

MDxHealth's ConfirmMDx DOCUMENT Validation Study Published in the *Journal of Urology*

ConfirmMDx is Most Significant Independent Predictor for Prostate Cancer in a Repeat Biopsy

IRVINE, CA, and HERSTAL, BELGIUM – May 8, 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 that results from DOCUMENT, a blinded, multicenter clinical validation study, substantiate that its ConfirmMDx[®] for Prostate Cancer test is a significant independent predictor of the risk for cancer on repeat biopsy. The accepted manuscript describing the study results is posted on the *Journal of Urology* ([http://www.jurology.com/article/S0022-5347\(14\)03341-2/abstract](http://www.jurology.com/article/S0022-5347(14)03341-2/abstract)) website and the data will be presented by principle investigator Alan Partin, MD, PhD, Professor and Chief of Urology at the James Buchanan Brady Urological Institute at Johns Hopkins School of Medicine, at the upcoming 2014 Annual Meeting of the American Urology Association (AUA) in Orlando, Florida.

The multicenter DOCUMENT (Detection of Occult Cancer Using Methylated Events in Negative Tissue) study was conducted with 350 PSA-screened men from five major urologic centers, including Johns Hopkins University, Cleveland Clinic Foundation, Lahey Clinic, University of California Los Angeles (UCLA) and East Virginia Medical School. The study involved patients with negative index prostate biopsies and compared assay results to cancer detection in subsequent repeat biopsies within 24 months. Index and repeat biopsy tissues were subjected to blinded, centralized pathology review by Jonathan Epstein, MD, Reinhard Professor of Urologic Pathology and Director of Surgical Pathology at Johns Hopkins. The ConfirmMDx for Prostate Cancer test was used to analyze the DNA from 3,687 negative tissue cores from the index prostate biopsy for epigenetic abnormalities. The ConfirmMDx test proved to be the most significant, independent predictor (Odds Ratio = 2.69, p-value 0.0002) for the risk of prostate cancer in a repeat biopsy, outperforming standard clinical risk factors such as age, prostate specific antigen (PSA), digital rectal exam (DRE), and pathology in multivariate logistic regression analysis. This U.S. based blinded, multicenter validation study confirmed the results of the previously published MATLOC validation study (Stewart et al, *J Urol*, 2013).

"The DOCUMENT study validates the three-gene epigenetic assay as a better predictor of risk for the presence of occult cancer than any other factor in the clinic today," said Dr. Partin. "Results from this study provide further clinical evidence that the epigenetic test delivers actionable information to help guide urologists on the decision for repeat prostate biopsy."

"DOCUMENT was a pivotal validation study, demonstrating that the test's high negative predictive value and odds ratio are robust and reproducible in different cohorts of patients," stated Dr. Epstein. "The importance of this blinded, multicentered study is that it validated the performance of the test using

predetermined analytical cutoff values in a population of U.S. patients undergoing routine PSA screening for prostate cancer.”

About ConfirmMDx® for Prostate Cancer

Over 975,000 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 greater than 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 rule in high-risk patients who may require repeat biopsies and potential treatment. Performance of the proprietary ConfirmMDx genes and technology has been published in 42 studies with over 4,100 patients.

About MDxHealth

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. 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, bladder and lung cancers. For more information visit www.mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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