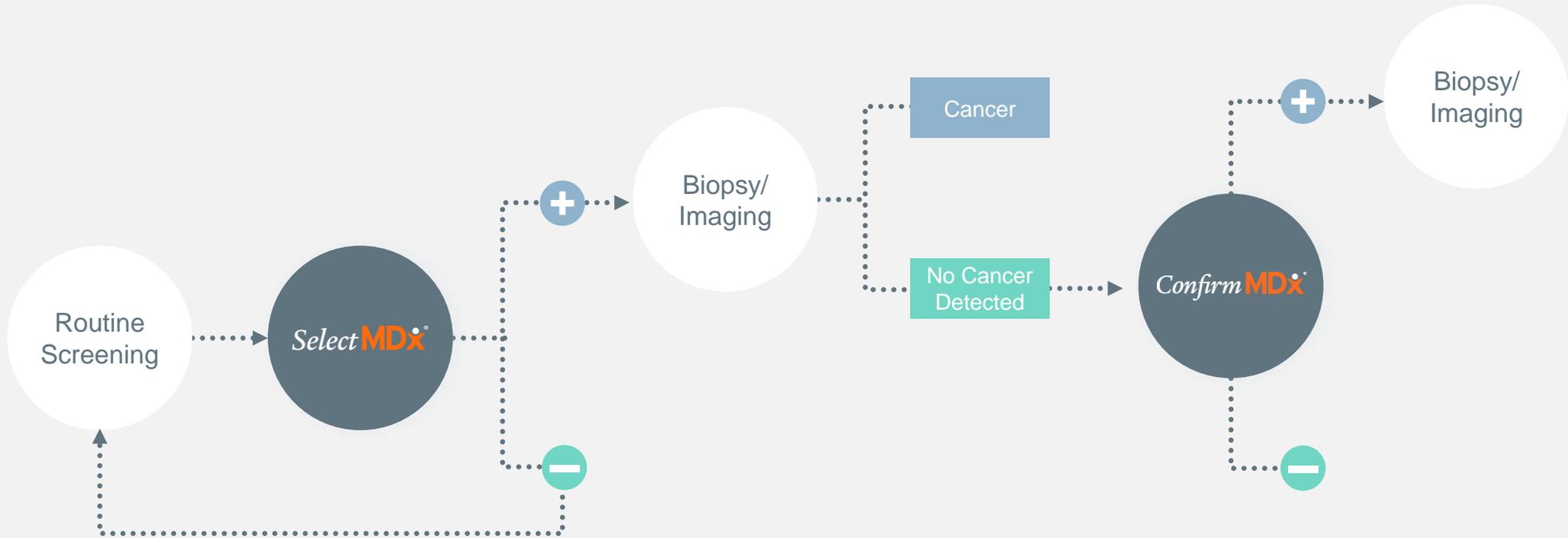
Clinical pathway for diagnosing aggressive prostate cancer

*Select* MDx

Improving the decision for **initial** prostate biopsy

*Confirm* MDx

Improving the decision for **repeat** prostate biopsy



# SelectMDx 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

**SelectMDx**  
for Prostate Cancer

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>
- **National guidelines:** Included in EAU and NCCN guidelines <sup>(3-4)</sup>

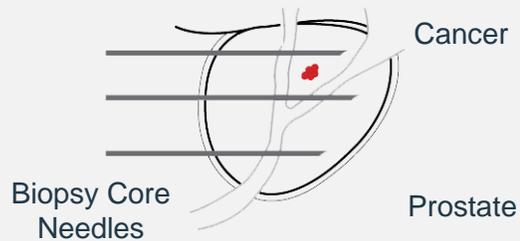


60% of initial biopsies do not reveal cancer <sup>(5-8)</sup>

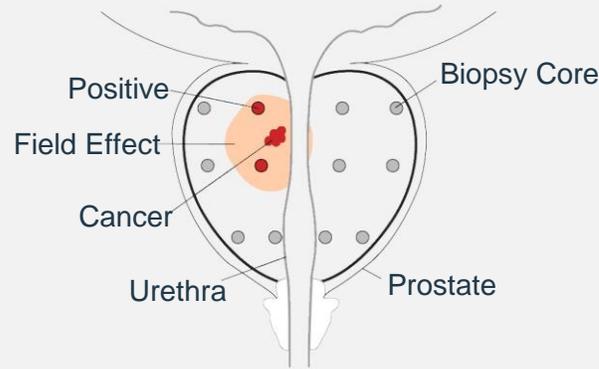
# ConfirmMDx improves diagnostic confidence of biopsy result

