

HEALTH CARE PROVIDER GUIDE

# ExoDx™ Prostate Test

A Simple Urine Test for Risk  
Assessment of High-Grade  
Prostate Cancer (HGPCa)



# ExoDx™ Prostate Test

The only noninvasive, urine biomarker for risk assessment of HGPCa relying on genomic information, completely independent of standard of care features. It leverages the power of exosomes, capturing prostate cancer RNA signals to stratify a patient's risk of HGPCa. Included in the NCCN and AUA/SUO guidelines, the ExoDx Prostate Test provides an additional data point to assist and inform the decision to proceed with or defer biopsy.



## At-Home Kit

Reduce office workload and patient waiting times by allowing patients to collect samples in the comfort of their homes. The ExoDx Prostate Test is the only biomarker test with At-Home testing and no DRE needed.

At-Home collection kits are sent directly to patients who may choose to follow the included instructions without further assistance; or may choose to schedule a telemedicine visit with their HCP, watch the online instructional videos, or call the customer support team.

## In-Office Kit

The ExoDx In-Office Kits are shipped in sets of five containing the required Colli-pee collection devices, ice packs for cold shipment, Test Requisition Forms (TRFs), and instructions for return shipping.

**Important:** After collection, pack samples for shipping with frozen ice packs. If ice packs are not yet frozen, the sample may be refrigerated until ice packs are ready for packing. It is recommended to pre-freeze ice packs so they are ready when needed.

## ExoDx™ Prostate Test at a Glance

### Who's the test for?



Men 50 years of age or older



Considering an initial or repeat biopsy



PSA levels of 2-10 ng/mL

### How does it work?



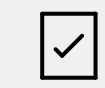
Non-DRE First Catch Urine Sample



Extraction and Amplification of Exosomal RNA



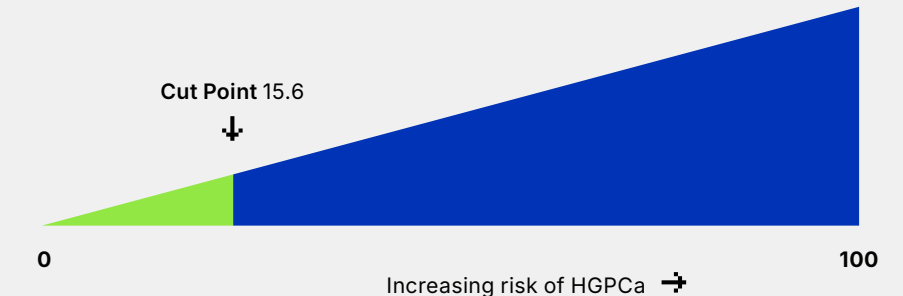
Gene Signature (Proprietary Algorithm)  
ERG | PCA3 | SPDEF



ExoDx Score

### What does the test score mean?

A result below the cut point of 15.6 has a 91.3% negative predictive value (NPV) for predicting the absence of high-grade prostate cancer.

