MDxHealth’s SelectMDx Test Successfully Stratifies Men Who May Benefit from mp-MRI

Multiple SelectMDx Clinical Study Abstracts presented at 2018 Global Prostate Congress in Frankfurt, Germany

HERSTAL, BELGIUM and IRVINE, CA – 07:00 CEST, June 27, 2018 – MDxHealth SA (Euronext Brussels: MDXH.BR), today announced the publication of positive data demonstrating the value of the SelectMDx liquid biopsy test for Prostate Cancer in guiding patient management for men being considered for multiparametric MRI and the clinical utility in guiding biopsy decisions in real-world clinical practice. Data will be presented at the sixth Global Congress on Prostate Cancer (PROSCA) in Frankfurt, Germany, June 28-30, 2018.

The data will be presented by researchers from Belgium and The Netherlands and are the first demonstration of SelectMDx for Prostate Cancer for guiding multiparametric MRI inclusion.

Assessment of a urinary TRUS/biomarker-based risk score as inclusion criteria for multiparametric MRI to detect clinically significant prostate cancer

Non-invasive techniques like SelectMDx and Magnetic Resonance Imaging (MRI) show great promise for the detection of prostate cancers that are clinically significant, avoiding over-diagnosis and over-treatment of cancers with low malignant potential. Although several studies support the promise of MRI in this arena, there remains a lack of consensus of its diagnostic accuracy, and its adoption faces further challenges due to the high cost of setting up, staffing and maintaining an MRI unit. Upfront risk stratification could significantly lower the cost of multiparametric MRI (mpMRI) by excluding patients who are at very low risk for high grade prostate cancer.

The study demonstrated that use of the SelectMDx liquid biopsy test for Prostate Cancer significantly reduces over-diagnosis and over-treatment, helping to identify patients who may forgo unnecessary MRI procedures.

The abstract can be found here.

Dr. Jan Groen, Chief Executive Officer of MDxHealth, commented: “These new studies show the clinical utility of SelectMDx for biopsy decision-making in real-world clinical practice. Significant results from multiple prior and ongoing studies on thousands of patients continue to support the value of SelectMDx as a tool to prevent unnecessary biopsy procedures in men demonstrating prostate cancer symptoms, benefiting patients and reducing the cost of public healthcare.”
Professor Christopher Eden, Professor of Urology at The Royal Surrey County Hospital and Director of the Santis prostate cancer clinic in London, commented: “The use of genomic classifiers such as SelectMDx is set to revolutionise the way that we manage patients with prostate cancer, predicting with extreme accuracy the likely biopsy findings and allowing us to tailor our advice and investigations appropriately.”

In addition to the above study the following abstracts will also be presented at PROSCA:

SelectMDx Impacts Prostate Biopsy Decision Making in Routine Clinical Practice
The study was conducted at five U.S. community urology practices, which sequentially enrolled 418 patients who received a SelectMDx test while undergoing consideration for an initial prostate biopsy. SelectMDx tests were ordered by the treating urologist for patient management (i.e., not as part of a planned or ongoing study), therefore reflecting real-world utility.

The study showed that SelectMDx had a significant impact on initial prostate biopsy decision-making in a U.S. community urology setting. Biopsy rates in men testing positive with SelectMDx were 5-fold higher than in men testing negative with SelectMDx. In the subset of patients biopsied within 3 months of receiving test results, 19/27 biopsies performed on SelectMDx positive men were cancer positive, including 10 with high grade disease. In SelectMDx negative men, cancers were identified in 4/9 men biopsied, and all were low-grade disease.

The abstract of the full study, SelectMDx Impacts Prostate Biopsy Decision Making in Routine Clinical Practice, can be found here.

Robust performance of a Urinary Molecular Biomarker–Based Risk Score to detect High-grade Prostate Cancer using optimised cascading models
The SelectMDx test results incorporate certain identified key clinical variables to improve the identification of patients at increased risk for high-grade PCa on prostate biopsy. The study demonstrates that, even in circumstances where not all clinical factors are available, the performance of SelectMDx remains robust, maintaining a >95% sensitivity.

The abstract can be found here.

About MDxHealth
MDxHealth is a multinational healthcare company, listed at the Brussels, Belgium, stock exchange (Euronext Brussels: MDXH.BR), 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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