

## **MDxHealth's ConfirmMDx Stratifies Risk for Aggressive Prostate Cancer**

*Multicenter validation study published in the journal **The Prostate***

**IRVINE, CA, and HERSTAL, BELGIUM** – May 9, 2016 – MDxHealth SA (Euronext: MDXH.BR) announced today the publication of multicenter validation data demonstrating that ConfirmMDx® for Prostate Cancer can aid in the identification of men with clinically significant prostate cancer (PCa) in the journal *The Prostate*.

This study entitled "[Risk Score Predicts High-Grade Prostate Cancer in DNA-Methylation Positive, Histopathologically Negative Biopsies](#)" demonstrates the ConfirmMDx test's ability to improve the identification of men with aggressive cancer. Results from two previously studied cohorts, on 803 men from 8 clinical centers (3 in the EU and 5 in the US), were used to develop a methylation intensity algorithm, and combined with the standard clinical risk factors, i.e. age, PSA, DRE and histopathological findings, to predict the outcome of the repeat biopsy. With an AUC of 0.76, the ConfirmMDx risk score was a significantly better predictor for the presence of aggressive prostate cancer compared to PSA ( $p = 0.004$ ) and the Prostate Cancer Prevention Trial Risk Calculator ( $p = 0.029$ ). A ConfirmMDx-negative result yielded a Negative Predictive Value of 96% for high-grade cancer, and 90% for all prostate cancer.

The study results support use of ConfirmMDx to improve patient risk stratification, helping physicians to more accurately identify and focus on those men at highest risk for aggressive cancer who will benefit from repeat biopsy, improving early detection and allowing treatment at the earliest possible stage. For men with DNA methylation negative results, the test aids in the reduction of over-diagnosis and treatment of patients with no or indolent disease, which is consistent with the NCCN guidelines.

"This multicenter validation study shows that ConfirmMDx can help urologists identify men at high risk for aggressive prostate cancer who would benefit most from a repeat biopsy," **reported Dr. Wim van Criekinge, Professor in Mathematical Modeling, Statistics and Bio-Informatics at Ghent University in Ghent, and Chief Scientific Officer of MDxHealth.** "The very high NPV of 96% exhibited by ConfirmMDx can generate a significant reduction in unnecessary repeat biopsies."

### **About ConfirmMDx® for Prostate Cancer**

ConfirmMDx for Prostate Cancer is the first epigenetic, and only tissue-based test in the 2016 NCCN Guidelines for early detection of prostate cancer which addresses false negative biopsy concerns. It is the only molecular diagnostic test that provides a very high negative predictive value (NPV) of 96% for clinically significant prostate cancers, and 90% NPV for all prostate cancers, as well as prostate mapping of the test results to help guide repeat biopsies. Each year, more than 1 million American men undergo an invasive prostate biopsy with a negative result, however approximately 30% of those men actually have prostate cancer. The current standard of care for prostate biopsy procedures samples less than 1% of the prostate, leaving men at risk for undetected cancer and leading to a high rate of repeat biopsies, even on cancer-free men. ConfirmMDx for Prostate Cancer helps urologists identify low-risk men who may forego an unnecessary repeat biopsy and high-risk men who may benefit from intervention. To date nearly 2,800 urologists have

ordered ConfirmMDx on more than 40,000 patients. ConfirmMDx has qualified for Medicare reimbursement 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 molecular diagnostic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) and other molecular technologies 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](http://mdxhealth.com) and follow us on Twitter at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth).

### For more information:

Dr. Jan Groen, CEO  
MDxHealth  
US: +1 949 812 6979  
BE: +32 4 364 20 70  
[info@mdxhealth.com](mailto:info@mdxhealth.com)

Amber Fennell, Chris Welsh, Hendrik Thys (PR & IR)  
Consilium Strategic Communications  
UK: +44 20 3709 5701  
US: +1 917 322 2571 (Rx Communications Group LLC)  
[mdxhealth@consilium-comms.com](mailto:mdxhealth@consilium-comms.com)

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