



## **MDxHealth Announces Publication of Positive Data from a Blinded Multicenter Clinical Study Demonstrating the Utility of *ConfirmMDx*<sup>TM</sup> for Prostate Cancer to Address False-negative Biopsies**

### **Results of the Study Published in the Journal of Urology**

**IRVINE, CA, and LIEGE, BELGIUM** – February 11, 2013 – [MDxHealth](#) SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support the diagnosis and treatment of cancer patients, today announced the publication of results from a large clinical study on its epigenetic *ConfirmMDx*<sup>TM</sup> for Prostate Cancer test in the March 2013 issue of *Journal of Urology*. The results demonstrate the utility of the *ConfirmMDx* test as a powerful tool to address well-documented concerns over false-negative biopsy results.

The blinded, multicenter study named MATLOC (Methylation Analysis To Locate Occult Cancer), was conducted at University of Edinburgh Urological Cancer Group in the UK, the University Hospital of Liège, Belgium and the Institut de Génétique et Pathologie in Gosselies, Belgium. The investigators compared the performance of the *ConfirmMDx* assay to the current standard of care for men with high-risk clinical factors for prostate cancer, but negative biopsy results. Archived tissue samples from previous negative biopsies of 483 men at high risk were tested with the *ConfirmMDx* assay. The *ConfirmMDx* test results were then compared to the cancer detection rate in the repeat biopsies conducted on the same patients within 30 months.

In a multivariate model, correcting for age, PSA, DRE and histopathological characteristics of the first biopsy, the *ConfirmMDx* assay proved to be the most significant, independent predictor of patient outcome with an odds ratio of 3.17 (95% confidence interval: 1.81-5.53) along with atypical cells in the first biopsy (3.17 odds ratio; 95% confidence interval: 1.31-7.70). The investigators report that *ConfirmMDx* accurately identified 64% of the prostate cancer-free men who could safely avoid a repeat biopsy with a negative predictive value (NPV) of 90%. Importantly, the test also correctly identified 68% of men who were harboring undetected prostate cancer at the time of their previous histopathologically negative biopsy, many presenting with clinically significant cancer upon repeat biopsy who would merit aggressive treatment.

“Concerns over false-negative biopsy results are universally shared by all urologists, especially when considering that the current standard of care involving 12 needle biopsy tissue cores effectively samples less than 1% of a man’s prostate. The MATLOC study demonstrates that the *ConfirmMDx* for Prostate Cancer test can provide urologists with a critical tool to better stratify patients at low risk of prostate cancer from those men at high risk and to make more informed decisions on the need for repeat biopsy,” said Eric Wallen, MD, a practicing urologist at the Division of Urology and Professor of Surgery at the University of North Carolina at Chapel Hill, who serves as a consultant in the role of Chief Medical Officer for MDxHealth. “As the cost of cancer continues to rise and challenge healthcare budgets throughout the world,

well-validated biomarkers like those used in the ConfirmMDx test will play an increasingly important role in improving patient care while reducing health care costs.”

### **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 3<sup>rd</sup> and 4<sup>th</sup> 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 in cells adjacent to cancer foci. 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, the ConfirmMDx for Prostate Cancer test, has been shown to help distinguish patients who have a true-negative biopsy from those who may have occult 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 brain and lung cancers. The company is based in Irvine, California with a European headquarters in Liege, Belgium. For more information visit MDxHealth website at [www.mdxhealth.com](http://www.mdxhealth.com).

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