



MDxHealth's ConfirmMDx Genes Identify Aggressive Prostate Cancer

Data Presented at the 2014 ASCO Genitourinary Cancers Symposium

IRVINE, CA, and HERSTAL, BELGIUM – February 3, 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 results from an important study designed to identify patients with aggressive prostate cancer (PCa). The study, presented at the 2014 ASCO Genitourinary Cancers Symposium in San Francisco, USA (January 30 - February 1, 2014), confirmed that epigenetic profiling of selected genes provides prognostic information, corresponding to Gleason score (GS), that could help to identify patients with aggressive PCa.

“One of the most significant challenges in managing newly diagnosed prostate cancer patients is choosing the best treatment plan. Men diagnosed with GS6 cancer, may be eligible for active surveillance. However, today’s standard 12-core TRUS-guided (transrectal ultrasound) biopsies are susceptible to under-sampling, leaving men at risk for undetected aggressive disease,” noted E. David Crawford, Professor of Surgery, Professor of Radiation Oncology, and Head of the Section of Urologic Oncology at the University of Colorado Denver School of Medicine. “These promising data demonstrate that epigenetic testing is not only valuable for the decision on repeat biopsy, but may also yield important prognostic information that could help us to identify men who are at risk for aggressive disease.”

In this study, the prognostic value of the epigenetic status of five genes (*GSTP1*, *APC*, *RASSF1*, *RARB* and *LGALS3*) in 84 prostatectomy samples with different GS's was evaluated. The results of a hierarchical clustering analysis showed that low gene methylation levels were detected in the vast majority of patient samples with GS6 and GS7 (3+4) PCa. In contrast, respectively 81% and 91% of the GS7 (4+3) and GS \geq 8 samples fell into the category with intermediate to high methylation levels. These data provide evidence of the potential prognostic value of epigenetically profiling selected genes to identify men with a low versus high risk for aggressive PCa.

“These important study results support our overall strategy of leveraging epigenetics to improve the diagnosis and treatment of prostate cancer patients. We were pleased to see that the data generated with the ConfirmMDx for Prostate Cancer genes, suggest the potential for prognostic utility,” explained Dr. Jan Groen, CEO of MDxHealth. “With this information, we are in a position to explore expansion of the ConfirmMDx indication for use in men diagnosed with GS6 prostate cancer, which may help urologists make more informed treatment decisions.”

[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.

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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