

NEWS RELEASE  
ABSTRACT #PD07-04

## ConfirmMDx Improves Prostate Cancer Diagnosis in African American Men

**IRVINE, CA, and HERSTAL, BELGIUM** – 16:00 CEST, May 12, 2017 – MDxHealth SA (Euronext: MDXH.BR) today announced that results from a retrospective study demonstrated that its ConfirmMDx® for Prostate Cancer test improved the identification of African American men at risk for aggressive cancer missed by a prostate biopsy. The study findings were presented in a podium session at the 2017 American Urological Association (AUA) Annual Meeting in Boston, Massachusetts in the US.

In the study of 211 African American men, the test successfully identified men with false-negative biopsy results, meaning cancer was missed in a previous prostate biopsy. Upon repeat biopsy, 38% of patients were diagnosed with prostate cancer, of which 33% were diagnosed with clinically significant disease (Gleason Score >7). Importantly, when the test was negative, it yielded a powerful 96% negative predictive value for aggressive prostate cancer, confirming the test's strong performance as previously reported.

"African American men have a greater risk of clinically significant prostate cancer than the general population; however, because their cancer behaves differently on a molecular level, we do not yet have a tool to safeguard against potentially fatal false-negative results," **said Dr. Robert Waterhouse, study investigator and urologist at Carolina Urology Partners, North Carolina, US.** "The findings from this study are critical because they demonstrate that we finally have a test that can help urologists accurately identify men at increased risk for aggressive disease in this population. It's reassuring that ConfirmMDx provides consistently accurate results across ethnic groups."

African American men have the highest incidence of prostate cancer and are roughly 1.6 times more likely to develop the disease than Caucasians and 2.7 times more likely than Asian Americans.<sup>2</sup>

"Our mission is to deliver molecular diagnostic solutions for patients with urologic cancers, so it is fulfilling to see that our lead product, ConfirmMDx serves African American men, who have a greater risk for potentially lethal disease," **said Dr. Jan Groen, CEO of MDxHealth.** "The data demonstrate that the test performance is consistent with our previous validation studies, and can therefore provide physicians and their patients with greater peace of mind when making decisions on the need for a biopsy."

Additional data on the clinical utility of ConfirmMDx will be presented in a moderated poster session on 13 May, abstract #MP33-10.

### 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](http://mdxhealth.com) and follow us on Twitter at: [twitter.com/mdxhealth](https://twitter.com/mdxhealth).

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### References:

1. van Neste L, *et al.* (2017) Clinical Performance of an Epigenetic Assay to Identify Occult High-Grade Prostate Cancer in African American Men. American Urological Association (EAU) Annual Meeting. Abstract # PD07-04. 12 May 2017.
2. Surveillance, Epidemiology, and End Results (SEER) database, 2000–2013, National Cancer Institute.

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