

NEWS RELEASE

MDxHealth Announces Presentation of Positive Data for SelectMDx and ConfirmMDx in Prostate Cancer Diagnosis

Data to be Presented at the Annual ASCO Genitourinary Cancers Symposium

Data to further support clinical adoption of SelectMDx and ConfirmMDx

IRVINE, CA, and HERSTAL, BELGIUM – February 15, 2019 - MDxHealth SA (Euronext: MDXH.BR) today announced that positive data and observations from multiple studies and patient registries demonstrating the value of SelectMDx and ConfirmMDx for Prostate Cancer diagnosis, will be presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), taking place in San Francisco, California, February 14-16, 2019.

The data, to be presented in four separate poster presentations, highlights:

- Annual cost savings of nearly \$500 million when SelectMDx is used prior to multi-parametric magnetic resonance imaging (mpMRI) for the identification of US patients at high risk for aggressive prostate cancer.
- SelectMDx outperforms the Prostate Health Index (Phi) blood test for the detection of high-grade prostate cancer prior to tissue prostate biopsy.
- Retrospective validation of SelectMDx in German patients confirms robust clinical performance.
- Clinical utility study demonstrates that ConfirmMDx had a significant positive impact on repeat prostate biopsy decision-making.

"These new positive results from multiple studies with SelectMDx further strengthens our medical dossier and bring us an important step closer toward reimbursement and inclusion in clinical guidelines," stated **Dr. Jan Groen, CEO of MDxHealth**. "In addition, the completion and positive outcome from the second clinical utility study with ConfirmMDx will be of important value to further increase coverage, reimbursement and clinical adoption for this test." Dr. Groen concluded: "These results clearly demonstrate the superiority of our diagnostic tests and confirm our commitment to improving the lives of patients at high risk of aggressive prostate cancer by offering a valuable alternative for early and selective diagnosis of prostate cancer."

Further details of the studies can be found below. All abstracts were presented at the Poster Session entitled "[Trials in Progress Poster Session: Prostate Cancer](#)", on Thursday, February 14 from 11:30 AM-1:00 PM and 5:30-6:30 PM.

Abstract 91, Poster E15: Cost-effectiveness of a two-gene urine biomarker assay in MRI strategies for the initial detection of prostate cancer, First Author: Tim Govers, PhD

MRI is increasingly used in men with suspicion for prostate cancer (PCa) to target abnormal areas in addition to systematic biopsy. Although, MRI increases the detection of clinically significant PCa compared to systematic biopsy alone, overdiagnosis and overtreatment of insignificant disease still exists. A decision-analytic model was used to simulate downstream outcomes in the current MRI strategy. Using SelectMDx prior to MRI resulted in cost savings of \$1,590 per patient and approximately \$496 million annually for the US population of men at elevated risk of PCa. The use of SelectMDx to guide prostate biopsy decision-making can improve health outcomes and lower costs.

Cost savings were highest when SelectMDx was used prior MRI to select patients for MRI and prostate tissue biopsy.

Abstract 30, Poster B18: SelectMDx versus Prostate Health Index in the identification of high-grade prostate cancer, First Author: Gretchen Hoyer

SelectMDx was compared with the Phi blood test (Beckman Coulter) for the diagnosis of high-grade PCa in a cohort of 80 patients undergoing transperineal mapping biopsy. Multivariate logistic regression showed that SelectMDx was significantly better than Phi for detecting high-grade PCa ($\beta = 8.45$, $p = 0.0002$). With its high sensitivity and high Negative Predictive Value (NPV), SelectMDx is more useful than Phi for screening patients at risk of high-grade PCa prior to tissue prostate biopsy.

Abstract 96, Poster E20: Validation of a two-gene mRNA urine test for detection of high-grade prostate cancer in German men, First Author: Derya Tilki, MD

SelectMDx was performed in a study population of 443 German men with an average age of 66 years who underwent initial prostate biopsy due to suspected PCa. The study showed that if SelectMDx would have been used prior biopsy, 46% of potentially unnecessary biopsies would have been avoided, while 5.8% of men with biopsy-detectable high-grade PCa (seven GG2 and one GG3) may have had their diagnosis too late. The clinical performance of SelectMDx was comparable to the published European validation study, showing a high NPV 95% (90-97%) for detection of GG2 or higher PCa. These results provide further evidence for the clinical validity of SelectMDx.

Abstract 94, Poster E18: Clinical utility study of ConfirmMDx for prostate cancer in a community urology practice, First Author: Paul Yonover, MD

The study population consisted of 605 men with a prior PCa-negative prostate biopsy, who were counseled on the need to undergo repeat biopsy at a large community urology practice due to persistent elevated risk of PCa. Of the 605 subjects enrolled, 308 (51%) had a negative ConfirmMDx test result and 297 (49%) were tested positive. In the entire study population, average age was 64 (median 64, interquartile range 59 to 69) and the average serum Prostate-Specific-Antigen (PSA) level was 6.8 ng/mL (5.7, 4.3 to 8.1). The median follow-up for both ConfirmMDx positives and negatives was 10 months post-testing. Repeat biopsy rates for ConfirmMDx positive and negative men were 32.3% (96/297) and 5.8% (15/308), respectively ($P < 0.001$). ConfirmMDx had a significant impact on repeat prostate biopsy decision-making in a U.S. community urology setting. Repeat biopsy rates in ConfirmMDx positive men were six-fold higher than in ConfirmMDx negatives. These results reflect the clinical utility of ConfirmMDx for biopsy decision-making in real world clinical practice.

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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