

MDxHealth Presents SelectMDx™ Results from Multicenter Validation Study at the 2016 Annual EAU Congress

SelectMDx awarded best poster presentation by EAU's Scientific Congress Office

IRVINE, CA, and HERSTAL, BELGIUM – March 14, 2016 – MDxHealth SA (Euronext: MDXH.BR), announced today that positive results of a prospective, multicenter validation study of SelectMDx™ for Prostate Cancer were presented at the 2016 Annual European Association of Urology (EAU) Congress, March 11-15 in Munich, Germany.

The major challenge in prostate cancer (PCa) diagnostics is to improve the early detection of aggressive and potentially lethal prostate cancer. Ideally, prostate cancer-specific biomarkers could be assessed non-invasively, for example in urine. The aim of this study was to develop and validate a model that combines such biomarkers with traditional risk factors into a risk score that expresses an individual patient's risk of harboring high-grade prostate cancer.

Urine samples from two prospective, multicenter studies (cohort A: n=492 and cohort B: n=371) were collected after digital rectal examination (DRE) to measure the mRNA expression levels of the two genes included in the SelectMDx test. These results were combined with traditional clinical risk factors, i.e. DRE, PSA, PSA density, age and family history to further improve patient stratification. An algorithm was developed in cohort A, and successfully validated in the independent cohort B. The optimal model was generated to assess the likelihood of detecting high-grade disease upon biopsy for an individual patient. The SelectMDx urinary molecular biomarker-based risk score resulted in an improved detection of men harboring high-grade PCa, with a negative predictive value (NPV) for significant cancer of 98% and an area under the curve (AUC) of 0.88.

“This multicenter validation study demonstrates that the non-invasive SelectMDx test is able to effectively predict the presence of high-grade prostate cancer from urine samples collected from men with an increased PSA level,” reported **Dr. Jack Schalken, Professor of Experimental Urology at the Radboud Medical Center in Nijmegen, The Netherlands**. “The very high NPV of the test could reduce unnecessary biopsies by approximately 50%, as well as other expensive diagnostic procedures such as MRI scans, and thus could result in significant cost savings for healthcare providers.”

The poster presentation, entitled '[Multicenter validation study of a urine-based molecular biomarker algorithm to predict high-grade prostate cancer](#)' (Abstract #383), was presented by Rianne Hendriks, MD at the 'Novel Biomarkers for Prostate Cancer Prediction' session (poster session 31) and was awarded a best poster presentation out of over 1100 submitted abstracts, by EAU's Scientific Congress Office. The full poster and abstract can be accessed via the EAU website (<http://eaumunich2016.uroweb.org/>).

About SelectMDx™ for Prostate Cancer

Of the nearly 2 million prostate biopsies performed each year, in less than 20% significant cancer is found. Most of these men could have avoided a painful and invasive prostate

biopsy procedure, with its associated side effects and costs. SelectMDx for Prostate Cancer is a proprietary urine-based, molecular diagnostic test that offers a non-invasive "liquid biopsy" method to identify patients at low risk for prostate cancer, helping to both reduce unnecessary prostate biopsy procedures with their concomitant complications and expense and to identify those men at increased risk of harbouring high-grade disease who may benefit most from earlier detection.

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 and epigenetic (methylation) molecular technologies and assist physicians with the diagnosis of urological cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information, visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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