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

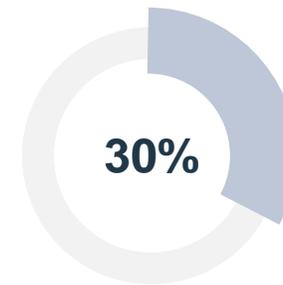
## False-negative biopsy



## 96% NPV (1)

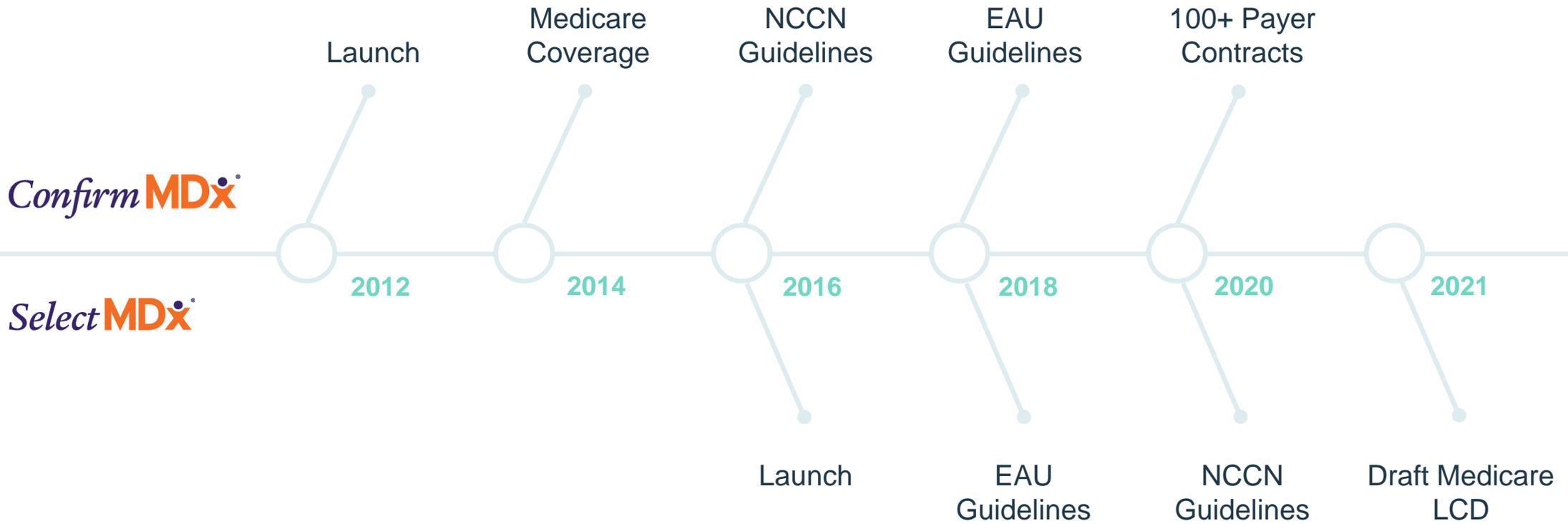


- **Non-invasive:** “Rule-out” test performed on previous biopsy tissue
- **Accurate:** 96% Negative Predictive Value for aggressive prostate cancer (1)
- **Validated:** Over 55 published studies on genes and technology
- **Cost effective:** Potential annual U.S. health system savings of \$500K per 1M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



