- Innovative Award Winning Technology
- FDA Breakthrough Device Designation

miR Sentinel™

PROSTATE CANCER TEST

Accurate Classification

Supports

Clinical Decisions

ACCURATE

Risk Classifies prostate cancer with 97% sensitivity

COMPREHENSIVE

Detects the presence or absence of prostate cancer by sequencing exosomal small non-coding RNA

SIMPLE

A one-step non-DRE urine sample is all that's needed

How It **Works**

Simple Urine Collection

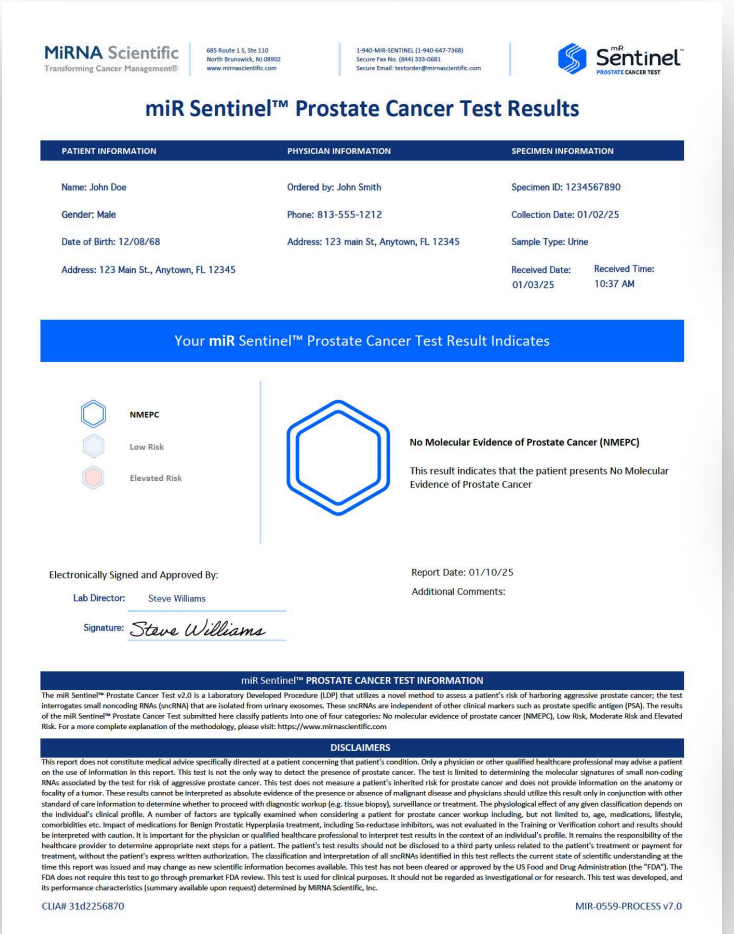
A simple urine sample is provided.
No digital rectal exam required

sncRNA Extraction & Interrogation

>40 small non-coding RNA entities of interest extracted from exosomes in cell-free urine & interrogated via a high throughput OpenArray™

Simple and Accurate Result

PSA agnostic results categorize patients into three distinct result groups



MiRNA Scientific
Transforming Cancer Management®

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miR Sentinel™ PROSTATE CANCER TEST

miR Sentinel™ Prostate Cancer Test Results

PATIENT INFORMATION	PHYSICIAN INFORMATION	SPECIMEN INFORMATION
Name: John Doe	Ordered by: John Smith	Specimen ID: 1234567890
Gender: Male	Phone: 813-555-1212	Collection Date: 01/02/25
Date of Birth: 12/08/68	Address: 123 main St, Anytown, FL 12345	Sample Type: Urine
Address: 123 Main St., Anytown, FL 12345		Received Date: 01/03/25 Received Time: 10:37 AM

Your **miR** Sentinel™ Prostate Cancer Test Result Indicates

NMEPC
Low Risk
Elevated Risk

No Molecular Evidence of Prostate Cancer (NMEPC)

This result indicates that the patient presents No Molecular Evidence of Prostate Cancer

Electronically Signed and Approved By:
Lab Director: Steve Williams
Signature: Steve Williams

Report Date: 01/10/25
Additional Comments:

miR Sentinel™ PROSTATE CANCER TEST INFORMATION

The miR Sentinel™ Prostate Cancer Test v2.0 is a Laboratory Developed Procedure (LDP) that utilizes a novel method to assess a patient's risk of harboring aggressive prostate cancer; the test interrogates small noncoding RNAs (sncRNA) that are isolated from urinary exosomes. These sncRNAs are independent of other clinical markers such as prostate specific antigen (PSA). The results of the miR Sentinel™ Prostate Cancer Test submitted here classify patients into one of four categories: No molecular evidence of prostate cancer (NMEPC), Low Risk, Moderate Risk and Elevated Risk. For a more complete explanation of the methodology, please visit: https://www.mirnascientific.com

