



It's time to take
diagnostic testing
beyond doubt.



About MDNA Life Sciences

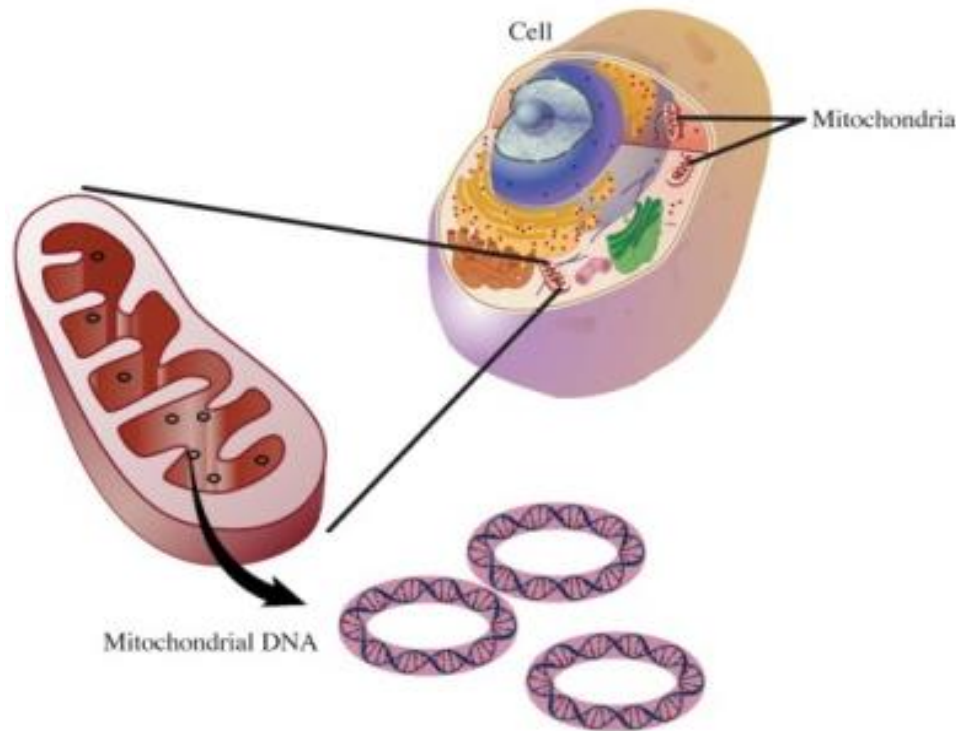
- Market disruptive **molecular diagnostic platform** company.
- Exploiting the **biological advantages** of mitochondrial genomics.
- Non-invasive, **blood-based, liquid biopsy** format to diagnose cancer and other major diseases.
- **Deep product pipeline** focused on cancer diagnostics and oncology.
- Unmatched **rapid, agile development** of proprietary diagnostic tests.
- **Low-cost testing** structure translates to high profit margins.
- State-of-the-art, ISO 15189 accredited, commercial diagnostic testing laboratory and R&D laboratory in Newcastle-upon-Tyne, UK.
- ISO 13485 compliant quality management system for medical device design, development, production, and related activities.