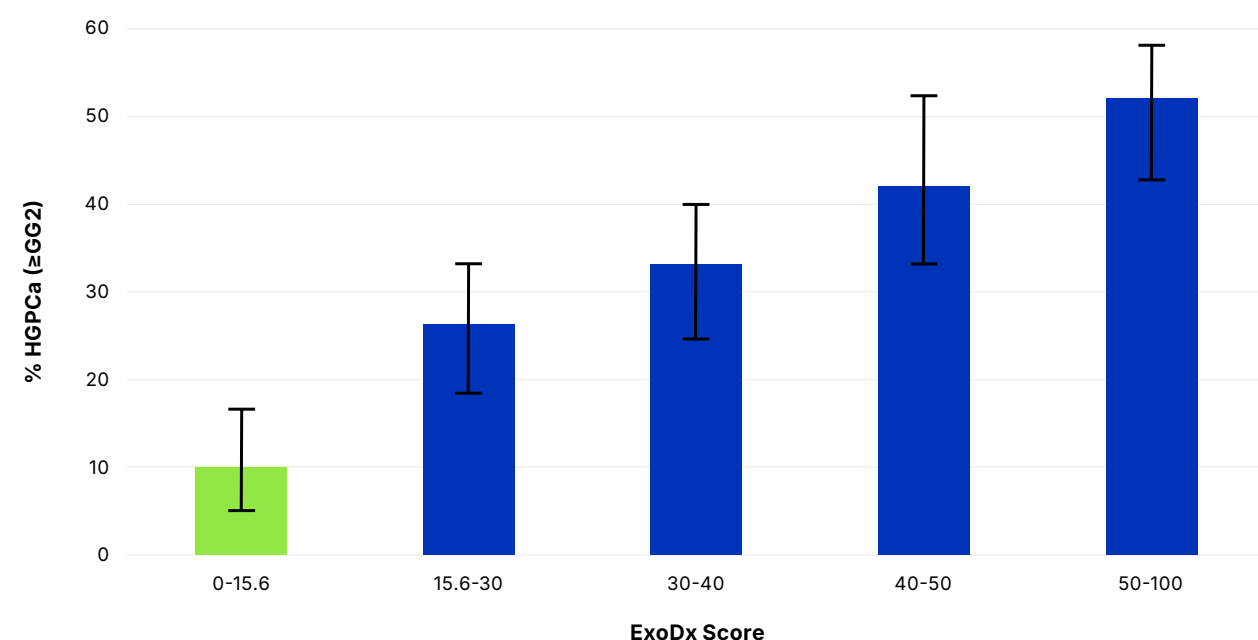


The test was developed as a rule-out test (91.3% negative predictive value in the initial biopsy cohort for  $\geq$  GG2, 97% NPV for  $\geq$  GG3).<sup>11</sup>

## Interpreting the ExoDx™ Prostate Test Score

The ExoDx Prostate Test score ranges from 0 to 100 with a cut point at 15.6. Score ranges are proportional to increased likelihood for HGPCa.

### Likelihood of Finding HGPCa on Biopsy in Intended Use Population<sup>4,5</sup>



From two prospective studies with a combined total of 1022 men, the graph above shows the percentage of men within each ExoDx score range with high-grade prostate cancer.<sup>14</sup>

#### Key Points:

- As the ExoDx Prostate Test score increases, the likelihood of finding HGPCa on prostate biopsy increases.
- Every patient in this data set is in the intended use population (PSA 2–10 ng/mL, presenting for initial biopsy, and 50 years and above).
- The patient population included a representative sampling of African Americans and excluded patients on 5-alpha-reductase inhibitors.
- The ExoDx Prostate Test provides a risk assessment that's independent of PSA level or other clinical features.

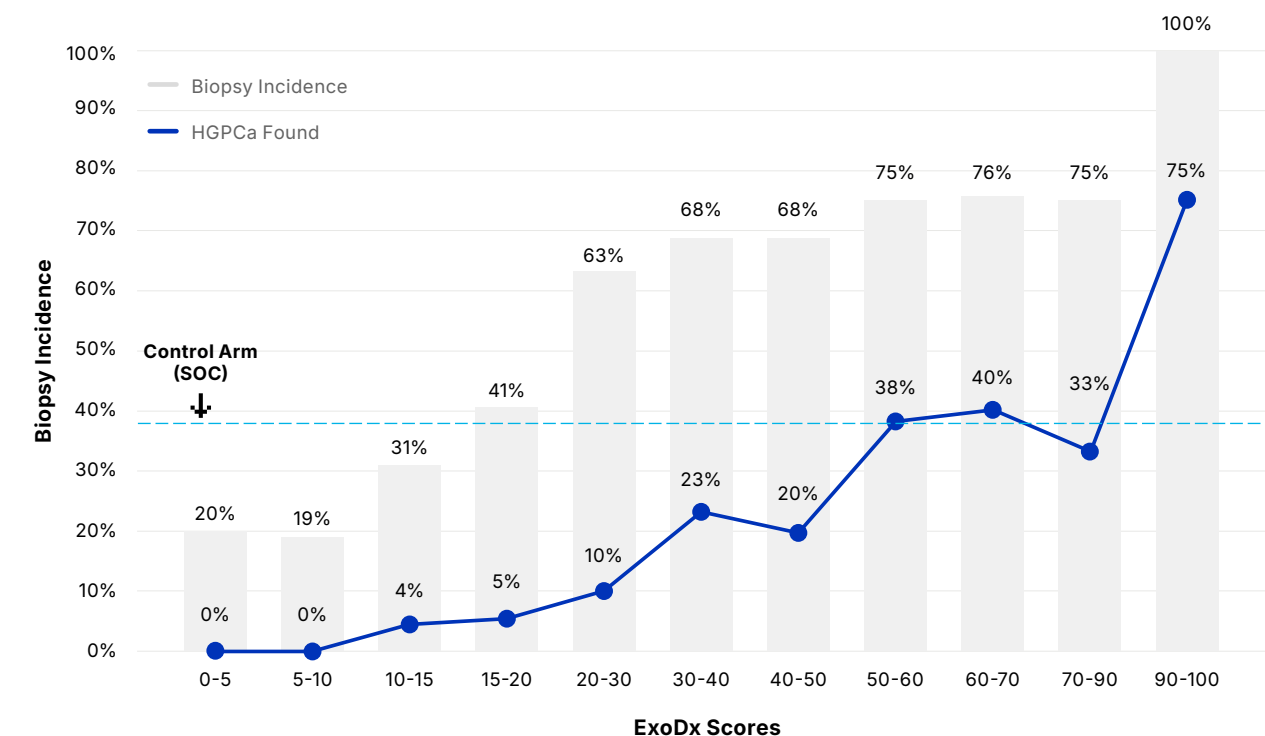
**The ExoDx Prostate Test Performed the Same in Two Prospective Validation Studies Published in Top-Tier Peer-Reviewed Journals and Included Over 1,000 Patients.<sup>4,5</sup>**

