Exosome Diagnostics Prostate Cancer Liquid Biopsy Test

Frequently Asked Questions

What is the test?
Exosome Diagnostics is developing a non-invasive, non-digital rectal exam (DRE), urine-based liquid biopsy test to predict the aggressiveness of prostate cancer prior to initial tissue biopsy.

The test is being designed to enable physicians, along with the prostate-specific antigen (PSA) test and other standard of care factors (including age, race, and family history), to more accurately predict whether a patient presenting for an initial tissue biopsy does not have high-grade prostate cancer and, thus, could potentially avoid an initial biopsy and instead continue to be monitored.

How will the test work?
For the Exosome Diagnostics liquid biopsy test in development, patients submit a simple, non-digital rectal exam (DRE) urine sample. The test analyzes the urine for three biomarkers on exosomal RNA that are expressed in men with high-grade prostate cancer. Using a proprietary algorithm that integrates the three-gene signature, the test assigns an individual risk score for patients that predicts the presence of high-grade (Gleason Score ≥ 7) prostate cancer.

What is exosomal RNA?
Exosomes are messengers released by all living cells into biofluids, such as plasma/serum, urine, cerebrospinal fluid, and saliva. Exosomes contain RNA, DNA, and proteins from their cell of origin. By isolating and analyzing exosomal RNA, Exosome Diagnostics’ technology platform can reveal important information about cells in the body, including specific biomarkers and mutations linked to certain cancers, in real time without needing direct access to the actual cells.

In addition to the prostate cancer liquid biopsy test, Exosome Diagnostics is also currently developing blood-based liquid biopsy tests for lung and other types of solid tumor cancers.

How accurate is the test?
We understand that clinicians and their patients need to have the utmost confidence when relying on a new test to inform critical treatment decisions. We conducted a large, well-designed, prospective clinical validation study to evaluate the test’s performance on key accuracy and sensitivity measures.

In the study, the test demonstrated a high negative predictive value, or NPV, of 91.3 percent. NPV is a commonly used measure of a diagnostic’s predictive accuracy. The test was able to predict high-grade prostate cancer biopsy results with 91.9 percent sensitivity. “Sensitivity” (also called the true positive rate) measures the percentage of high-grade prostate cancer that the test correctly identified.
Based on these results, the test’s high NPV and high sensitivity will help physicians more accurately predict whether a patient presenting for an initial prostate biopsy does not have high-grade prostate cancer and, thus, could potentially avoid an initial biopsy and instead continue to be monitored.

**When will the test be available?**
In 2015, we plan to conduct additional clinical studies, including outcome and economic-based analyses, for our prostate cancer liquid biopsy test. We plan to proceed with a commercial launch of a laboratory developed test (LDT) in the United States in 2016. We also plan future submissions in Europe for a CE Mark, as well as for approval of an in vitro diagnostic version of the test with the U.S. Food and Drug Administration.

**How long will it take to get results?**
Once the test is commercially available in 2016, we anticipate that we will be able to provide results to physicians within five working days upon receipt of a urine sample.

**Where will the test be performed?**
The test will be performed at Exosome Diagnostics’ CLIA-certified laboratory.

**Can I participate in one of the studies planned for 2015?**
We will be partnering with targeted organizations, including health plans, to conduct outcomes and economic studies in 2015. We will not be actively enrolling patients in studies outside of those partnerships.

**Will the test be able to be used to monitor patients who have already had an initial prostate biopsy?**
The test was optimized for men presenting with equivocal clinical features for an initial biopsy. Although patients with a prior negative biopsy were enrolled in the clinical validation study, they represented a much smaller percentage of men and, therefore, additional confirmatory studies will be necessary to assess assay performance. We have not yet evaluated the test in men previously diagnosed with prostate cancer and currently on or contemplating an active surveillance protocol. Similar to the prior negative biopsy group, further studies are required.

**Is someone from Exosome Diagnostics available to speak with my doctor?**
We welcome physicians and other clinicians who would like to learn more about our prostate cancer liquid biopsy test to call us at 1-844-EXOSOME or to send us an email at info@exosomedx.com.