

MDxHealth's ConfirmMDx™ Combined with PSA and Other Risk Factors, Improves Diagnosis of Prostate Cancer

ConfirmMDx Highlighted in Presentation on New Biomarker Algorithm for Prostate Cancer at 2013 AUA Conference

IRVINE, CA, and LIEGE, BELGIUM – 8:00 AM, May 8, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment, today announced that an integrated risk management approach combining epigenetic profiling using the ConfirmMDx for Prostate Cancer test, combined with PSA, histopathological findings and other risk factors, improves the detection of prostate cancer, stratifying men at high risk for prostate cancer from those at low risk who may forego a repeat biopsy. Data were presented at the American Urology Association annual meeting in San Diego, USA.

The standard of care for screening has been PSA and DRE exam, however this has generated a great deal of controversy within the medical community. The American Urological Association supports use of PSA in the appropriate age group of men, despite the USPSTF recommendation to restrict its use. One of the biggest challenges with PSA screening is the high number of false-positive test results leading to prostate biopsies on men suspected to have prostate cancer. The majority of men will receive a negative biopsy result, however due to sampling errors, cancer can be missed in up to 25% of biopsied men. This leads to uncertainty of diagnosis and a high rate of repeat biopsies.

“Results from clinical studies have demonstrated that the ConfirmMDx for Prostate Cancer test can help urologists confirm negative biopsy results, reducing the need for repeat biopsies, and ensure men with positive results are managed appropriately,” explained Prof Wim van Criekinge, Head of the Laboratory for Computational Genomics and Bioinformatics (Biobix), University of Ghent, Belgium, who presented the data. “These studies show that integrating multiple traditional risk factors with this type of DNA methylation profiling increases the specificity of testing. Ultimately this could decrease the risk of misdiagnosis and improve patient management.”

Study Details

Logistic regression models were used to evaluate a population of 391 men with a first, prostate cancer-negative biopsy with a complete panel of risk factors (age, PSA, digital rectal examination, histopathology and the epigenetic profile). All risk factors were tested individually and in combinations. The epigenetic profile was found to be the strongest individual predictor (odds ratio (OR) = 3.46; p-value < 0.001). The clinical utility was optimal for a model including the epigenetic profile and the histological findings of the first biopsy, resulting in a sensitivity of 74%, a specificity of 63% and an NPV of 91%.

Clinical Update on Novel Prostate Cancer Biomarkers

In a session at the AUA conference titled "Understanding How New Biomarkers Will Assist in the Diagnosis and Prognosis of Prostate Cancer", urology experts Dr. David Crawford and Dr. Neal Shore examined the clinical utility and current status of new prostate cancer biomarkers, such as MDxHealth's ConfirmMDx for Prostate Cancer and Genomic Health's Oncotype DX. The discussion described how these tests can aid in the improved detection and treatment of prostate cancer.

The session provided an overview of the prostate cancer diagnostic pathway that included the role of biomarkers. In addition, a case study was presented that highlighted the urologist's dilemma

when presented with a patient with elevated PSA and other high risk factors. MDxHealth's ConfirmMDx for Prostate Cancer was used to highlight how the significant issue of false-negative biopsies can be addressed.

"When a prostate biopsy is performed for appropriate indications, there may be concern that the cancer may have been missed, despite the usual 10-14 core sampling. Tests which can improve the negative predictive value for a 1st time biopsy have clinically significant benefit, thus potentially avoiding unnecessary repeat biopsies," said Neal Shore, MD, FACS, CPI, Medical Director at the Carolina Urologic Research Center. "ConfirmMDx is a valuable addition to our armamentarium and addresses an unmet need in diagnostic evaluation. Many men are subjected to unnecessary repeat biopsies, with the attendant morbidity and cost, as a result of an elevated PSA as well as the concern of missing an undetected cancer. ConfirmMDx assists in the avoidance of unnecessary repeat biopsies."

The program was supported by the Prostate Conditions Education Council, a consortium of leading physicians, health educators, scientists and prostate cancer advocates.

About ConfirmMDx for Prostate Cancer

Over 650,000 American men receive a negative prostate biopsy result each year; though approximately 25% of these men may still harbor occult prostate cancer. This well-documented risk of undetected cancer, often with clinically significant Gleason scores, leads to a high rate of repeat biopsies with over 40% of men receiving at least one repeat biopsy, and many receiving a 3rd and 4th biopsy. Today's gold standard diagnostic approach is the prostate biopsy procedure, collecting 10-12 needle core biopsy samples, however this sampling represents less than 1% of a man's prostate. ConfirmMDx for Prostate Cancer is an epigenetic assay to help urologists distinguish patients who have a true-negative biopsy from those at risk for occult cancer. The test is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This molecular "halo" around a cancer lesion can be present despite having a normal appearance under the microscope. The test helps urologists rule out prostate cancer-free men from undergoing unnecessary repeat biopsies and, helps rule in high risk patients who may require repeat biopsies and potential treatment.

About MDxHealth

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. The company's first commercial product, ConfirmMDx™ for Prostate Cancer, has been shown to help distinguish patients who have a true-negative biopsy from those who may have undetected cancer. MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain and lung cancers. The company is based in Irvine, California with a European headquarters in Liege, Belgium. For more information visit MDxHealth's website at www.mdxhealth.com and follow us on Twitter at: <http://www.twitter.com/mdxhealth>

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