

ConfirmMDx Study Provides Further Validation of Epigenetic Risk Profile

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, August 10, 2017 – MDxHealth SA (Euronext: MDXH.BR) today announced that results from a study published in [The Prostate](#) further validated ConfirmMDx® for Prostate Cancer and showed that the test can provide treating urologists with deeper insights into a patient's risk for aggressive prostate cancer.

The ConfirmMDx clinical model combines standard clinical risk factors with DNA-methylation intensity of *GSTP1*, *APC* and *RASSF1* genes to improve patient risk stratification and guide repeat prostate biopsy decisions. Each of the 102 men enrolled in this multicenter study received a standard 12-core diagnostic biopsy, and the ConfirmMDx test was performed on all biopsy tissue cores. Histopathologic assessment revealed that 20 men had cancer-negative biopsy results, 46 men had low-grade (Gleason Score 6, GS ≤6) cancer and 36 high-grade (GS ≥7) disease. ConfirmMDx risk scores were significantly higher in biopsy cores of men with high-grade disease. Moreover, in men with high-grade prostate cancer, the GS6 and cancer-negative biopsy cores also yielded high methylation intensities (both $p < 0.001$). Importantly, even after removing all the high-grade cancer cores and analyzing only the cancer-negative and GS6 cores, men diagnosed with GS ≥7 cancer still had the highest methylation intensities ($p < 0.001$). These results demonstrated the test's ability to help improve the identification of men with undetected aggressive disease from negative biopsies.

"The ConfirmMDx clinical model is a powerful molecular tool that can help compensate for prostate biopsy limitations and provide a more accurate risk assessment without conducting further invasive procedures," said **Prof. Dr. Sandra Gaston, Department of Pathology and Laboratory Medicine at Tufts University School of Medicine, Boston, Massachusetts**. "In addition to ConfirmMDx identifying false-negative biopsy results, the risk score can more accurately predict a patient's cancer grade upon repeat biopsy. This information is critical to determining who would benefit most from a repeat procedure."

ConfirmMDx is already included in the National Comprehensive Cancer Network (NCCN) Guidelines for Early Prostate Cancer Detection, helping urologists determine the necessity of a repeat prostate biopsy. Used in conjunction with other clinical information, ConfirmMDx also aids in the identification of men with occult high-grade disease, and may therefore help clinicians and patients to make better-informed treatment decisions.

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 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. ConfirmMDx has qualified for Medicare reimbursement and covered by numerous 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 genetic, epigenetic (methylation) and other molecular technologies and assist physicians with the diagnosis of urologic cancers, prognosis of recurrence risk, and prediction of response to a specific therapy. The Company's European headquarters are in Herstal, Belgium, with laboratory operations in Nijmegen, The Netherlands, and US headquarters and laboratory operations based in Irvine, California. For more information, visit mdxhealth.com and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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