#### Key Points:

- The ExoDx Prostate Test accurately identified patients with low risk of HGPCa with a score of 15.6 or less.
- The ExoDx Prostate Test accurately identified patients with moderate/high risk of HGPCa with a score of 15.6 or more.

## Find More HGPCa with the ExoDx™ Prostate Test

### Level 1 Evidence Clinical Utility Data Identifying High- and Low-Grade Patients Appropriately



Rates of biopsies performed (bar graph) and detection of High-Grade Prostate Cancer (HGPCa) (line graph) as functions of the ExoDx Prostate Test score. As illustrated, urologists used the ≤15.6 cut point as a rationale to support biopsy deferral and a >20 ExoDx Score for proceeding with a biopsy due to the increased risk of finding HGPCa.

# 30%

**More High-Grade Prostate Cancer (HGPCa) Detected vs. the Standard of Care Control Arm**

The Clinical Utility Study with the ExoDx Prostate Test showed 30% more HGPCa diagnosed.<sup>3</sup> The study is the first-ever prospective, multi-center, randomized clinical utility trial with a blinded control arm for a prostate cancer marker in the early detection setting. There were 72 urologists, 24 sites, and more than 1,000

patients that participated in real-world clinical settings, demonstrating that the ExoDx Prostate Test delivered improved patient outcomes over standard of care. 92% of Patients complied with physician recommendation to defer biopsy when the ExoDx Prostate Test result was low risk.

# How to Order the ExoDx™ Prostate Test

## EMR Integrations & Portal Ordering

### EMR Integration

Full bi-directional integration of the ExoDx Prostate Test with an EMR system can help streamline the process of ordering and receiving test results. This integration can help reduce the time and effort required to manually enter patient data and test results into the EMR system, which can lead to improved efficiency and accuracy. Please contact us to determine whether your EMR provider currently offers integration.

Email: [EMR@bio-techne.com](mailto:EMR@bio-techne.com)



### Portal Ordering

For offices which do not yet have an available EMR integration, we offer a portal that can be used to electronically order the ExoDx Prostate Test. This portal can also be used to view and manage patient test results securely and efficiently. For a preview and step-by-step instructions:



Scan the QR Code or Visit:  
[exosomedx.com/physicians/how-to-order-exodx-prostate-test](https://exosomedx.com/physicians/how-to-order-exodx-prostate-test)

Paper-based ordering is still available, visit:  
[exosomedx.com/contact-us](https://exosomedx.com/contact-us)

## ExoCARES Patient Assistance Program

Health insurance can be complicated and frustrating for patients to navigate. Some patients may not fully understand their coverage, and our ExoCARES team is here to help.

The ExoDx Test is covered by Medicare and many commercial plans. While ~95% of all test costs are covered by insurers, the level of coverage may vary depending on the individual and their plan, and deductibles and coinsurance may apply. Patients not wholly covered are automatically enrolled in

ExoCARES, a program to ensure the test is affordable and accessible to all patients.

Once a claim is submitted, the patient should expect to receive an Explanation of Benefits (EOB). Please reassure them that an EOB is not a bill and is standard for insurance companies to send.

If a claim is denied, as part of ExoCARES, we will reach out to the patient by phone to assist them. Practices are encouraged to direct any and all coverage and billing related questions to our team.



# Frequently Asked Questions

## Is this covered by insurance?

The ExoDx Prostate Test is covered by Medicare and many commercial plans. While ~95% of all test costs are covered by insurers, the level of coverage varies. Patients not wholly covered are automatically enrolled in ExoCARES, a program to ensure the test is affordable and accessible to all patients.

## The ExoDx Prostate Test came back at "Higher Risk" but a biopsy result came back negative. How should I interpret this result?

In this case there are two possible interpretations:

1. Although the ExoDx Prostate Test returned a result indicating a higher risk, this patient does not have HGPCa.
2. The biopsy sampling missed the HGPCa.

## What is the Negative Predictive Value (NPV)?

Negative Predictive Value is a statistical measure that says how confident we are about a negative outcome. In the initial biopsy population, the NPV was 91% for HGPCa (defined as  $\geq$ GG2).<sup>6</sup> Calculated initial biopsy NPV from the same dataset for  $\geq$ GG3 resulted in 97%.<sup>4,6</sup>

## What is the sensitivity of the ExoDx Prostate Test?

The sensitivity of the ExoDx Prostate Test is 92% in the initial biopsy population, and the sensitivity of the ExoDx Prostate Test is 82% in the repeat biopsy population.<sup>6</sup> The sensitivity measures the proportion of actual GG2 and above that are correctly identified as positive.

