

AssureMDx validation study published, 2/16

MDxHealth 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 hematuria, has been published in The Journal of Urology.

The AssureMDx for Bladder Cancer test, which analyzes 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 hematuria patients without (n=80) and with (n=74) bladder cancer. The study demonstrated the test's high negative predictive value (99.2 percent) for the detection of bladder cancer in this cohort of hematuria patients (van Kessel KE, et al. J Urol. Epub ahead of print Aug. 29, 2015).

Assuming a general prevalence rate of five percent for bladder cancer in patients with hematuria, the test generated a 99.2 percent 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 percent. Current diagnostic tools are prone to miss some small bladder tumors and satellite lesions, as well as carcinoma in situ, leaving some patients at risk for undetected cancer. 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 in a company statement: "The powerful and positive results of this study clearly support the continued development of our noninvasive 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."

In a separate announcement, MDxHealth reported that it received the 2016 Frost & Sullivan Global Technology Innovation Award for its commitment to technological innovation to reduce unnecessary prostate biopsies.

Frost & Sullivan senior industry analyst, Divyaa Ravishankar, said in a company statement: "MDxHealth has maintained its commitment to advancing molecular diagnostic tests for urological cancers, continuing to generate data supporting its ConfirmMDx for Prostate Cancer test, and furthermore, recently launched its urine-based 'liquid-biopsy' test, SelectMDx for Prostate Cancer. Frost & Sullivan believes that these two offerings can significantly reduce the number of men undergoing unnecessary invasive biopsy procedures, and importantly helps avoid the associated pain, risk of complications, and cost."

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