

Reporter Backgrounder: Oncotype DX® 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 commonly used hormone therapies** (also called androgen receptor-signaling inhibitor (ARSI) therapies), such as enzalutamide and abiraterone.
- Each year **50,000 men in the United States must decide** between continuing with enzalutamide and abiraterone, starting a different ARSI drug or switching to chemotherapy.
- This is a critical decision since switching to another treatment, such as chemotherapy, **has been shown to prolong survival** in two validation studies led by Memorial Sloan Kettering Cancer Center (MSKCC).
- 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.

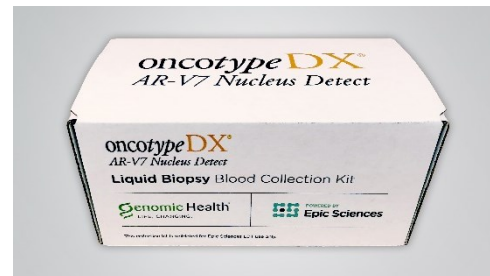
**First and Only
 Liquid Biopsy of
 its Kind to Predict
 Treatment
 Response in Men
 with Metastatic
 Prostate Cancer**

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 that are ineffective in more than 20 percent of patients with mCRPC.
- Supported by multiple clinical studies, the test was developed by Epic Sciences in partnership with MSKCC, and it 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. The 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-centered, 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 ARSI therapy. Results also demonstrated that approximately 20 percent of men who received initial ARSI treatment became AR-V7 positive and developed drug resistance as a result.

The first validation study was led by Memorial Sloan Kettering Cancer Center, and results were published in JAMA Oncology. The research suggests that patients with detectable blood levels of AR-V7 should consider life prolonging chemotherapy as an alternative to potentially less effective and more expensive hormonal treatment.

Results from the second validation study, also led by Memorial Sloan Kettering Cancer Center, were recently presented at the 2018 Genitourinary Cancers Symposium of the American Society of Clinical Oncology (ASCO) and were recently accepted for upcoming publication in a peer-reviewed oncology journal. This study reconfirmed the results of the first validation, demonstrating the Oncotype DX AR-V7 Nucleus Detect test as a predictive biomarker to inform the decision between ARSI therapies or chemotherapy for mCRPC patients who have become resistant to hormone therapy. Specifically, the test is validated to predict resistance in positive patients and the magnitude of the response to ARSI therapies in negative patients.



“The growing body of evidence for the clinical utility of AR-V7 supports its use in clinical practice as a treatment-specific biomarker to guide treatment selection for patients with advanced prostate cancer.”

- Howard Scher, M.D., study principal investigator and chief of Genitourinary Service at Memorial Sloan Kettering Cancer Center, New York