

Exosome Diagnostics and Chesapeake Urology Partner to Evaluate Clinical Value of ExoDx® Prostate(IntelliScore) in First Study Under Novel Evidence Development Collaboration

Leading Urology Practice in the US to Evaluate Clinical Utility and Health Economic Value of Exosome Liquid Biopsy Test in Avoiding Unnecessary Prostate Biopsies

September 19, 2017 - Baltimore, MD and Boston, MA – Exosome Diagnostics (ExoDx) and Chesapeake Urology announced today that they have initiated a new evidence development study to demonstrate the value of [ExoDx® Prostate\(IntelliScore\) \(EPI\)](#) in avoiding unnecessary prostate biopsies and the overtreatment of localized, low-risk prostate cancer. The study is part of an evidence development collaboration agreement announced in August 2017, between CareFirst BlueCross BlueShield (CareFirst) and ExoDx focused on evaluating innovative products using clinical outcome and cost analyses. The objective of the collaboration is to accelerate medical coverage for products that demonstrate benefits for patient care.

“As we discussed moving forward under the new agreement, we felt Chesapeake Urology was a strong fit for this study process,” said CareFirst Chief Medical Officer Rahul Rajkumar. “This clinical study with ExoDx and Chesapeake Urology advances our efforts to implement medical best practices in a time of increased focus on better patient outcomes, quality care and cost-effective delivery of medical services.”

The clinical study titled “A Prospective, Randomized Blinded, Shared Decision Impact Trial of the ExoDx Prostate(IntelliScore), EPI Test, in Men Presenting for Initial Biopsy” is a prospective clinical study of 1,000 patients being evaluated for an initial prostate biopsy. Subjects are being randomized into two cohorts of 500 patients each. An EPI test result will be provided for patients in the first cohort. The remaining 500 patients will be treated based on current standard of care. Endpoints for the study include the reduction in biopsies for patients with a reported EPI test result, urologist and patient satisfaction with the EPI test and the economic savings based on use of the EPI test result.

“We are committed to providing access to the most advanced diagnostics and treatments to optimize patient outcomes,” stated Ronald Tutrone, MD, FACS, CPI, Director of Chesapeake Urology Research Associates. “Working with a new test like EPI that is designed to avoid unnecessary procedures, complications and costs is fully aligned with our mission and core values.”

This evidence development collaboration complements other ongoing clinical studies designed to demonstrate the clinical and economic value that EPI offers to men being evaluated for an initial prostate biopsy. “Exosome Diagnostics is thrilled to partner with Chesapeake Urology to assess the clinical and economic value of EPI,” stated John Boyce, CEO of Exosome Diagnostics. “We are committed to overcoming the revenue and reimbursement challenges that have limited patient access to novel liquid biopsy tests like EPI up until this point. Partnering with Chesapeake Urology, a champion for improving patient care and implementing best practices, is an incredible opportunity to demonstrate the value of exosome based liquid biopsy tests for clinical care.”

About the EPI Test

The [EPI test is a completely non-invasive, urine-based test](#) designed to be used along with clinical assessment and other standard of care factors (including age, race and family history) to enable physicians to assess whether an individual patient presenting for an initial biopsy is at greater risk for

high-grade prostate cancer. As a “rule out” test, it is designed to more accurately predict whether a patient presenting for an initial biopsy does not have high-grade prostate cancer and, thus, could potentially avoid the discomfort, complications and cost of an initial biopsy and, instead, continue to be monitored. EPI, which is intended for use in men 50 years or older with a prostate-specific antigen (PSA) result of 2-10ng/mL presenting for an initial biopsy, involves patients submitting a simple urine sample, without having to first undergo a digital rectal exam (DRE).

This test was evaluated and its performance characteristics determined by Exosome Diagnostics Inc. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. Exosome Diagnostics is certified under the Clinical Laboratory Improvement Amendments (CLIA) act of 1988 as qualified to perform high complexity clinical testing.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company’s novel exosome-based technology platform, ExoLution™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored. Visit www.exosomedx.com to learn more.

About Chesapeake Urology

Chesapeake Urology is the largest urology practice in Maryland and the Mid-Atlantic region, providing a comprehensive array of urologic services to patients. Chesapeake Urology's 63 physicians, 14 physician assistants and three patient navigators work throughout 21 medical offices and 14 AAAHC-certified ambulatory surgery centers in the region. The combination of a large network of urology specialists and referrals to fellowship trained doctors within their group provides patients with an unparalleled continuum of care. Visit www.chesapeakeurology.com to learn more.

Media Contact

Dan Baughman
dbaughman@exosomedx.com
(248) 613 2247