Key Facts

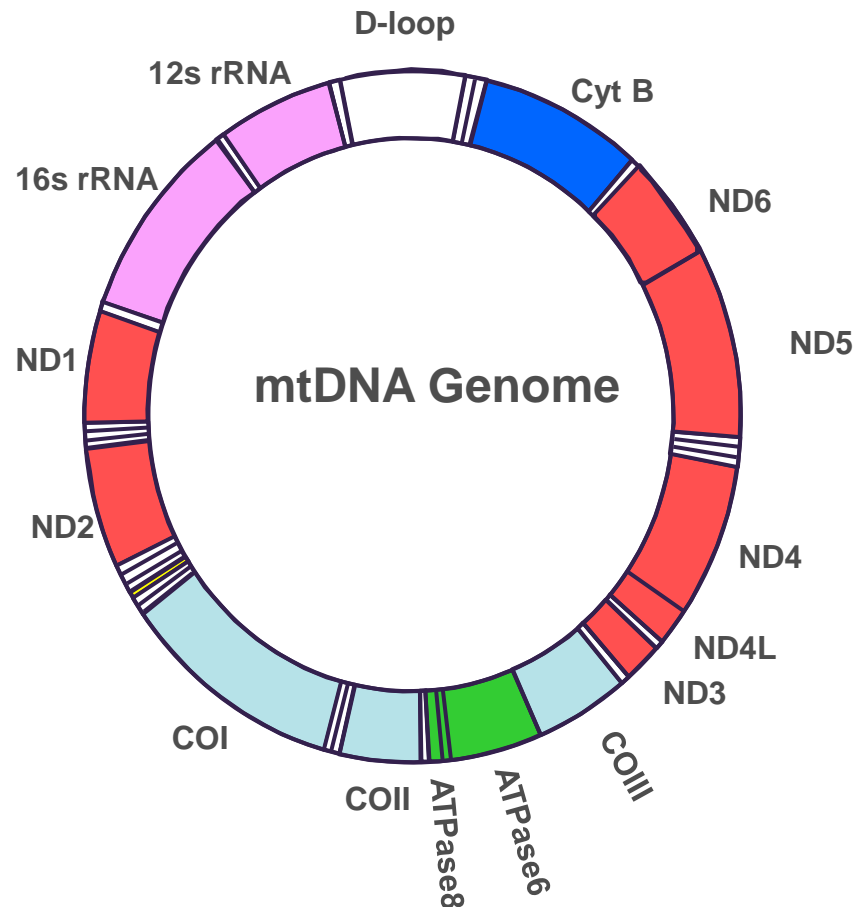
- 2 IVD products under development (prostate cancer and endometriosis)
- ISO 15189:2012 (Medical Laboratories) Accredited
- ISO 13485:2016 (Medical Devices) QMS Compliant
- Multiple layers of intellectual property
- Thousands of novel, proprietary mitochondrial DNA biomarkers

Human Mitochondria



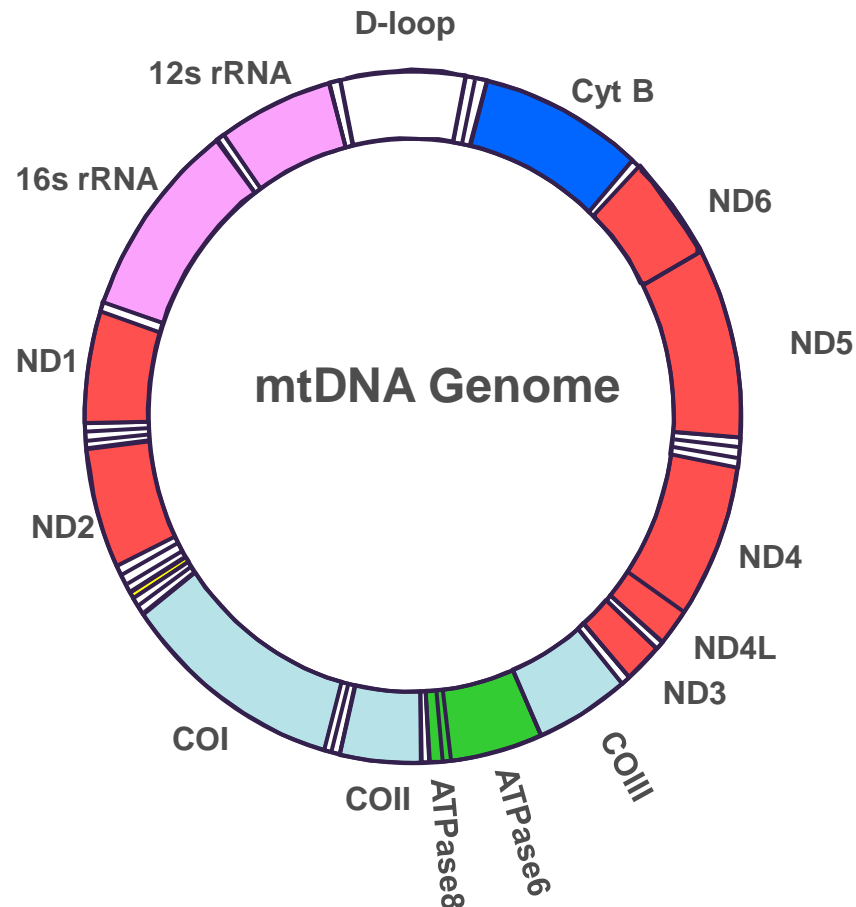
- Most cells in the body contain two organelles with DNA – the nucleus, home to the nuclear genome, and the mitochondrion, home to many (hundreds to thousands) mitochondrial genomes.
- Mitochondria are responsible for multiple cellular functions important to disease processes including energy production, cellular proliferation, and apoptosis.
- Mitochondria are the primary source of intracellular reactive oxygen species (ROS) that cause damage to DNA.

