

Reporter Backgrounder: Oncotype DX® Test for Late-Stage Prostate Cancer

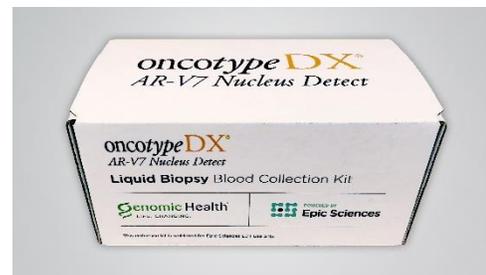
Important Facts

- Metastatic castration-resistant prostate cancer (mCRPC) is an advanced stage of the disease in which the cancer continues to grow and spread despite treatment with AR-targeted therapies, such as enzalutamide and abiraterone.
- It's estimated that about 50,000 mCRPC patients each year could benefit from knowing their AR-V7 status prior to selecting treatment.
- A new blood-based liquid biopsy test identifies a **predictive and prognostic biomarker called AR-V7**. When present, **AR-V7 signals that a patient has become resistant to hormone therapy**, and guides this difficult decision with unparalleled accuracy.

**First and Only
 Liquid Biopsy of
 Its Kind to Predict
 Treatment
 Response in Men
 with Metastatic
 Prostate Cancer**

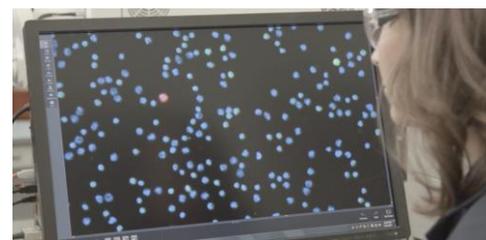
What is the Oncotype DX AR-V7 Nucleus Detect® Test?

- The Oncotype DX AR-V7 Nucleus Detect® test helps physicians select the most effective treatment for their mCRPC patients by identifying the presence or absence of the AR-V7 protein from a single, standard blood draw.
- By knowing a patient's AR-V7 status, the test can help doctors prolong the lives of men with late-stage prostate cancer. The test can also help avoid the use of cancer drugs such as enzalutamide and abiraterone that are ineffective in more than 20 percent of patients with mCRPC.
- Supported by multiple clinical studies, the test was developed by Epic Sciences and is offered by Genomic Health.



Clear Results Powered by Proprietary Technology

The Oncotype DX AR-V7 Nucleus Detect test utilizes Epic Sciences' proprietary No Cell Left Behind® platform. This groundbreaking platform takes high-definition images of every single cancer cell found in a blood sample, making it possible to characterize each cell – an unbiased approach that delivers superior test performance, sensitivity and specificity through a clear binary result. Additionally, single cell genomic analysis is often performed to gain deeper insight into individual cells.



What Does Research Say?

Two multi-center, clinical validation studies that included 360 patients have demonstrated and confirmed that men who are AR-V7 positive and treated with chemotherapy survive longer than those on AR-targeted therapy.¹ Results also demonstrated that approximately 20 percent of men who received initial AR-targeted treatment became AR-V7 positive and developed drug resistance as a result.²



“AR-V7 is an exciting breakthrough in fighting prostate cancer as it immensely helps in determining the best treatment pathways for patients. Men and families face anxiety and tough decisions over treatments but this tool, for example, will enable those men to make determinations like when to move on from hormonal therapy to chemotherapy to improve patient outcomes.”

- Jamie Bearse, CEO

[ZERO - The End of Prostate Cancer.](#)

Is It Covered by Insurance?

Effective December 10, 2018, the Oncotype DX AR-V7 Nucleus Detect[®] test is covered by Medicare in the United States.



“New technologies like the Oncotype AR-V7 test make personalized medicine a reality for advanced stage patients. The ability to more confidently and quickly make decisions around treatment can be a significant relief for patients and their families.”

- Wendy L. Poage, MHA, President

[Prostate Conditions Education Council.](#)

¹ Scher, H.I., et al., *Assessment of the Validity of Nuclear-Localized Androgen Receptor Splice Variant 7 in Circulating Tumor Cells as a Predictive Biomarker for Castration-Resistant Prostate Cancer.* JAMA Oncol, 2018.

² Scher, H.I., et al., *Association of AR-V7 on Circulating Tumor Cells as a Treatment-Specific Biomarker With Outcomes and Survival in Castration-Resistant Prostate Cancer.* JAMA Oncol, 2016. 2(11): p. 1441-1449.

Genomic Health Inc. • 301 Penobscot Drive • Redwood City, CA 94063 • 1(866)-ONCOTYPE • GenomicHealth.com

In the U.S. and certain other jurisdictions, Genomic Health, Oncotype DX, Oncotype IQ, Recurrence Score, Oncotype DX Breast Recurrence Score, Oncotype DX Colon Recurrence Score, Oncotype DX Genomic Prostate Score, and Oncotype DX AR-V7 Nucleus Detect are registered trademarks, and "Making cancer care smarter" and GPS are pending registered trademarks, of Genomic Health, Inc.