

MDxHealth Analytical Validation Study on AssureMDx for Bladder Cancer Published in The Journal of Urology

Liquid Biopsy Test Delivers High Negative Predictive Value of 99.2% for Bladder Cancer

IRVINE, CA, and HERSTAL, BELGIUM, January 19, 2016 – MDxHealth SA (Euronext: MDXH), today announced that data demonstrating the clinical potential of its urine-based epigenetic bladder cancer test AssureMDx to aid urologists in the management of patients presenting with haematuria (blood in the urine), has been published in *The Journal of Urology*.

Prof. Dr. Ellen Zwarthoff, Erasmus MC Cancer Institute and a principal investigator of the published study stated: “Haematuria accounts for approximately 20% of all visits to the urologist, so it is important to distinguish patients at low risk for bladder cancer from those who may have bladder cancer. The data are compelling and strongly support the clinical utility of this non-invasive test that can help reduce unnecessary invasive cystoscopy procedures in patients presenting with haematuria, but at low risk for bladder cancer. Importantly, the test will help identify those patients at highest risk for bladder cancer who may benefit from early detection.”

Study Details

The AssureMDx for Bladder Cancer test, which analyses DNA methylation of three genes (*TWIST1*, *ONECUT2* and *OTX1*) in combination with mutation analyses of three others, was used to create an epigenetic profile of 154 urine samples from haematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2%) for the detection of bladder cancer in this cohort of haematuria patients ([van Kessel et al; J Uro 2016](#)).

Assuming a general prevalence rate of 5% for bladder cancer in patients with haematuria, the test generated an impressive 99.2% NPV to rule out the presence of bladder cancer in this study. When DNA mutations are combined with the epigenetic results, and the effect of cytology is estimated, the NPV could further increase to 99.9%. Current diagnostic tools have some limitations, not the least of which are cost and invasiveness, but also these methodologies are prone to miss some small bladder tumors, satellite lesions as well as carcinoma in situ, leaving some patients at risk for undetected cancer. Importantly, with a low prevalence of bladder cancer, the vast majority of patients could avoid an invasive cystoscopy procedure and the associated costs and morbidity.

Dr. Jan Groen, Chief Executive Officer of MDxHealth, added: “The powerful and positive results of this study clearly support the continued development of our non-invasive bladder cancer test. We are currently running a prospective study as part of our ongoing clinical validation strategy, preparing the AssureMDx test for commercial launch as a laboratory developed test in Q4 2016.”

About AssureMDx™ for Bladder Cancer

AssureMDx for Bladder Cancer is a non-invasive, urine-based DNA methylation test designed to help rule out the presence of bladder cancer, sparing many patients unnecessary invasive and potentially harmful procedures, while aiding in the identification of high-risk patients requiring further examination.

In the US and EU, over 170,000 patients are diagnosed with bladder cancer every year, and more than 50,000 patients will die from the disease. Annually in the US alone, it is estimated that over 1 million patients with haematuria (blood in urine) are referred to urologists for fear of bladder cancer. Importantly, bladder cancer is one of the most expensive cancers to treat given more than half of all early stage bladder cancer patients will suffer a recurrence in the three years following treatment.

While 90% of bladder cancer patients present with haematuria, however only a small percentage of patients with haematuria are diagnosed with bladder cancer. The traditional tools and procedures, cytology and cystoscopy, employed for the detection of bladder cancer have some limitations, not the least of which are cost and invasiveness, but also these methodologies are prone to miss some small bladder tumors. Fear of undetected cancer leads to a high rate of CT scans on patients to exclude upper tract disease, and this exposes patients to radiation and potential iatrogenic cancer later in life.

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 and follow us on Twitter at: twitter.com/mdxhealth.

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