Human Mitochondrial DNA



- 16,568 base pairs of circular, double-stranded DNA.
- High copy number (1000 to 10,000 per cell).
- DNA mutations occur at high frequency (10-17 fold greater than nuclear DNA).
- Mutations can occur in a subset of mitochondrial genomes (known as heteroplasmy) which allows for low mutation detection.
- Limited ability to repair DNA.
- Replication is independent of cell cycle.

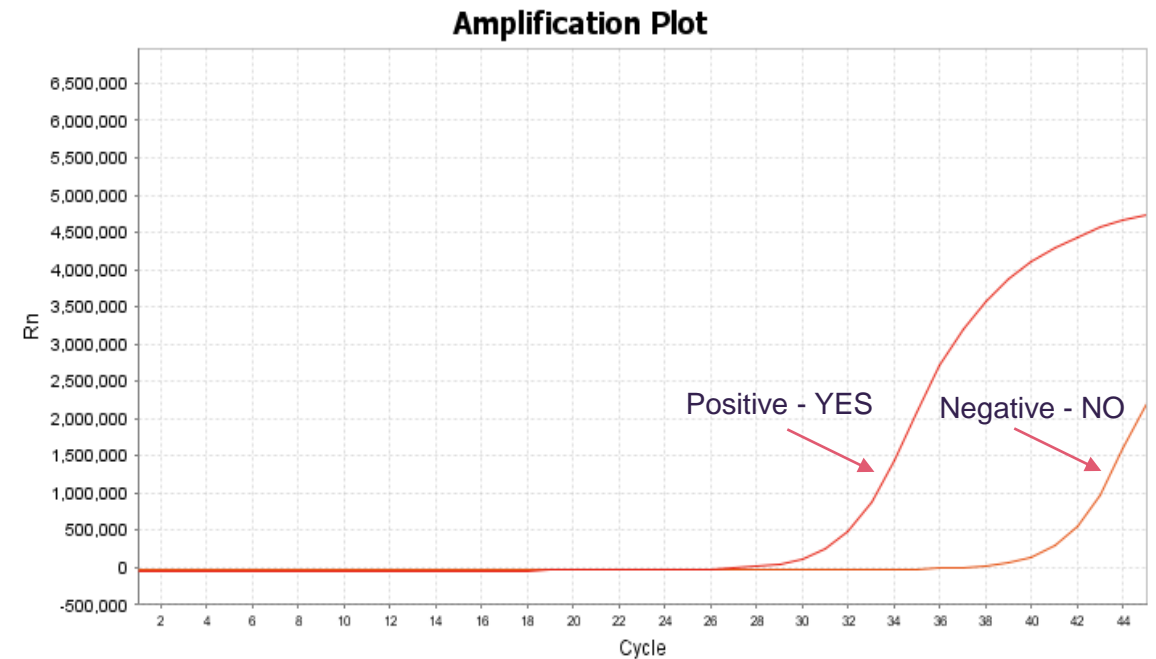
Mitochondrial DNA Deletions



- Deletions are genome copies, which are missing large parts of the genome.
- Large-scale deletions in mtDNA indicate cellular changes that are associated with the development of disease.
- Deletions often result in loss of complete genes, impact energy production, and result in production of oxidants (i.e. reactive oxygen species).
- Though deletions can be inherited, **somatic mutation deletions** are optimal predictors of diseases such as cancer.

Using Deletions for Disease Detection

- Specific deletions are involved with specific diseases.
- A particular deletion, or a combination of deletions, is definitive for a specific disease, (creating an opportunity to develop molecular tests for multiple purposes across all diseases since detection is possible in various sample types – tissue, biofluids, blood).
- ***Importantly, deletions accumulate in a way that enables quantitative measurement using standard laboratory equipment platforms (e.g. rtPCR or dPCR).***



Mitochondrial DNA: The Perfect Biosensor

Biological Feature

High Copy Number

Mutation at High Frequency

Lack of Repair/
Cell Death

Occur in
"Healthy" Cells

Disease-Specific



Enables much earlier detection

Tests are highly sensitive / specific

Mutations persist...
Accumulate in detectable state

Actionable...
Detects real-time disease, not hereditary risk

Multiple biomarkers per disease state

Highly quantitative...
Even with low sample material

Clinical Benefit

Clinical Benefits Drive Commercial Advantages

Clinical Benefit

Early Detection

High Sensitivity /
Specificity

Persistent
Detection

Actionable, Real
Time

Multiple
Biomarkers

Quantitative and
Reliable



Best-in-class, non-invasive blood-based tests

Can be optimized for screening, diagnosis,
prognosis, and/or treatment decisions

Biomarker discovery and proof of concept
development is efficient and cost effective

