



## **MDxHealth's ConfirmMDx Genes Detect Clinically Significant Prostate Cancer**

### **Data Supporting Expanded Prognostic Application of Epigenetic Test Presented at the ASCO Genitourinary Cancers Symposium 2015**

**IRVINE, CA, and HERSTAL, BELGIUM** – March 2, 2015 – [MDxHealth](#) SA (Euronext: MDXH.BR), today announced that data demonstrating the prognostic value of its ConfirmMDx<sup>®</sup> for Prostate Cancer genes and technology was presented at the ASCO Genitourinary Cancers Symposium 2015 in Rosen Shingle Creek, Orlando, Florida, USA (February 26-28, 2015). The data support the ability to predict the presence of clinically significant cancer in biopsy-negative patients based on the DNA hypermethylation of the biomarkers in the ConfirmMDx test.

ConfirmMDx for Prostate Cancer is an epigenetic test that was developed and validated to rule out the presence of undetected cancer in men with benign prostate biopsy results. This is achieved by measuring the intensity of DNA hypermethylation of the three ConfirmMDx biomarkers in histologically benign tissue. This study was designed to evaluate if those patients testing positive for ConfirmMDx could be further stratified for the risk for clinically significant cancer. A total of 102 patients (12 cores per patient), 20 with no cancer, 46 with Gleason score 6 prostate cancer and 36 with Gleason score 7 prostate cancer were tested with the ConfirmMDx test. Gleason score (GS) is the current standard pathological classification for prostate cancer aggressiveness. The results showed that the intensity of the DNA hypermethylation in benign needle biopsy cores is higher in patients with GS7 cancer compared to those with GS6 cancer alone. These findings support the feasibility of an algorithm that is sensitive to the GS of undetected foci of aggressive prostate cancer and could translate into a prognostic score to help stratify patients eligible for active surveillance from those who may benefit from earlier intervention.

“For all three ConfirmMDx biomarkers, we observed a positive correlation between the highest level of DNA hypermethylation in the adjacent benign cores with the cancer cores from the same patient. Interestingly, for each marker, the GS6 cores from the group with clinically significant cancer (GS7) showed significantly higher levels of DNA hypermethylation than the group with only GS6 cancer,” reported Professor Sandra M. Gaston PhD, Director of Urological Research at New England Baptist Hospital and Director of the Molecular Biomarkers Research Laboratory in the Department of Pathology and Laboratory Medicine at Tufts Medical Center in Boston. “These results suggest that risk stratification predicting the presence of clinically significant cancer in biopsy-negative patients based on the DNA hypermethylation of the ConfirmMDx genes is feasible.”

“These data clearly support the prognostic power of the ConfirmMDx genes. The addition of a risk score for ConfirmMDx methylated patients, which enhances the test's positive predictive value, will provide deeper insights into a patient's risk for undetected clinically significant cancer,” stated Dr. Jan Groen, CEO of MDxHealth. “The urology community has widely adopted ConfirmMDx for its ability to reduce unnecessary repeat biopsies, and these data will further augment the assay's clinical utility by aiding in the identification of patients who may benefit from early detection and treatment.”

#### **About ConfirmMDx<sup>®</sup> for Prostate Cancer**

Over 975,000 American men are diagnosed with a negative prostate biopsy each year; however approximately 25-35% of those men receive false-negative results. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of undetected cancer, leading to a high rate of repeat biopsies, even on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx for Prostate Cancer is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This "halo" around a cancer

lesion can be present despite cells having a normal appearance under the microscope. Thus ConfirmMDx for Prostate Cancer aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure. Performance of the proprietary ConfirmMDx genes and technology has been published in 45 studies on over 5,000 patients tested. The ConfirmMDx test has qualified for Medicare reimbursement as of November 3, 2014 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 epigenetic information to personalize the diagnosis and treatment of cancer. The company's tests are based on proprietary gene methylation (epigenetic) technology 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).

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