

MDxHealth Launches AssureMDx for Bladder Cancer Liquid Biopsy Test

Study reports test could reduce invasive diagnostic procedures by 77%

IRVINE, CA, and HERSTAL, BELGIUM – 07:00 CEST, July 6, 2017 – MDxHealth SA (Euronext: MDXH.BR) today announced the commercial launch of its AssureMDx™ for Bladder Cancer test in the United States as a laboratory developed test (LDT). Testing will be conducted at the Company's state-of-the-art CAP and CLIA accredited laboratory facilities in Irvine, California.

Each year in the United States, it is estimated that nearly 11 million patients are referred to a urologist for clinical evaluation due to hematuria (blood in urine).¹ Hematuria is the most common symptom of bladder cancer, yet only 3% to 28% of hematuria patients are diagnosed with bladder cancer.² The current standard of care for bladder cancer diagnosis is a cystoscopy, which is an invasive procedure where a cystoscope is inserted into the patient's urethra to visualize the bladder wall and to perform a biopsy if a lesion is identified. However, given the low prevalence of bladder cancer, the vast majority of hematuria patients could avoid the unnecessary discomfort and cost of cystoscopy, if cancer could be ruled out by a less intrusive method.

AssureMDx is a non-invasive, urine-based test, combining methylation and mutation biomarkers, to assess the risk of bladder cancer for patients diagnosed with hematuria. AssureMDx has been validated to improve upon the standard of care, helping rule out the risk of bladder cancer with a negative predictive value (NPV) of 99%.² The high NPV led study investigators to report that the test could potentially spare as many as 77% of hematuria patients from undergoing a cystoscopy.² Furthermore, the test's 93% sensitivity and 85% specificity can help doctors identify patients at increased risk for bladder cancer, who may benefit from cystoscopy.²

"AssureMDx is our third molecular diagnostic test in the field of urology, and our second liquid biopsy test," **stated Dr. Jan Groen CEO MDxHealth.** "With AssureMDx, we continue to deliver on our mission to offer 'best in class' molecular tests that improve patient outcomes, while reducing healthcare costs."

References:

1. David SA, et al; Urology 2017 Feb;100:20-26
2. Kessel K, et al; Journal of Urology 2017 Mar; 197(3): 590-595

[About AssureMDx for Bladder Cancer](#)

Of the 11 million patients with hematuria (blood in urine) referred to urologists each year in the United States, 3% to 28% are diagnosed with bladder cancer. The traditional tools and procedures, cytology and cystoscopy, employed for the detection of bladder cancer have limitations including cost and invasiveness. The standard of care methodologies is also 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. AssureMDx for Bladder Cancer is a proprietary urine-based, molecular diagnostic test that offers a non-invasive 'liquid biopsy' method 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 the need for unnecessary invasive cystoscopy procedures by up to 77%, 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 and follow us on social media at: twitter.com/mdxhealth, facebook.com/mdxhealth and linkedin.com/company/mdxhealth.

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