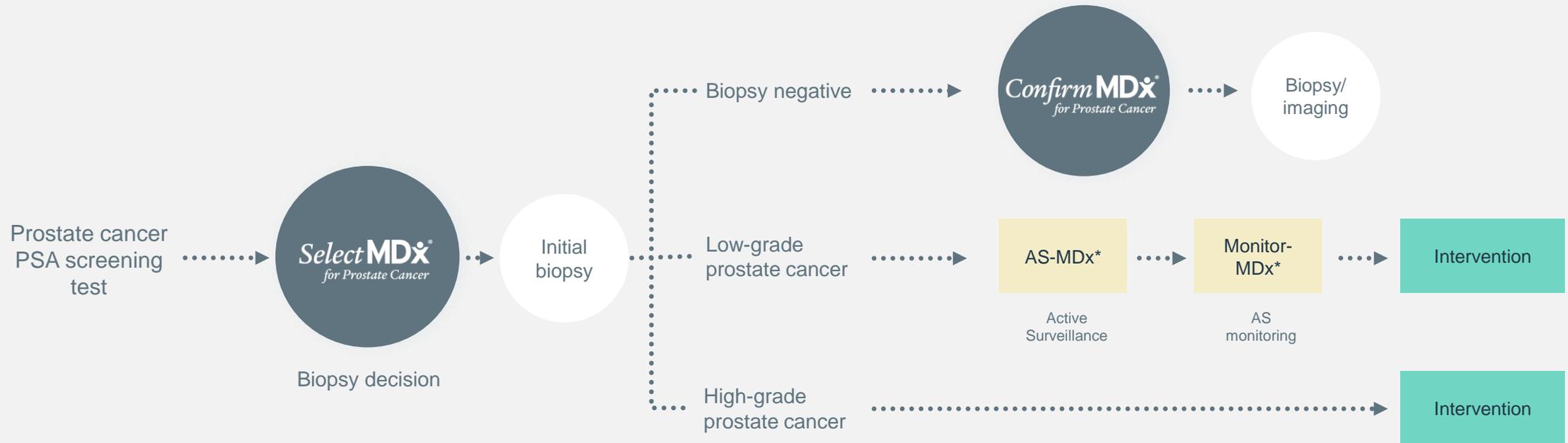
30% of men with a cancer-negative biopsy result actually have cancer (5)

# Evolution and catalysts of revenue growth



# Expanding menu in the prostate cancer diagnostic pathway

Active surveillance and “watchful waiting” require additional diagnostic disposition



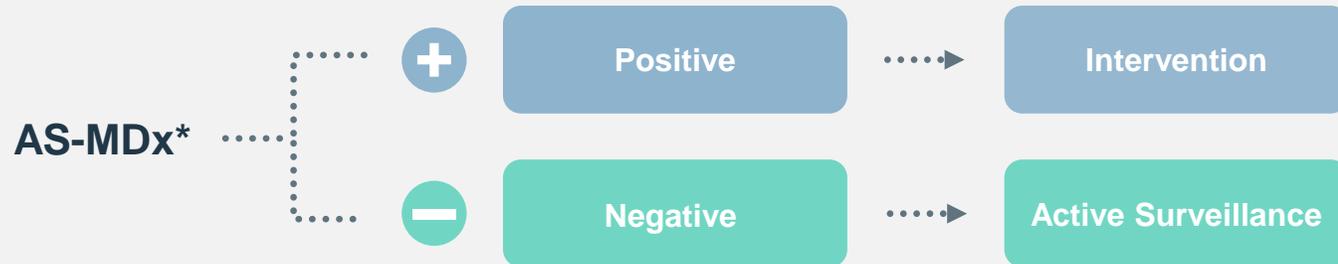
\*In development

# AS-MDx to stratify patients for active surveillance

## Low-grade prostate cancer

# 134K

Est. market size  
(men annually)



## AS-MDx

Not all men diagnosed with **localized prostate cancer benefit from intervention**; many tumors are slow-growing and non-life threatening

AS-MDx will risk-stratify patients who will benefit from immediate intervention versus active surveillance



