

NEWS RELEASE

MDxHealth's ConfirmMDx Genes Identify Prostate Cancer Aggressiveness in Diagnostic Biopsies

Data Presented at the 2014 European Association of Urology Meeting

IRVINE, CA, and HERSTAL, BELGIUM – October 10, 2014 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to improve the diagnosis and treatment of cancer patients, today announced positive data from an important study confirming the ability of the ConfirmMDx® genes to identify prostate cancer (PCa) aggressiveness in diagnostic biopsies. The data, presented at the European Association of Urology, Section Urological Research (ESUR) meeting in Glasgow, UK (October 9-11, 2014), confirmed that the epigenetic profile of ConfirmMDx genes generated by the test is strongly correlated with established risk stratification metrics, such as Gleason Score (GS) and the NCCN (National Comprehensive Cancer Network) risk categories.

“These data demonstrate that ConfirmMDx for Prostate Cancer not only provides important diagnostic information to help guide the decision on repeat biopsy, but that the genes may also deliver significant prognostic value, potentially determining whether a man has an aggressive or non-aggressive form of prostate cancer,” noted 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 Massachusetts. “This study suggests that the epigenetic markers used in the ConfirmMDx test could have an expanded role in stratifying prostate biopsy patients by providing information that cannot be obtained from the histological examination of the tissue. The current ConfirmMDx test is highly sensitive for DNA hypermethylation of *GSTP1*, *APC* and *RASSF1* in the tissue surrounding a prostate cancer. For men who have a histological diagnosis of “no cancer,” a negative result with the current ConfirmMDx test predicts that a subsequent biopsy will also be negative, identifying the majority of men who may avoid repeat biopsy. In this study, we found that hypermethylation of these markers is more intense in the tissue surrounding high grade prostate cancer potentially providing additional insights into the clinical significance of a potential undetected prostate cancer on methylation-positive patients.”

In this study, hypermethylation levels of the three ConfirmMDx genes (*GSTP1*, *APC* and *RASSF1*) were evaluated on biopsies from 102 men with various GS (ranging from 3+3 to 4+4) and NCCN (ranging from very low to high) risk profiles. All men had undergone a 12-core prostate biopsy under routine clinical practice resulting in their PCa diagnosis. No epigenetic aberrations for any of these three genes were found in 20 control patients, who had non-cancer histology in all of their 12-core biopsy specimens.

- For 46 men, the highest observed GS was 6, classifying these men as potential candidates for active surveillance; however, 17% (n=8) of them exhibited an epigenetic profile that is indicative of higher-grade disease.

- Of the nine men with GS 4+3 or higher, 88% (n=8) had many epigenetic aberrations, in addition to 17 out of 27 (63%) of the men with GS 3+4.
- When epigenetic profiling was compared to NCCN risk categories, similar results were obtained, identifying 79% (31 out of 39) of the men with intermediate or high NCCN risk profiles. Roughly one third of the patients in the very low and low risk categories showed similar epigenetic profiles.

In conclusion, epigenetic profiling using the ConfirmMDx test on individual biopsy cores could help identify patients harboring aggressive prostate cancer, aiding patient management.

“This study clearly demonstrates the power of ConfirmMDx to help guide management decisions for men who may harbor aggressive disease, and illustrates that our epigenetic genes clearly add prognostic information which correlates with the Gleason Score and NCCN risk categories,” stated Dr. Jan Groen, CEO of MDxHealth.

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 occult cancer, leading to a high rate of repeat biopsies, often 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 leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment. The company's tests are based on proprietary gene methylation (epigenetics) 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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