

BREAKTHROUGH, STANDALONE LIQUID BIOPSY

URINE TEST FOR PROSTATE CANCER

ABOUT MIR

Founded in 2014, miR Scientific is a precision healthcare company committed to improving public health by transforming cancer management globally. The Company's proprietary disease management platform is set to revolutionize the standard of value-based care for urological cancers.

miR Scientific's miR Sentinel® Prostate Cancer Test is the only standalone, non-invasive liquid biopsy urine test that detects, classifies and can monitor prostate cancer at the molecular level with >90% sensitivity and specificity accuracy.

WHY IT MATTERS

Prostate cancer is not only very prevalent but also potentially deadly, and is currently the second leading cause of cancer deaths among men.¹ One in eight men will be diagnosed with the disease in their lifetimes, representing the highest number of new cancer cases diagnosed annually. Early detection and the ability to identify high grade disease are key to effective disease management. Unlike other cancers, most prostate cancers are indolent and unlikely to ever need treatment; only a relatively small number of prostate cancer patients have aggressive disease that requires intervention.

The challenge lies in effectively differentiating between the indolent and aggressive disease quickly. Until now, no effective, accurate, and non-invasive urine-based test has been developed for the early detection and grade classification of prostate cancer.

Current screening procedures for the early detection of prostate cancer involve a digital rectal exam (DRE) and a blood test to measure Prostate Specific Antigen (PSA). These invasive methods are inaccurate; when PSA is used to trigger a biopsy for the diagnosis of prostate cancer, 70% of patients undergo costly and painful core needle biopsies only to verify a true negative diagnosis.² As a result, many men are deterred from maintaining screening schedules, forgoing the life-saving benefits of early detection. In the U.S. and Puerto Rico, fewer than 30% of age-eligible men are currently screened for the disease, resulting in later-stage detection and a higher disease burden that is estimated to reach \$23 billion in treatment costs alone by 2025.³

OUR SOLUTION

The miR Sentinel® Prostate Cancer Test can accurately distinguish between those who present with molecular evidence of prostate cancer and those who do not, and, for those who test positive for cancer, the test then classifies the severity, or the risk grade, of the malignancy. Based on the interrogation of small noncoding RNAs extracted from urinary exosomes, the liquid biopsy urine test clearly yields one of the following results:

- **NO MOLECULAR EVIDENCE OF CANCER**
- **MOLECULAR EVIDENCE OF LOW RISK CANCER**
equivalent of pathology's grade group 1 cancers
- **MOLECULAR EVIDENCE OF INTERMEDIATE RISK CANCER**
equivalent of pathology's grade group 2 cancers
- **MOLECULAR EVIDENCE OF HIGH RISK CANCER**
equivalent of pathology's grade group 3-5 cancers

Broad adoption of the miR Sentinel® technology could lead to the elimination of unnecessary biopsies, which would reduce the overall number of biopsies and their associated morbidities by up to 80%. Time and resources previously spent on biopsies can be redirected to provide more effective care for other patients, particularly those requiring immediate intervention. This higher quality of care reduces the economic burden currently associated with ineffective, inaccurate, and unnecessary biopsies currently used to triage patients, and demonstrates the potential to revolutionize the global standards of care supporting urologic oncology.

Additional advantages to a urine-based diagnostic include increased accessibility (urine can be provided at any time and there are no requirements for "first-stream" or a digital rectal exam before collection) and stability (the exosomal sncRNA analyzed are stable at a wide range of temperatures and conditions).

70%
OF CURRENT
PROSTATE BIOPSIES
ARE UNNECESSARY

1. Excluding basal cell and squamous cell skin cancers. "Cancer Facts & Figures 2021." American Cancer Society, 2021

2. "Negative Biopsies with rising prostate-specific antigen. What to do?" European Medical Journal, 2017

3. Mariotto, Angela B., et al. "Projections of the Cost of Cancer Care in the United States: 2010–2020." OUP Academic, Oxford University Press, 2011

HOW THE MIR SENTINEL® TECHNOLOGY WORKS:



URINE COLLECTION

*A urine sample is provided.
No Digital Rectal Exam required.*



sncRNA EXTRACTION

A standard RNA extraction method is used for prostate cancer: Exosomes in cell-free urine are captured and lysed to enable RNA extraction.



sncRNA INTERROGATION

A high throughput OpenArray™ system is used to interrogate sncRNA entities of interest.



PROPRIETARY ALGORITHM

A proprietary algorithm is used to calculate the miR Sentinel Score® for each patient based on the results of the sncRNA Interrogation.



SIMPLE, ACCURATE RESULT

*Dichotomizes patients into definitive Yes/No results.
Yes results are further classified into high, intermediate and low risk.*

CLINICAL VALIDATION

miR Scientific's data science platform provides actionable information with a low false positive and effectively zero false-negative accuracy rate. In a recent clinical study published in the Journal of Urology, the test demonstrated 94% sensitivity and 92% specificity in the detection of molecular evidence of prostate cancer, as well as 95% sensitivity and 96% specificity for prostate cancer classification (aggressiveness).⁴ In comparison, the existing diagnosis processes for prostate cancer, including biopsy processes, yield just 44% sensitivity and 68% specificity.

**>90%
SENSITIVITY
AND
SPECIFICITY**

The miR Sentinel® technology has been validated and presented in other peer-reviewed venues as well, including the World Urological Oncology Forum (2018), the European Association of Urology (2019), and the American Society of Clinical Oncology (2019 and 2020). miR Scientific also won the

2020 Fierce Innovation Award for Life Sciences, a testament to the transformative potential the miR Sentinel® technology has in the urologic oncology field.

4. "Expression of Small Noncoding RNAs in Urinary Exosomes Classifies Prostate Cancer into Indolent and Aggressive Disease." *Journal of Urology*, 2020

TEAMING UP WITH PUERTO RICO

For the past two years, miR Scientific and the Puerto Rico Government have been working together to deploy an innovative solution in the fight against prostate cancer, the most common cancer and the most common cause of cancer death among Puerto Rico's men. A collaborative effort between miR Scientific and local doctors, government and business leaders is helping to bring miR Scientific's breakthrough technology to Puerto Rico.

Due to the shortcomings in current standards of care, only a small percentage of the age-eligible male population in Puerto Rico chooses to get screened, further compounding the healthcare and economic burden of the disease and limiting the opportunity to identify dangerous cancers earlier to allow for better outcomes.

miR Scientific's growing proactive and multifaceted collaborations in Puerto Rico can measurably improve outcomes in the war against cancer, and in doing so, contribute to the emergence of Puerto Rico as a leading center for medical innovation.

miR Scientific

1 Discovery Drive Ste. 202
Rensselaer, NY 12144
+1-518-650-6909
www.mirscientific.com

Please direct questions and requests for additional information to Mindy Figueroa, Puerto Rico Country Manager, at mindy.figueroa@mirscientific.com