Low sample quantity is not a limiting factor

Layers of IP protection

Robust, yet simple clinical implementation

“Plug & Play” roll out based on extensive
cross-platform validation

Development & Commercial
Advantages

End-to-End Market Application

Development Platform

Thousands of
Proprietary
Biomarkers

Product and Market Application

Molecular Dx

- Screening
- Diagnosis
- Prognosis

Companion Dx

- Drug Development
- Patient Selection
- Monitoring

CNS

Oncology

Diabetes

Endocrinology


CVD

Dermatology

Many Potential
Application
Opportunities

Our Pipeline is Supported by Top Performing Biomarkers

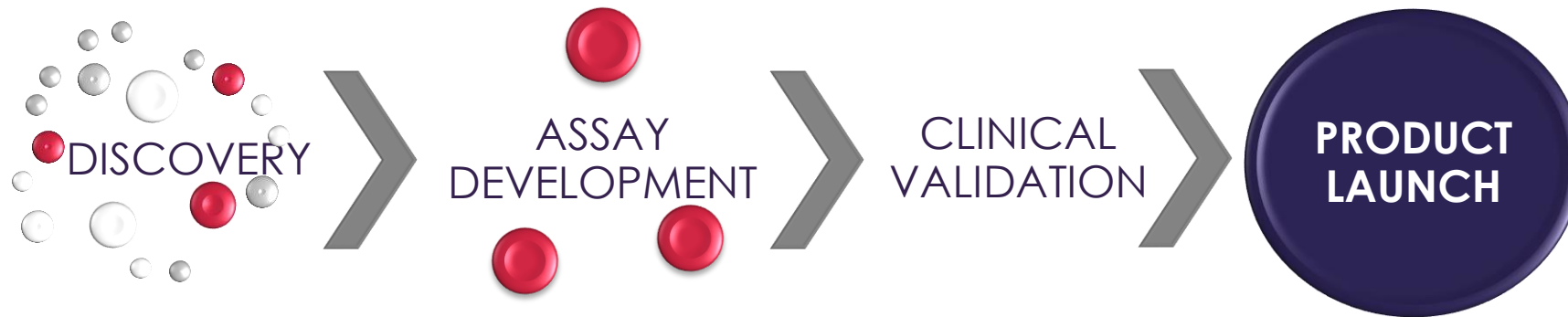
- Identified **multiple, independent disease-specific biomarkers** in each listed category:
 - Underserved with significant testing need;
 - Established at-risk population;
 - Reliant on invasive diagnostic procedures; with
 - Opportunity to reduce costs
- Successful proof-of-concept studies highlight **exceptional performance** in many different disease states.
- Reveals the depth of our **proprietary & patented** technology and future product launches.



Disease State	Biomarker Performance (AUC %)
Ovarian Cancer	99
Uterine Cancer	87
Cervical Cancer	97
Breast Cancer	89
Testicular Cancer	99
Lung Cancer	89
Bladder Cancer	89
Colorectal Cancer	84
Melanoma	96

New Product Development – Discovery to Launch

← 24 Months →



- Identify unique independent biomarkers (next-generation sequencing)

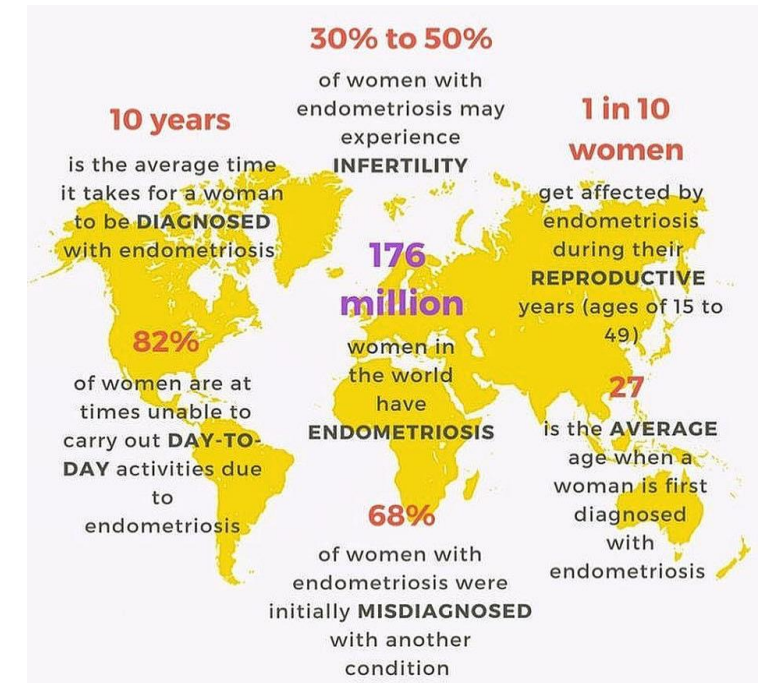
- Develop rtPCR and/or dPCR assay(s)
- Test against control blood samples (blinded)

