

SelectMDx improves prostate biopsy decision-making in urology practices

Real-world study shows that SelectMDx helps urologists more confidently determine the need for an initial prostate biopsy

IRVINE, CA, and HERSTAL, BELGIUM – 07.00 CEST, 7 November 2018 – MDxHealth SA (Euronext: MDXH.BR) or the “Company” today announces that the journal [Urology Practice](#) has published a study demonstrating the clinical utility of SelectMDx, the Company’s non-invasive ‘liquid biopsy’ test to identify patients at increased risk of aggressive prostate cancer, in guiding initial prostate biopsy decision-making.

Existing research shows that survival rates for patients are better when intermediate and high-risk prostate cancer are caught earlier. However, the low specificity of PSA screening, which is the current standard of care, often leads to unnecessary invasive prostate biopsies and the ‘over-detection’ of lower-risk cancers, which may not benefit from costly treatment.

“These data further demonstrate the importance of adjunctive biomarkers regarding PSA assessment, especially regarding the decision to either avoid or to proceed to prostate biopsy,” **said principal investigator Neal Shore, M.D., Medical Director at the Carolina Urologic Research Center, Atlantic Urology Clinics in Myrtle Beach, South Carolina.** “The SelectMDx biomarker offers physicians and patients an easily obtained urine-based test, which combines cost effectiveness with clinical utility, improving urologists’ ability to diagnose and treat prostate cancer.”

The study involved five U.S. community urology practices which sequentially enrolled 418 patients who received a SelectMDx test while undergoing evaluation for initial prostate biopsy. All tests were ordered by the urologist for patient management. The investigators determined biopsy and prostate cancer detection rates in SelectMDx-positive (high-grade, or aggressive, prostate cancer detected) versus SelectMDx-negative patients (those at lower risk for aggressive prostate cancer).

SelectMDx was shown to have a significant impact on initial prostate biopsy decision-making. SelectMDx-positive men, who are more likely to benefit from treatment, were five times more likely to receive a biopsy than SelectMDx-negative men. In the subset of patients biopsied within three months of receiving test results, high-grade cancers were discovered only in the SelectMDx-positive men, with none of the SelectMDx-negative patients biopsied within three months of testing being diagnosed with a clinically-significant disease.

“This new research shows that urologists can have confidence in the accuracy of SelectMDx results and can rely on the test when making clinical decisions,” **said Dr. Jan Groen, Chief Executive Officer of MDxHealth.** “In addition to decreasing potentially unnecessary diagnostic procedures and treatments, routine implementation of SelectMDx could lead to substantial cost savings for the healthcare system.”

According to a recent *JAMA Oncology* paper, reducing ‘over-detection’ of low-grade prostate cancer in elderly patients represents a potential source of significant cost savings for the U.S. Medicare program.¹ Separate research published earlier this year estimated that routine use of SelectMDx to guide biopsy decision-making could provide over \$500 million in potential annual cost savings for the U.S. healthcare system.²

“This clear benefit supports our efforts to expand SelectMDx into active monitoring and primary care settings. We believe this strategy has the potential to quadruple the market opportunity for SelectMDx in the mid-term to more than two million patients annually in both the U.S. and Europe,” **Dr. Groen**

added.

The full paper is accessible through the online edition of [Urology Practice](#).

1. [Jama Oncology](#) (JAMA Oncol. Published online September 13, 2018)
2. [Journal of Urology](#) (Published online July 15, 2018)

About SelectMDx® for Prostate Cancer

SelectMDx for Prostate Cancer is a proprietary urine based, molecular diagnostic test that offers a non-invasive 'liquid biopsy' method to assess a man's risk for prostate cancer. SelectMDx helps identify men at increased risk of harboring aggressive, potentially lethal, prostate cancer who may benefit most from a prostate biopsy and earlier detection. The test helps to reduce the need for MRI procedures and invasive prostate biopsies by up to 50%, thereby improving quality of life and lowering healthcare costs per patient. SelectMDx is available in the US and all EU member states. Since the introduction of the SelectMDx test in mid-2016, over 23,000 patients have been tested and 15 commercial contracts have been signed with US based insurance companies. The test has been included in the 2018 European Association of Urology (EAU) clinical guidelines.

About MDxHealth®

MDxHealth is a multinational healthcare company that provides actionable molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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