

## MDxHealth's AssureMDx Multi-Center Validation Study Published in the Journal of Urology

***99% Negative Predictive Value could lead to 77% reduction in invasive cystoscopy procedures***

**IRVINE, CA, and HERSTAL, BELGIUM, November 10, 2016** – MDxHealth SA (Euronext: MDXH), today announced that a second clinical validation study, demonstrating the performance of its urine-based epigenetic test AssureMDx™ for Bladder Cancer, has been published in *The Journal of Urology*.

**Prof. Dr. Ellen Zwarthoff, Erasmus MC Cancer Institute** stated: "This pan-European multi-center validation study confirms the very high negative predictive value (99%) of the AssureMDx test. The clinical utility of this test lies in its ability to significantly reduce (77%) unnecessary invasive cystoscopy procedures in patients presenting with haematuria."

In the 200 patient study spanning three European countries, voided urine samples were collected from haematuria patients undergoing a cystoscopy procedure (n=97 Bladder Cancer, n=103 non-malignant) to rule out bladder cancer (BC) and analysed them using the AssureMDx biomarkers to determine an association between clinical risk variables. Combining the methylation and mutation markers with age led to an Area Under Curve (AUC) of 0.96 (95% CI 0.92-0.99, sensitivity 93% and specificity 86%). The AUC was higher in high grade tumors (1.00) compared to low grade tumors (0.93). The study demonstrated that AssureMDx can deliver an overall negative predictive value of 99%, based on the 5-10% prevalence of BC in patients with haematuria.

Annually, approximately a million haematuria patients are referred to urology for further clinical evaluation, with a large proportion of patients subjected to an invasive cystoscopy procedure, however less than 10% are diagnosed with BC. The authors believe that in the clinic, utilization of the test could potentially result in a 77% reduction in diagnostic cystoscopies.

"These very positive results further underscore the clinical validity and utility of AssureMDx and publication of these data will support the Q4 beta launch in the US, with a full scale launch of the test nationwide in early 2017," **reported Dr. Jan Groen, Chief Executive Officer of MDxHealth**. "Cystoscopies lead to high diagnostic costs and patient burden, so the ability of our test to improve patient selection for this invasive and sometimes painful procedure, will undoubtedly reduce costs and over-testing."

The full paper is accessible via the online edition of the [Journal of Urology](#).

### About AssureMDx™ for Bladder Cancer

Annually it is estimated that over 1 million patients with haematuria (blood in urine) are referred to urologists for fear of bladder cancer however, while 90% of bladder cancer patients present with haematuria, only 5-10% of haematuria patients are diagnosed with

bladder cancer. The vast majority of these patients could avoid an invasive cystoscopy procedure. AssureMDx for Bladder Cancer is a non-invasive, urine-based DNA methylation and mutation test designed to improve the identification of patients at increased risk for bladder cancer who will benefit from further clinical evaluation. The test delivers a negative predictive value (NPV) of 99% for bladder cancer, helping to reduce unnecessary invasive cystoscopy procedures by approximately 70%, thereby reducing healthcare costs.

### 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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