- Establish clinical performance statistics
- Develop and manufacture IVD reagent kit

- Regulatory submission and global market launch

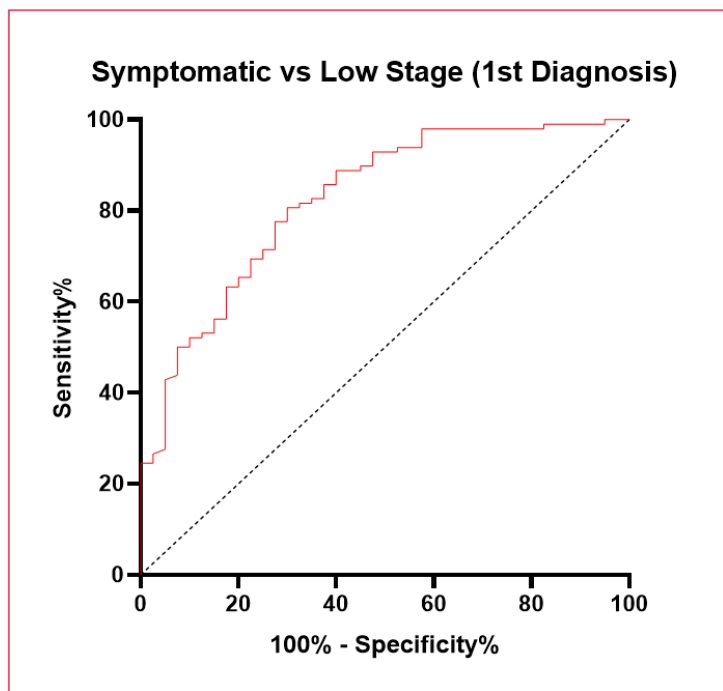
Endometriosis – Significant Clinical Problem & Unmet Need

- Globally, **1 in 10 women** get affected by endometriosis during their reproductive years.
- There is a **significant diagnostic delay in diagnosing** endometriosis.
- Symptoms of the disease are **not readily recognised in primary care**.
- When patients are finally diagnosed, greater than 90% have moderate to severe symptoms.
- The disease can progress for many years resulting in greater treatment costs, prolonged negative impact on quality of life and psychological well-being, surgical interventions and infertility.
- **There is a significant need for a non-invasive, blood-based test to aid earlier diagnosis.**