\*In development

# Monitor-MDx to validate continued active surveillance

Under active surveillance  
(Low-grade cancer)

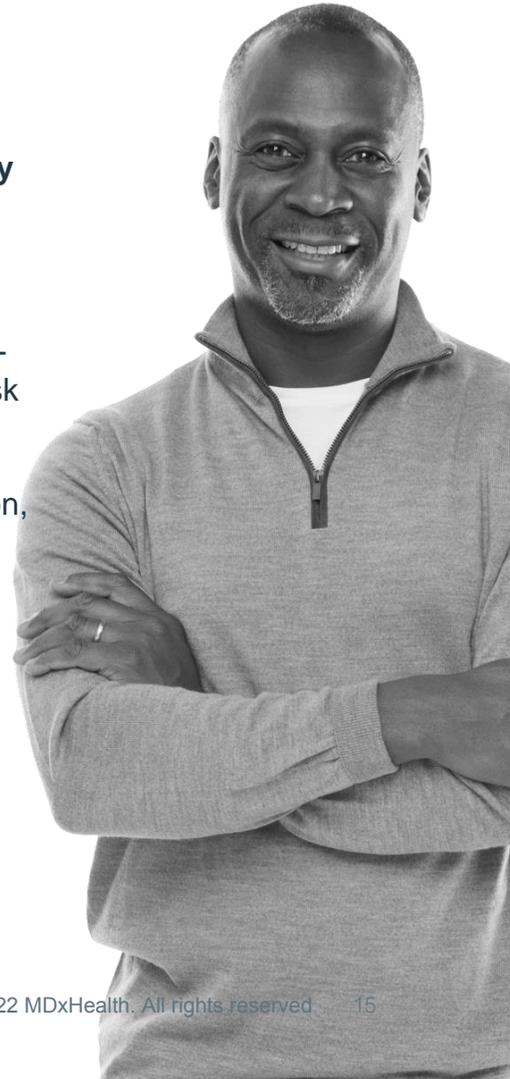
**1.5M**  
Est. market size  
(men annually)



## 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



\*In development

# U.S. Urinary Tract Infection (UTI) annual market opportunity

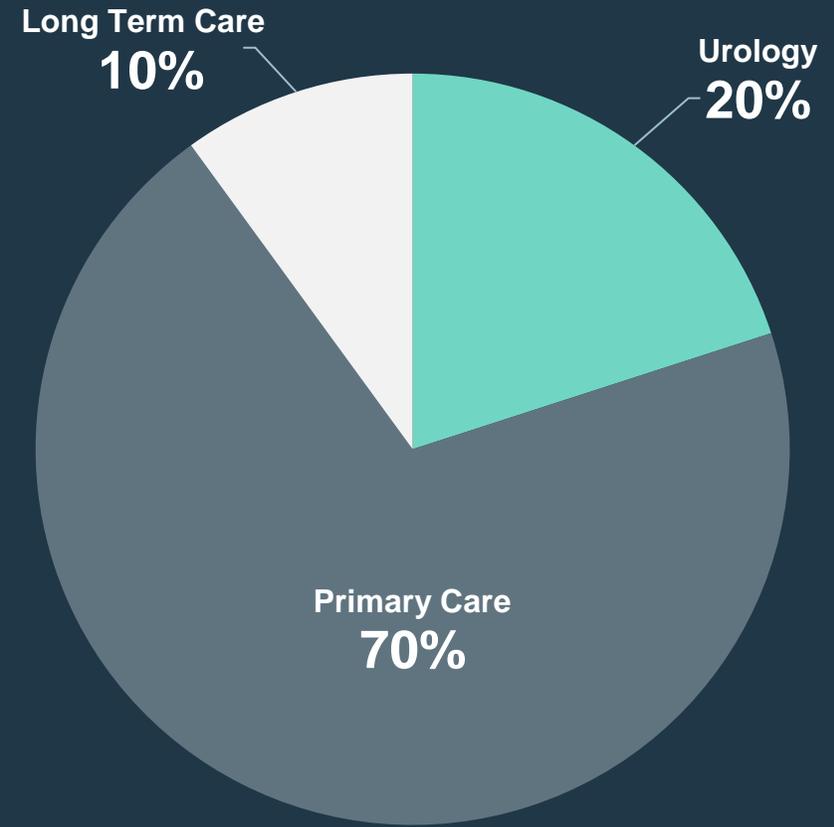
## UTIs are the most common outpatient infection<sup>(1)</sup>

