AR-V7 Nucleus Detect Report

oncotypeDX® AR-V7 Nucleus Detect powered by Epic Sciences

PATIENT LAST NAME, FIRST NAME MIDDLE I.

Date Of Birth: **01-Jan-1950** Gender: **Male** Report Number: **OR000123456** Report Date: **23-Oct-2018**

Ordering Physician: **Dr. First-Name I. Last-Name**

Client:

Medical Record/Patient #: **1234567-01** Date of Collection: : **17-Oct-2018**

Specimen Source/ID: **Blood/SP-18_0123456** Specimen Received: **18-Oct-2018**

Additional Recipient: **Dr. First-Name I. Last-Name** Study #: **XXXX** Lab ID: **E18-1234**

Results

Clinical Interpretation

- May have clinical response to and benefit from abiraterone, apalutamide, or enzalutamide regardless of prior line(s) of therapy. [1,2,3]

Negative: No nuclear localized AR-V7 positive CTCs identified

Intended Use

The AR-V7 Nucleus Detect test is intended for use in patients with metastatic castration-resistant prostate cancer (mCRPC) who are considering androgen receptor signaling inhibitors (eg, abiraterone, enzalutamide, apalutamide). The test identifies the presence of AR-V7 protein in the nucleus of circulating tumor cells (CTCs) in blood samples from mCRPC patients to inform clinical decision-making.

Limitations: While AR-V7 is one resistance mechanism to AR-targeted therapy, other mechanisms of resistance can occur. Consequently, patients who are AR-V7 negative by this test, may still not respond to an AR-targeted therapy. Cytokeratin negative cells[1] are not detected by this test. Patient management should be based on the information provided by the AR-V7 Nucleus Detect Test result, clinical correlation, and shared decision making.

Test Method: Nucleated cells from the patient's blood sample were individually analyzed to identify circulating tumor cells (CTCs), and the sub-cellular localization of AR-V7 protein within CTCs. All negative and positive controls were reviewed and determined to be within specification prior to reporting of results.

References:

1. Scher, H. I. et al. JAMA Oncol 2, 1441-1449 (2016). doi:10.1001/jamaoncol.2016.1828.
2. Scher, H. I. et al. JAMA Oncol (2018). doi:10.1001/jamaoncol.2018.1621
3. Armstrong AJ, et al. ASCO 2018; J Clin Oncol 36, 2018 (suppl; abstr 5004).

Signed By: [Digital Signature of Physician] on 23-Oct-2018 03:45 PM

Disclaimer: *This test is a laboratory-developed test that was developed and its performance characteristics determined by Epic Sciences, Inc. It has not been cleared or approved by the US Food and Drug Administration. Although laboratory-developed tests to date have not been required to obtain such clearance or approval, certification of the laboratory is required under Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the tests. Epic Sciences is certified under US CLIA as qualified to perform high-complexity clinical laboratory testing and accredited by the College of American Pathologists (CAP).*

Genomic Health

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