

MDxHealth's ConfirmMDx® Predicts Prostate Cancer Aggressiveness

Epigenetic Health Index Helps Urologists with Prognostic Recommendations

Data Supporting Expanded Application of ConfirmMDx Presented at the AUA 2015

IRVINE, CA, and HERSTAL, BELGIUM – May 18, 2015 – MDxHealth SA (Euronext: MDXH.BR) revealed data today demonstrating the prognostic value of its ConfirmMDx® for Prostate Cancer test. The data, presented in two presentations at the American Urology Association (AUA) 2015 Annual Meeting in New Orleans, Louisiana (May 15-21), demonstrate the ConfirmMDx test's ability to identify patients likely to harbor clinically significant prostate cancer from negative biopsy tissue. In histopathology positive biopsies the test showed a better separation between men with aggressive prostate cancer from those men with indolent disease.

Previous diagnostic studies have established the utility of ConfirmMDx as a significant, independent predictor of prostate cancer, with a negative predictive value (NPV) of 90% for all cancers and a NPV of 96% for significant cancers. Now, the prognostic value of ConfirmMDx has also been demonstrated. In the first study on 269 men with a histopathologically negative biopsy results and ConfirmMDx-positive, DNA-methylation levels of the standard 12-core biopsies combined with clinical risk factors were used to develop an Epigenetic Health Index (EHI). The EHI was significantly higher in patients with an aggressive cancer detected upon repeat biopsy. The EHI of patients showed a strong correlation with the National Comprehensive Cancer Network (NCCN) score obtained on a second biopsy taken 3-15 months later. These findings confirm the results from previous studies that ConfirmMDx is able to segregate aggressive from non-aggressive prostate cancer in histopathological negative biopsies.

"Based on the results of this study, we can, with a high degree of confidence, stratify patients based on their ConfirmMDx EHI into low and high risk patients. This additional actionable information from ConfirmMDx will provide urologists with enhanced diagnostic, prognostic and clinical guidance to help manage their patients," stated Prof. Dr. Wim Van Criekinge, CSO of MDxHealth. "This new EHI forms part of an expanded outcome from the ConfirmMDx test that we plan to make available to urologists in the course of 2015."

In the second study, the newly developed EHI was validated in 12-core biopsies from 102 men with either no cancer, insignificant or significant cancer detected upon biopsy. The EHI was significantly higher in those men with high-grade cancer versus those with low-grade cancer. Also in this study, a strong correlation between the EHI and the NCCN risk stratification for prostate cancer was observed. Both of these studies demonstrate that the ConfirmMDx EHI has significant prognostic value and is able to identify men at increased risk for high-grade, aggressive prostate cancer in both histopathology negative and positive biopsies. ConfirmMDx EHI shows a better separation between men with aggressive prostate cancer from those men with indolent disease.

"Currently Gleason scoring and NCCN are the gold standards to assess a patient's risk of harboring aggressive prostate cancer. However, due to the limitations of a standard biopsy procedure the risk is underestimated in up to 30% of men. The EHI might help to better

stratify patients and identify more objectively candidates for active surveillance strategies,” reported Professor Sandra M. Gaston PhD, Director of Urological Research at New England Baptist Hospital and Director of the Molecular Biomarkers Research Laboratory in the Department of Pathology and Laboratory Medicine at Tufts Medical Center in Boston.

About ConfirmMDx® for Prostate Cancer

Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25-35% of those men receive false-negative results. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of undetected cancer, leading to a high rate of repeat biopsies, even on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx for Prostate Cancer is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This "halo" around a cancer lesion can be present despite cells having a normal appearance under the microscope. Thus ConfirmMDx for Prostate Cancer aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure. Performance of the proprietary ConfirmMDx genes and technology has been published in 45 studies on over 5,000 patients tested. The ConfirmMDx test has qualified for Medicare reimbursement as of November 3, 2014 and is also available to more than 152 million insured lives via private health insurance plans.

About MDxHealth

MDxHealth is a multinational healthcare company that provides actionable epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology and assist physicians with the diagnosis of 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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