- 10 million suspected UTI cases present annually<sup>(2)</sup>
- 20% of volume presents to urology\*

## The current UTI testing market is underserved

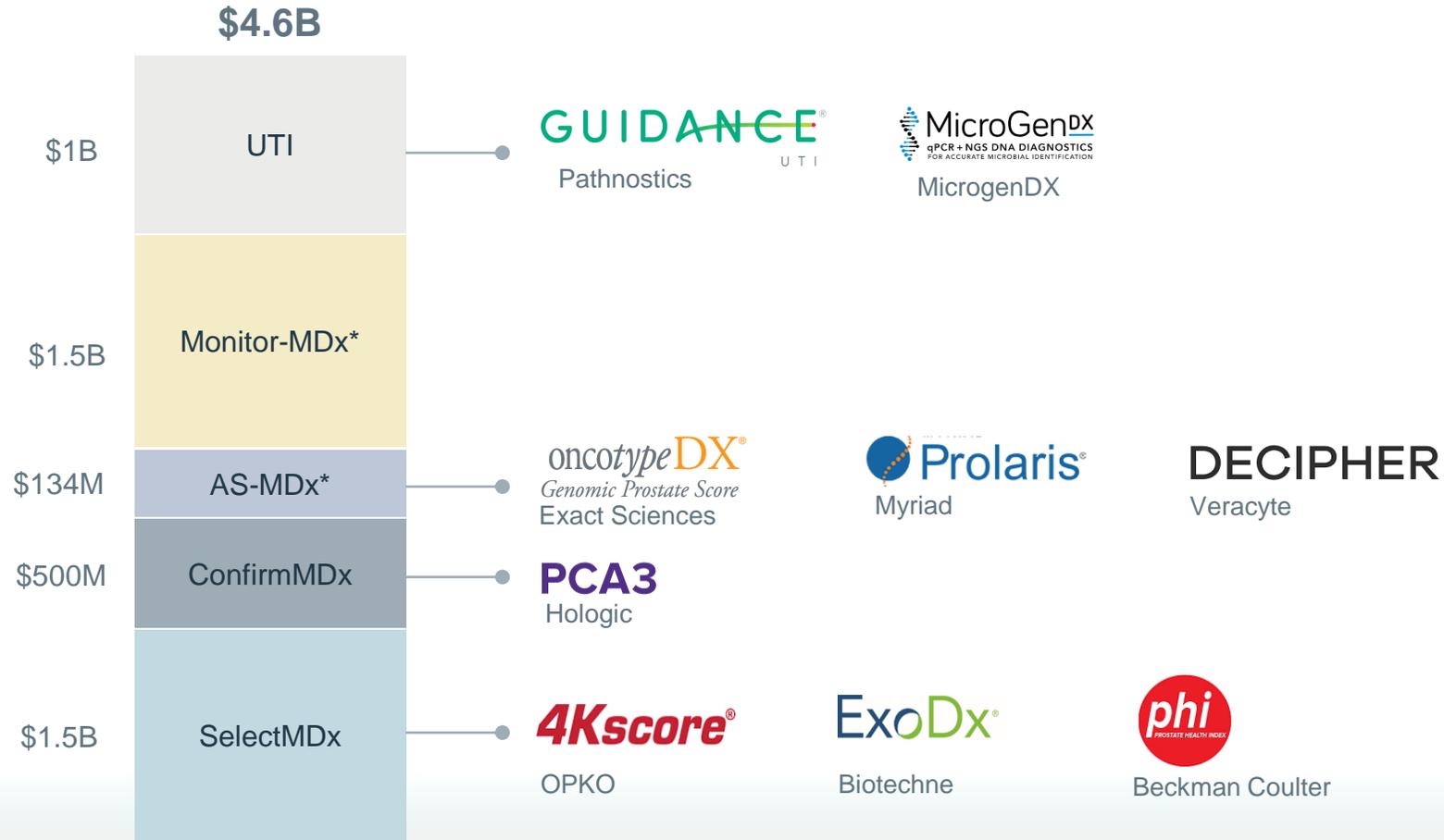
- Current standard is based on dated culture methodologies
- Complex molecular methods target both organism and susceptibility markers
- Market conversion comps: Virology and infectious disease
- Reimbursement well characterized (Medicare/commercial)