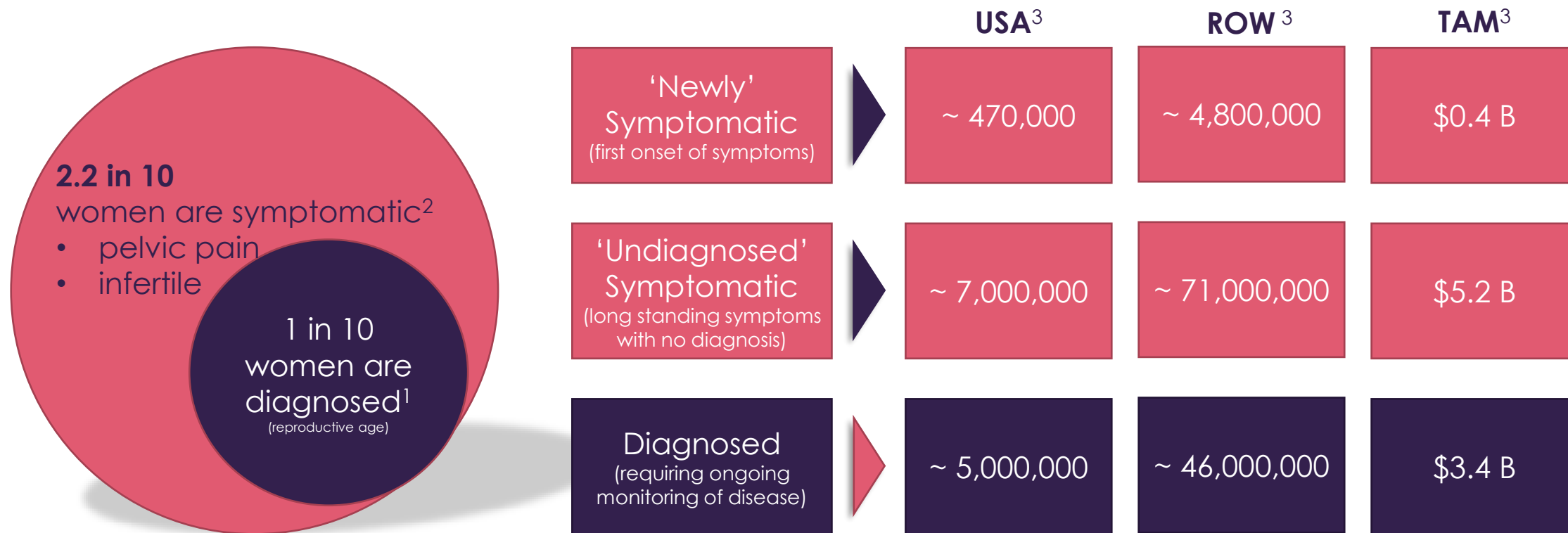
First-in-Class Endometriosis Test

- The Mitomic[®] Endometriosis Test (MET[™]) is expected to be the **first blood-based test** for endometriosis:



- **Disruptive** to current standards (i.e. surgery).
- For screening women presenting with symptoms...prior to laparoscopy.
- IVD test and reagent kit in development.
- Conducting CE clinical validation study in collaboration with leading medical centers in the UK and other markets.
- License and/or distribution agreements signed in 31 countries.

Endometriosis Addressable Market

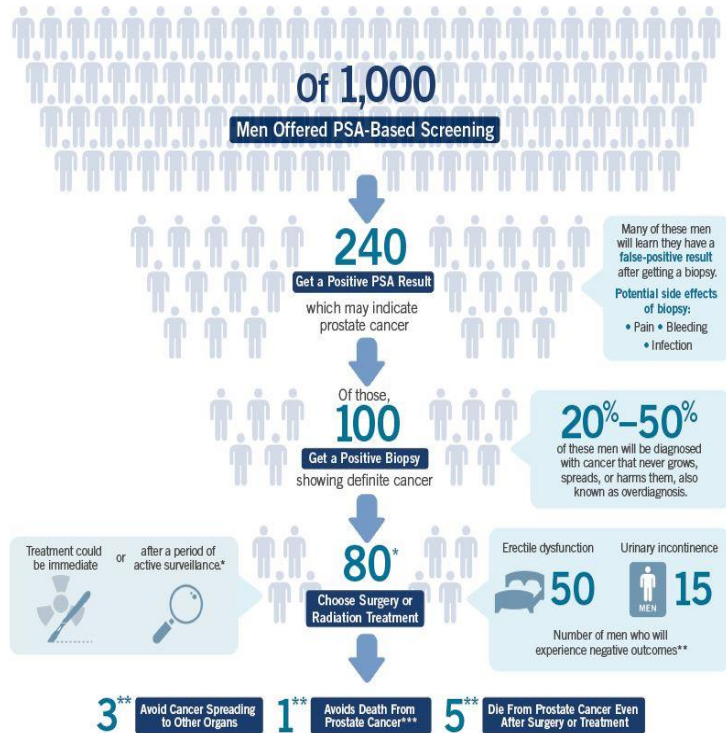


1. World Health Organization (<https://www.who.int/news-room/fact-sheets/detail/endometriosis>)

2. Endometriosis.org (<http://endometriosis.org/endometriosis/diagnosis/>). Company analysis.

3. The intended use population for MDNA Life Sciences' endometriosis test currently in development includes, initially, the disease screening for women of reproductive age who are symptomatic. MDNA's secondary endometriosis test offering is expected to be focused on women who are diagnosed with endometriosis and require monitoring of the disease's progression. In both cases, MDNA's total addressable market calculation is based on licensing and/or distribution in 60 target countries and factors in market specific royalty and/or product transfer prices.

