

SelectMDx Outperforms Prostate Health Index (phi) Blood Test for Detecting High-Grade Prostate Cancer

*Data to be presented at the 29th Annual IPCU meeting
Beaver Creek, Co, January 24-27, 2019*

IRVINE, CA, and HERSTAL, BELGIUM – January 24, 2019 - MDxHealth SA (Euronext: MDXH.BR) today announced data to be being presented at the 29th Annual International Prostate Cancer Update (IPCU) meeting in Beaver Creek, Co, January 24-27, 2019, demonstrating that SelectMDx® for Prostate Cancer urine test outperforms the Prostate Health Index (phi) blood test.

The study, titled “**Comparison of SelectMDx, Prostate Health Index, and MRI for Diagnosis of High-Grade Prostate’ (19-010)**”, compared the SelectMDx urine test with the prostate health Index (phi) blood test for identifying patients with high-grade (HG) aggressive prostate cancer who would likely benefit from prostate biopsy or a multiparametric MRI (mpMRI) scan.

“High-grade prostate cancer (HG PCa) has poor clinical prognosis. Thus, clinicians have to rely on PCa biomarkers and multiparametric magnetic resonance imaging (mpMRI) to screen patients prior to prostate biopsies,” said **E. David Crawford, M.D, Professor of Surgery, Urology and Radiation Oncology and head of section of Urologic Oncology at the University of Colorado**. “We have clearly shown in this exploratory study that SelectMDx is better suited to identify patients with HG PCa prior to biopsy compared to the phi blood test”.

Study Design

The study consisted of 39 men with a median age of 65 years and mean serum PSA 6.4 ± 5.9 ng/mL. Patients were tested with the SelectMDx urine test, phi blood test (Beckman Coulter), and mpMRI prior to transperineal mapping biopsy after inconclusive TRUS biopsy results. Mapping biopsy identified 34/39 (87%) patients with PCa, and 15/34 (44%) had HG PCa and 18/34 (53%) had clinically significant (CS) PCa (HG or tumor volume >=0.5 cc). There were no significant differences between ROC curves of SelectMDx, phi, mpMRI PIRADS, PSA, PSAD, proPSA, and free PSA for the detection of HG PCa. Multivariate logistic regression analyses revealed that the SelectMDx test was significantly better than the other tests for detection of HG PCa ($\beta = 5.57, p = 0.001$) and CS PCa ($\beta = 4.05, p = 0.004$)

See below for a summary of the performance of SelectMDx, phi and mpMRI (PIRADS ≥3) for high grade prostate cancer:

Performance Measures	SelectMDx	phi ≥27	MRI PIRADS ≥3
Sensitivity	80%	93%	93%
Specificity	88%	29%	21%
Positive Predictive Value	36%	10%	9%
Negative Predictive Value	98%	98%	97%
Accuracy	82%	54%	69%

Dr. Jan Groen, MDxHealth's CEO, said “We are very pleased with the outcome of this study, which clearly demonstrates the superiority of SelectMDx over phi blood testing in identifying patients at high risk for prostate cancer, with high sensitivity and specificity. Combined with enhancing mpMRI, SelectMDx can spare men from prostate biopsy, offering a valuable non-invasive alternative to this expensive, painful, invasive and often inaccurate procedure.” He added: “We maintain our focus on the commercialization and roll-out of SelectMDx in the United States and Europe and continue to see increased usage and adoption in clinical practice, with over 30,000 patients tested since the launch of SelectMDx two years ago.”

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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