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



U.S. Market for UTI\*

# Our broad urology-focused menu provides opportunity for growth



# Statement of profit or loss

## Revenue

Approximately 97% attributable to services and 3% to licenses and royalties

ConfirmMDx represents over 90% of services revenue

## Gross margin

Improved by 120 basis points year-over-year

## Cash and cash equivalents

\$31.3 million as of June 30, 2021

USD in thousands (unaudited)	6 months ended June 30, 2021	6 months ended June 30, 2020	% Change
SelectMDx test volume	7,051	6,485	9%
ConfirmMDx test volume	7,978	7,662	4%
<b>Total revenue</b>	<b>\$10,731</b>	<b>\$9,880</b>	<b>9%</b>
<b>Gross profit</b>	<b>\$5,215</b>	<b>\$4,686</b>	<b>11%</b>
Operating expenses	(\$17,658)	(\$17,674)	0%
<b>Operating loss</b>	<b>(\$12,443)</b>	<b>(\$12,988)</b>	<b>(4%)</b>
<b>Net loss</b>	<b>(\$13,299)</b>	<b>(\$13,709)</b>	<b>(3%)</b>

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

**Existing products provide foundational revenue and strong growth potential**

Generating revenue from clinically-proven commercial products; growth to occur via commercial execution and improving channel access

03

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

Experienced R&D team and business development opportunities that leverage existing channel into urology

04

**New leadership team with commercial focus**

Implementing proven strategies to support growth while maintaining operating cost discipline

# Thank you

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The Netherlands

# Presentation references

## SUMMARY REFERENCE CITATIONS

### Slide 7 – Current challenges with diagnosing prostate cancer in U.S.

1. NIH 8/20/2019 Website: <https://seer.cancer.gov/statfacts/html/common.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.

### 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. 2021 National Cancer Center Network Guidelines. Early Detection for Prostate Cancer. Version 2.2021 – July 14, 2021.
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.

### 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. 2021 National Cancer Center Network Guidelines. Early Detection for Prostate Cancer. Version 2.2021 – July 14, 2021.
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* 2013.

### Slide 16 – 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.

# —• Appendix

# SelectMDx 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



# ConfirmMDx 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

Edited By: John T. Isaacs  
Impact factor: 3.279



# SelectMDx & ConfirmMDx technology

Combined over 65 published studies

	SelectMDx <sup>(1)</sup>	ConfirmMDx <sup>(2)</sup>
Specimen	Urine	Prostate tissue
Science	mRNA RT-PCR assay	DNA Methylation Specific PCR assay
Biomarkers	DLX1, HOXC6	GSTP1, APC RASSF1
Clinical Model	Clinical model combines mRNA with established clinical risk factors	Clinical model combines DNA Methylation markers with established clinical risk factors
Performance	95% NPV for clinically significant prostate cancer	96% NPV for clinically significant prostate cancer

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.

# Prostate cancer precision diagnostics: menu and pipeline

Product name	Sample type	Clinical decision	R&D	Validation	Launch	Expanded coverage and utilization
ConfirmMDx	Tissue	Post biopsy	●			
SelectMDx	Urine	Pre biopsy	●			
AS-MDx	TBD	Active Surveillance (AS)	●			
Monitor-MDx	TBD	AS Monitoring	●			