



## NEWS RELEASE

### **MDxHealth's Methylation Markers Detect Prostate Cancer in Biopsies from Patients Deemed Low Risk by Pathology**

***Results of Collaboration with Beth Israel Deaconess Medical Center, Harvard Medical School, New England Baptist Hospital Presented at American Urology Association Annual Meeting***

**DURHAM, NC, and LIEGE, BELGIUM** – May 16, 2011 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostics company in the field of personalized cancer treatment, today announced the results from a collaborative study demonstrating that changes in DNA methylation patterns in adjacent benign tissue could predict the presence of prostate cancer not detected or missed using standard histopathology. An underestimation of prostate cancer stage or grade can result from errors in biopsy tissue sampling. Such underestimates are of concern due to vastly increased enrollment in Watchful Waiting Active Surveillance (WWAS) programs to avoid unnecessary radical therapy. The reported methylation patterns act as so-called “field cancerization effect” biomarkers to detect prostate cancer missed due to biopsy sampling errors. The presentation of this important new prostate cancer data at the American Urology Association (AUA) Annual Meeting in Washington DC by Dr. Sandra Gaston of Beth Israel Deaconess Medical Center resulted from a collaborative effort between MDxHealth, Beth Israel Deaconess, Harvard Medical School, the New England Baptist Hospital, and the NCI’s Early Detection research Network (EDRN). The AUA 2011 Annual Meeting takes place May 14-19, at the Walter E. Washington Convention Center, in Washington, DC.

“Watchful Waiting Active Surveillance is increasingly embraced as a strategy in managing patients with low risk prostate cancer. For this clinical decision to be effective, it is essential that we remain vigilant and ensure that occult high-grade cancer is not overlooked. The data presented at AUA point the way to a compelling strategy to avoid this by introducing prostate biopsy methylation marker tests that can be made available relatively quickly,” said Dr. Jan Groen, CEO of MDxHealth. Dr. Gaston added: “One striking feature of our results is the extent of gene methylation abnormalities observed in prostate tissues from many patients with only 1 of 12 biopsy cores positive for cancer, compared to men with normal biopsies. By providing information about the cancer status of tissue adjacent to the biopsy as well as the core sample itself, field effect assays using such molecular markers could prove to be an important addition to standard histopathology.”

In the study presented at the AUA Annual Meeting, three established DNA molecular markers of prostate cancer (GST-P1, APC and RAR-beta) were used to evaluate all of the diagnostic biopsy cores from a series of patients with 1 of 12 cores positive for cancer. The objective was to look for field effects that may provide a useful index of higher grade malignancy in the adjacent tissues. Results indicated that such field effects were detected at a distance a centimeter or more distant from the edge of the histological focus of cancer. Such a marker-positive zone is large enough to allow detection of cancer in one biopsy as a biomarker signal in an adjacent normal looking core. In addition, GST-P1 field effects, in particular, appear to be sensitive to the grade of the adjacent cancer. This strongly suggest that these biomarkers could be useful in detecting occult high grade prostate cancer in men whose biopsies show only one or two cores of low grade,

Gleason Score 6, cancer. This could be an especially useful test for patients for whom watchful waiting/ active surveillance is being considered, and where the presence of occult high grade cancer could increase the risk of deferring treatment. Additional clinical studies are underway among these collaborators to further define MDxHealth's marker panel's clinical potential for prostate cancer detection and prediction of aggressiveness.

#### **About MDxHealth**

MDxHealth is a leading molecular diagnostics company that develops and commercializes oncology-based molecular diagnostic testing for personalized medicine. The company's tests are based on proprietary gene methylation technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. MDxHealth collaborates with leading cancer research center such as Johns Hopkins University and Memorial Sloan Kettering, and major European academic medical centers. The company has a number of commercial and collaborative partnerships with LabCorp, Merck & Co./Schering Plough, GlaxoSmithKline Biologicals, Roche, Merck Serono, Pfizer, and other industry leaders. More information can be found on the Company website: [www.mdxhealth.com](http://www.mdxhealth.com) or on twitter at the following address : [www.twitter.com/mdxhealth](http://www.twitter.com/mdxhealth).

#### **MDxHealth to present at BioEquity Europe 2011**

MDxHealth will present at the BioEquity Europe in Paris on Tuesday May 24<sup>th</sup>. Dr Jan Groen, chief executive officer, will make a formal presentation on the company at 13:30 in Hotel Marriott Rive Gauche, room La Seine B, Boulevard Saint-Jacques, 75014 Paris, France.

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