



## **Exosome Diagnostics Announces Launch of ExoDx® *Prostate(IntelliScore)*, a Completely Non-Invasive Liquid Biopsy Test to Help Rule Out High-Grade Prostate Cancer**

*World's First and Only Test Analyzing Genetic Information from Exosomes Via a Simple Urine Collection Requiring No Digital Rectal Exam*

*Potential to Avoid Over One Million Unnecessary Prostate Biopsies Each Year Worldwide*

**CAMBRIDGE, MA- September 7, 2016**—Exosome Diagnostics, Inc. announced the launch of its ExoDx® *Prostate(IntelliScore)* test (EPI) through the company's CLIA certified laboratory in Cambridge, Massachusetts. EPI is a laboratory-developed test designed to provide clinicians and patients with information that will improve the prostate biopsy decision-making process. EPI is the first test using specific genetic information captured from a simple urine sample to provide physicians with a score to help evaluate their patient's risk for high grade, potentially more aggressive prostate cancer.

In the United States each year, approximately one million prostate biopsies are performed with up to 80 percent of the results indicating no cancer, or a low-grade cancer that could instead be monitored under a watchful waiting or active surveillance program. The EPI test was designed to reduce the number of unnecessary prostate biopsies and the associated overtreatment of low-grade disease. Complications associated with unnecessary prostate tissue biopsies range from discomfort and temporary incontinence or impotence, to hospitalization for serious infections in three to four percent of patients.

"Prostate cancer is really a spectrum of disease. Not all patients have the same type of tumor or the same grade of disease," stated Peter Carroll M.D., chair of urology at the University of California, San Francisco and an investigator in the EPI clinical validation trial. "Very few men need immediate treatment. Repeat PSA testing, PSA/protein based diagnostic tests, MRI scans and now molecular genetic testing with EPI will provide important data to help clinicians, patients and their families make better informed decisions about whether to proceed with an initial prostate biopsy. This test launch marks an important step forward in efforts to develop more sensitive markers for assessing the risk of aggressive prostate cancer and the ability to monitor disease progression in a completely non-invasive approach."

The scientists and clinicians at Exosome Diagnostics developed this innovative test with input from the Prostate Cancer Foundation, urologists, patients and insurance providers. The EPI test uses a simple urine catch without a digital rectal exam, making it completely non-invasive for the patient and easy to integrate into patient care. The EPI test utilizes a three-gene signature, in combination with a proprietary algorithm. The score generated is simple for physicians to understand and discuss with their patients. The EPI test is unique from other tests in this space because it is a stand-alone diagnostic, as it does not take into account other standard of care parameters in the score thus making it a powerful complement to the existing PSA test.

A final clinical evaluation study enrolled over 1,500 patients through collaborations with 26 leading urology centers across the United States. Results from the study demonstrated that the EPI test was highly accurate for ruling out the presence of high-grade cancer (Gleason score seven or higher) prior to

an initial prostate biopsy. The data from this blinded, prospective U.S. clinical validation study were published in JAMA Oncology in March 2016.

"Molecular and genetic testing are improving the quality of cancer care and patient outcomes. We are excited to provide this first-of-its-kind test to men at risk for prostate cancer," said Tom McLain, Chief Operating Officer of Exosome Diagnostics. "Using our patented technology to analyze the RNA released by prostate cancer cells, we provide a simple score to help evaluate the patient's risk for high-grade prostate cancer. This will better inform clinicians and patients and help to clarify the decision process surrounding prostate biopsy."

EPI is one test in a portfolio of diagnostic and companion diagnostic tests being developed and launched by the company. "Today's announcement provides another demonstration of the value of Exosome Diagnostics' platform combining patented, leading isolation methodologies, ancillary technologies to increase the signal over the noise, tissue specific exosome identification methodologies, and proprietary algorithms to develop sensitive diagnostic assays and accelerate the development of companion diagnostics," said John Boyce, President and CEO of Exosome Diagnostics. "Our tests are unique in the liquid biopsy space. By combining the information about disease from exosomes and cell-free DNA captured from any biofluid sample, we are able to achieve the clinical and analytical performance needed for liquid biopsy tests to provide clinicians with real-time, patient specific information that can be used to improve care, select the right therapy, avoid unnecessary procedures and lower overall healthcare costs."

#### **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).

The EPI test analyzes the urine for three biomarkers on exosomal RNA (exoRNA) that are expressed in men with high-grade prostate cancer. Using a proprietary algorithm that combines the relative weighted expression of the three-gene signature, the test assigns an individual risk score for patients ranging from zero to 100. Scores above a pre-defined cut point are associated with an increased likelihood of high-grade prostate cancer on a subsequent biopsy.

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 Prostate Cancer**

In 2014, over 233,000 new cases of prostate cancer were identified and more than 29,000 men died from the disease according to estimates released by the National Cancer Institute. That makes prostate cancer the second deadliest cancer in men in the United States. Prostate cancer is usually first detected by elevations in serum PSA. However, PSA level is often elevated for reasons unrelated to prostate cancer. Although an elevated PSA level often leads to biopsy, about 80 percent of all prostate biopsies performed are either negative or indicate a low likelihood of high-grade cancer.

**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 detected, diagnosed, treated and monitored. Visit [www.exosomedx.com](http://www.exosomedx.com) to learn more.

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