DISCLAIMERS

This report does not constitute medical advice specifically directed at a patient concerning that patient's condition. Only a physician or other qualified healthcare professional may advise a patient on the use of information in this report. This test is not the only way to detect the presence of prostate cancer. The test is limited to determining the molecular signatures of small non-coding RNAs associated by the test for risk of aggressive prostate cancer. This test does not measure a patient's inherited risk for prostate cancer and does not provide information on the anatomy or focality of a tumor. These results cannot be interpreted as absolute evidence of the presence or absence of malignant disease and physicians should utilize this result only in conjunction with other standard of care information to determine whether to proceed with diagnostic workup (e.g. tissue biopsy), surveillance or treatment. The physiological effect of any given classification depends on the individual's clinical profile. A number of factors are typically examined when considering a patient for prostate cancer workup including, but not limited to, age, medications, lifestyle, comorbidities etc. Impact of medications for Benign Prostatic Hyperplasia treatment, including 5α-reductase inhibitors, was not evaluated in the Training or Verification cohort and results should be interpreted with caution. It is important for the physician or qualified healthcare professional to interpret test results in the context of an individual's profile. It remains the responsibility of the healthcare provider to determine appropriate next steps for a patient. The patient's test results should not be disclosed to a third party unless related to the patient's treatment or payment for treatment, without the patient's express written authorization. The classification and interpretation of all sncRNAs identified in this test reflects the current state of scientific understanding at the time this report was issued and may change as new scientific information becomes available. This test has not been cleared or approved by the US Food and Drug Administration (the "FDA"). The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes. It should not be regarded as investigational or for research. This test was developed, and its performance characteristics (summary available upon request) determined by MiRNA Scientific, Inc.

CLIA# 31d2256870

MIR-0559-PROCESS v7.0

No Molecular Evidence of Prostate Cancer

This result indicates that the patient presents No Molecular Evidence of Prostate Cancer.

Low Risk

This result indicates that the patient presents Molecular Evidence of Low-Risk for Aggressive Prostate Cancer.

Elevated Risk

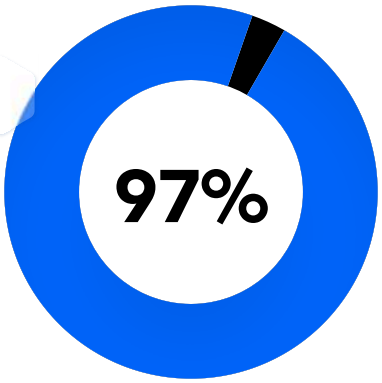
This result indicates that the patient presents Molecular Evidence of Elevated-Risk for Aggressive Prostate Cancer.

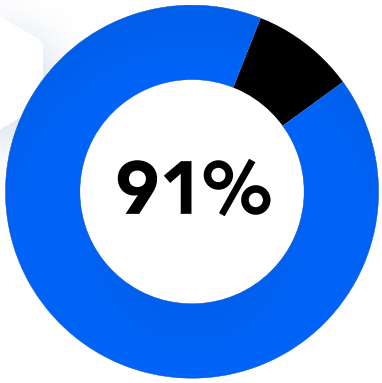
miR Sentinel™
PROSTATE CANCER TEST

A look at Accuracy

Uncovers Molecular Evidence of Cancer

97% of patients with pathological evidence of Prostate Cancer were accurately identified by miR Sentinel as having Molecular Evidence for Aggressive Prostate Cancer



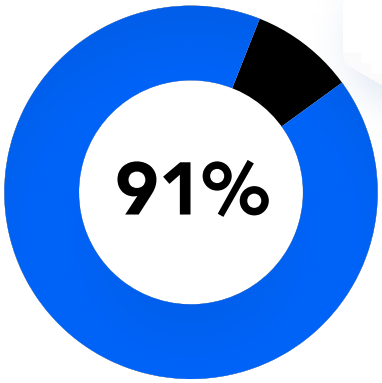


Identifies Clinically Significant Cancer

91% of patients with pathological evidence of GG ≥2 PCa were accurately identified by miR Sentinel as having Molecular Evidence of Elevated Risk for Aggressive Disease

Accurately Detects Aggressive Cancer

In subset analysis of pts who received TRUS & Fusion Bx, 22 Dx with GG≥2 PCa by one Bx & either no PCa or GG1 by the other, 91% correctly identified as having Molecular Evidence of Elevated Risk for Aggressive PCa



Non-invasive Risk Assessment of Aggressive Prostate Cancer Using sncRNAs from Urinary Exosomes in a prospective, multi-center clinical study. [Manuscript in preparation]

How to get

miR Sentinel™

miR Sentinel requires a medical provider's order and a specimen collection kit. There are two ways a healthcare provider can order a kit.

Call Customer Service

To order over the phone:
Call the miR Sentinel expert support line at
1-940-MIR-SENTINEL (1-940-647-7368)
Our team is available 9:00 AM – 5:00 PM EST
Monday through Friday

Visit Our Website

Complete a test requisition form at www.mirsentinel.com/order or scan the QR code to open the form and submit an order at your convenience

miR Access™

MiRNA Scientific is proud to offer needs-based financial assistance to help qualified patients with out-of-pocket costs for miR Sentinel, regardless of insurance status. To learn more, scan the QR code or visit www.mirsentinel.com/insurance-billing

miR Sentinel™
PROSTATE CANCER TEST