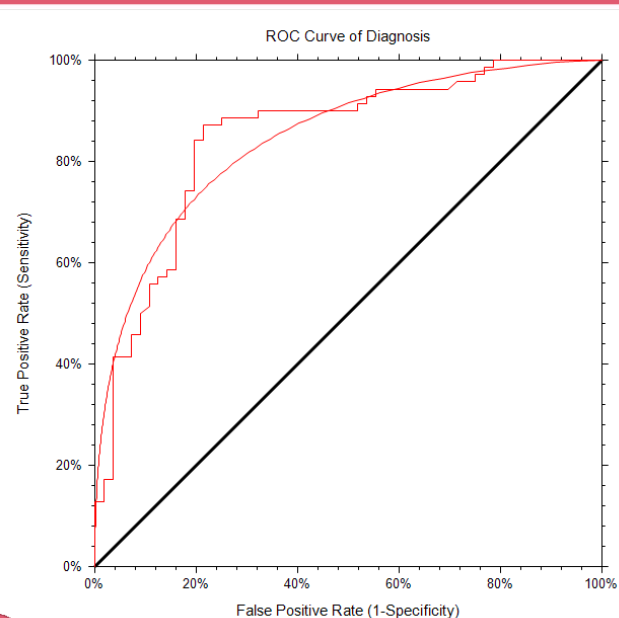
The Clinical Problem of Detecting Low Grade Prostate Cancers



Source: US Preventive Services Task Force 2018

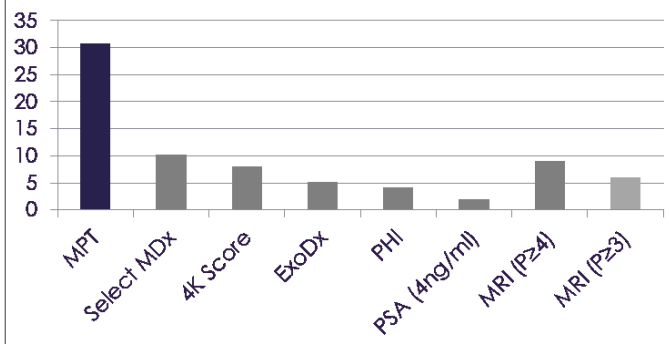
- PSA is not specific to prostate cancer.
- Many men with a positive PSA test are false-positive for prostate cancer.
- **Up to 50%** of these men will be ‘over’ diagnosed with cancer **that never harms them.**¹
- The **risks** associated with treatment of low-grade cancers (\leq Gleason 6) appear to **outweigh the benefits** – e.g. urinary incontinence, erectile dysfunction.
- **There is a significant need for a non-invasive, blood-based test to identify men with medium and high-grade cancer (\geq Gleason 7) that need treatment.**

Find Prostate Cancer in Blood



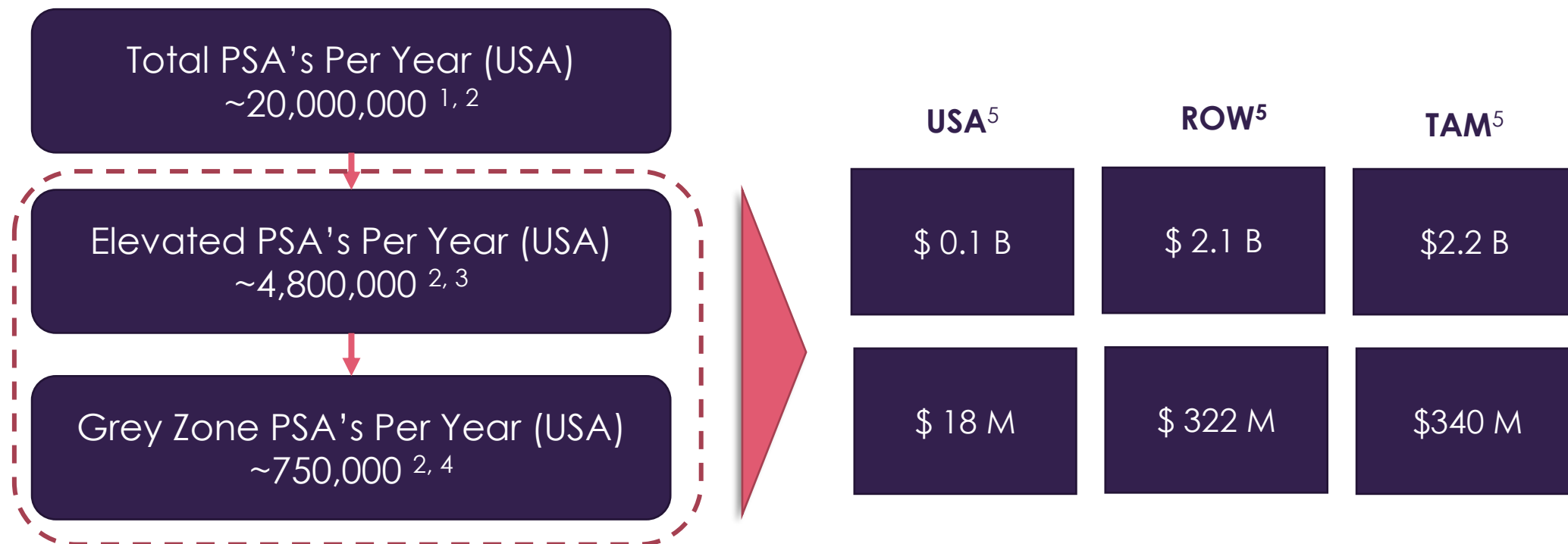
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Diagnostic Odds Ratio



