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 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:

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.

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.

Results

Clinical Interpretation
• May have clinical response to and benefit from abiraterone, apalutamide, or enzalutamide regardless of prior line(s) of therapy. 

Negative: No nuclear localized AR-V7 positive CTCs identified