## What is the cut point used to determine high risk vs. lower risk?

The ExoDx Prostate Test has been validated using a cut point of 15.6 to determine when patients are at low risk for high-grade prostate cancer, defined as Gleason 7(3+4) or Grade Group 2 or higher. Patients with an ExoDx Prostate Test score below this cut point have a very low risk (9%) of having high-grade prostate cancer.

## Does the ExoDx Prostate Test distinguish between GG1 and GG2 and higher prostate cancer?

Yes. The ExoDx Prostate Test is optimized as a rule-out test to distinguish high-grade prostate cancer (defined as GG2 and above) from low-grade prostate cancer. Patients above the cut point of 15.6 are associated with higher risk of finding high-grade prostate cancer upon biopsy. Patients with a score of 15.6 or less are associated with lower risk of high-grade prostate cancer. Reference the figure on page 4 to see the likelihood of finding HGPCa in the intended use population.

## Is the score a percentage of risk?

No. At or below the cut point, the NPV of 91.3% for finding HGPCa ( $\geq$ GG2) upon biopsy applies. A score  $>15.6$  indicates an increasing risk of high-grade prostate cancer. This score should be used with other clinical factors to inform further clinical management.

## Why do I need to use your collection cup?

The prostate biomarkers we are looking for have the highest concentration in the "first catch" urine sample which is the first 15 mLs of the void. Using the ExoDx™ collection cup that we provide allows us to capture this first catch and discard additional urine that would dilute the sample.

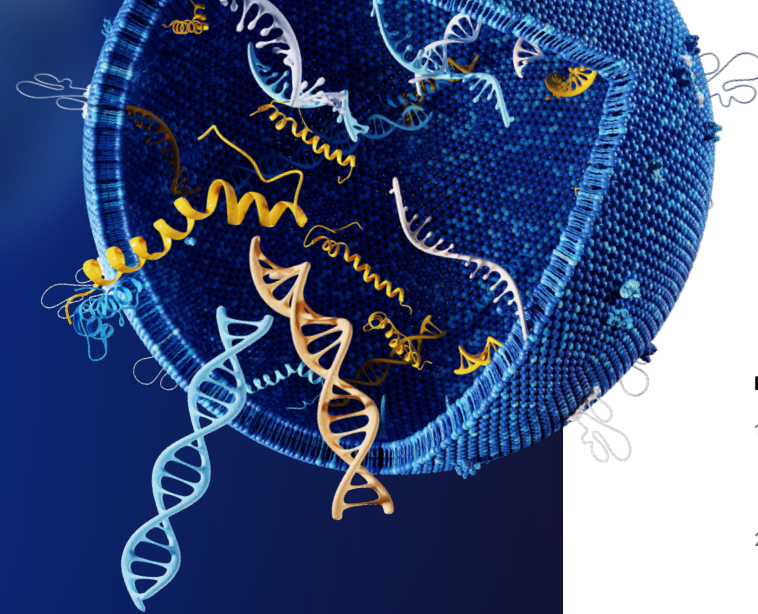
## Which RNA biomarkers are analyzed?

PCA3, ERG and SPDEF.

## What should I do if the patient voided 30 minutes ago?

Please have the patient wait one full hour before providing a new sample. The ExoDx Prostate Test is most accurate when there is sufficient signal in the urine sample, which occurs with the first catch. We also offer an At-Home collection kit that can be sent directly to the patient's home for later collection.

# Experience the Power of Exosomes



Strength of the Test	ExoDx™	Select mdx <sup>7</sup>	MPS2 <sup>®</sup>	PHI <sup>8, 9</sup>	IsoPSA <sup>®</sup>	4Kscore <sup>®</sup>
Level 1 Evidence	●	○	○	○	○	○
At-Home Collection Kit	●	○	○	○	○	○
Genomic Markers Only	●	○	●*	○	○	○
PSA or other Standard of Care (SOC) Clinical Risk Factors Excluded from Algorithm	●	○	●*	○	○	○
No DRE Required	●	○	○	●	●	○
Urine Test	●	●	●	○	○	○
No Blood Draw Required	●	●	●	○	○	○

The ExoDx Prostate Test is the only test completely independent of PSA, SOC, and clinical features; no DRE required and offering At-Home collection.

\*Although required on test requisition, MPS2<sup>®</sup> may exclude non-genomic markers such as PSA, or other standard of care parameters and clinical risk factors, which alters the performance of the test.

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