

Exosome Diagnostics Launches National Sales Team to Support Flagship Test, ExoDx®Prostate(IntelliScore)

EPI test could help avoid 900,000 unnecessary prostate biopsies performed each year

January 4, 2018 - Waltham, MA. Expanding upon the very successful regional introduction of the [ExoDx Prostate\(IntelliScore\)](#), or EPI, Exosome Diagnostics is thrilled to announce that EPI will now be supported by a national urology sales team.

EPI is designed to reduce unnecessary initial prostate biopsies in men 50 years of age or older, with a PSA value between 2-10ng/ml. In this patient population, 85% of all prostate biopsies are proven to be unnecessary because they detect benign or low-grade disease. There is both significant risk and cost associated with the prostate biopsy, as well as with the potential complications arising from the procedure in up to 5% of men. As such, EPI is an important tool that has the potential to reduce hundreds of thousands of unnecessary prostate biopsies each year and to offer both clinical and economic benefits to physicians, patients and payors alike.

“As a practicing urologist, one of the most challenging tasks we are faced with is identifying those men most appropriate for prostate biopsy. EPI helps distinguish those men who can safely avoid prostate biopsy through an easy to perform urine test.” says Preston Sprenkle, MD, Assistant Professor of Urology at Yale University; Division Chief, Division of Urology at VA Connecticut Healthcare System; Director, Urology Research Fellowship; Director, Urologic Oncology Clinical Fellowship Program.

"Building the commercial diagnostic strategy and framework for Exosome Diagnostics has been a tremendous experience," stated Elizabeth Cormier-May, Vice President & Head of Commercial Diagnostics. "We laid out a very deliberate plan and executed on the deliverables most important for market penetration, product adoption and physician education. Now with announced coverage decisions and a tenured national sales team, I am confident that the regional success EPI has seen thus far will translate across the country, aiding physicians and their patients in the prostate biopsy decision process," Cormier-May continued.

“In order to ensure the commercial success of the company’s diagnostic pillar, Exosome Diagnostics has executed against a strategic, phase-gated plan that encompasses reimbursement with commercial milestones,” stated John Boyce, President and CEO of Exosome Diagnostics. “The national demand for EPI, since its limited regional launch, has warranted the hiring of a urological

sales force in order to work with the country's leading urologists in order to alleviate unnecessary biopsies," Boyce continued. "Combined with its leading position in the companion diagnostics liquid biopsy market, the commercialization of its protein interrogation liquid biopsy system (Shahky), and the successful commercial launch of EPI, Exosome Diagnostics is poised to deliver clinically actionable diagnostic tests and tools to physicians worldwide," Boyce concluded.

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™, and point of care instrument for protein capture and analysis, Shahky™, 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.

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