- Mitomic[®] Prostate Test (MPT[™]) is a **liquid biopsy** assay for prostate cancer that detects Clinically Significant disease – i.e. Gleason 7 or higher – using a standard blood sample.
- **Top performing biomarker** supported by published analytical data.
- **Disruptive** to current standards (i.e. PSA and MRI). Independent of PSA. For screening at risk patients.
- IVD test and reagent kit in development.
- Developed in collaboration with the University of Cambridge in the UK.
- License and/or distribution agreements signed in 46 countries.

PSA 'Elevated' & 'Grey Zone' Addressable Market



1. CDC. "Patterns and Trends in Cancer Screening in the United States". CME Activity - Volume 15 - July 26, 2018.
2. Company analysis.
3. US Preventative Services Task Force. 2018.
4. Welch et al. Prostate-Specific Antigen Levels in the United States: Implications of Various Definitions for Abnormal. J Natl Cancer Inst 2005;97:1132 – 7
5. The intended use population for MDNA Life Sciences' prostate cancer test currently in development is men between 45 years and 79 years who have an elevated PSA result of 10 ng/ml or less. USA population and disease incidence data is extrapolated across the rest of the world on a country-by-country basis and uses country-specific population data and country-specific disease incidence data. MDNA's total addressable market calculation is based on licensing and/or distribution in 60 target countries and factors in market specific royalty and/or product transfer prices.

Highlights - \$595 Million USD in Product Agreements

- Approximately **\$185 Million USD** in future revenue for the **Mitomic[®] Prostate Test (MPT[™])** is supported by payment and volume commitments contained within signed license and distribution agreements. Consists of **sixteen (16) partners**. Coverage includes **forty-six (46)** countries in key geographies – North and South America, Europe, Middle East, Asia Pacific.
- Approximately **\$410 Million USD** in future revenue for the **Mitomic[®] Endometriosis Test (MET[™])** is supported by payment and volume commitments contained within signed license and distribution agreements. Consists of **nine (9) partners** in **thirty-one (31)** countries in key geographies – North America, Europe, Asia Pacific.
- **Groundbreaking, peer-reviewed publications** in the 'Biomarkers in Medicine' journal covering the use of MDNA's proprietary mitochondrial deletions circulating in blood for the detection of endometriosis.
- **Biomarker discoveries in ovarian cancer and lung cancer** add to the existing and growing portfolio of MDNA's novel and proprietary mitochondrial large-scale somatic deletions.

Key Takeaways

- **Unique, novel, proprietary platform** for molecular diagnostic development. No other company in the world offers a similar capability.
- **Well-positioned for growth** with a deep pipeline of products.
- Rapid, **low cost**, and flexible product development.
- **Twenty (20) year patent terms** on all pipeline products.
- Established global customer base through MDNA's current **global partner base**.
- **Highly scalable revenues** through IVD kit global distribution model.

Thank You

Corporate Headquarters:

2054 Vista Parkway, Suite 400
West Palm Beach, FL 33411
USA

R&D and ISO Laboratory Operations:

The Biosphere, Draymans Way
Newcastle Upon Tyne, NE4 5BX
United Kingdom

