

Press Release

ConfirmMDx Studies Highlighted by Elsevier, Publisher of The Journal of Urology®

Underscores Importance of Recent Confirmatory Clinical Validation Results Leading to Medicare Reimbursement Milestone

IRVINE, CA, and HERSTAL, BELGIUM - July 22, 2014 - MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to improve the diagnosis and treatment of cancer patients, today announced that its successful confirmatory clinical validation study of ConfirmMDx® for Prostate Cancer has been highlighted by Elsevier, publisher of *The Journal of Urology*®, in a press release entitled "*New, Accurate Epigenetic Test Could Eliminate Unnecessary Repeat Biopsies for Prostate Cancer.*" [http://www.eurekalert.org/pub_releases/2014-07/ehs-nae072114.php]

"We are pleased with the publisher's recognition of the importance of our sequential clinical validation studies, which definitively demonstrate the clinical performance of our ConfirmMDx test," noted Dr. Jan Groen, CEO of MDxHealth. "We believe that our commitment to scientific integrity is one of the leading factors behind the accelerating adoption of ConfirmMDx into the standard of care among the U.S. urology community."

"These featured studies, along with our recently published clinical utility study ([Wojno et al, American Health and Drug Benefits 2014;7\(3\):129-134](#)), served as the evidence required to pass Palmetto GBA's MoDx technology assessment and the basis for the recent draft Local Coverage Determination (LCD) establishing ConfirmMDx as "reasonable and necessary," enabling Medicare reimbursement," Dr. Groen continued. "We expect our LCD to be effective in Q4 of this year, triggering payment for testing of Medicare patients within our patient registry."

About ConfirmMDx® for Prostate Cancer

Over 975,000 American men receive a negative prostate biopsy result each year, though approximately 25% of these men may still harbor occult prostate cancer. This well-documented risk of undetected cancer, often with clinically significant Gleason scores, leads to a high rate of repeat biopsies with greater than 40% of men receiving at least one repeat biopsy, and many receiving a 3rd and 4th biopsy. Today's gold standard diagnostic approach is the prostate biopsy procedure, collecting 10-12 needle core biopsy samples; however this sampling represents less than 1% of a man's prostate. ConfirmMDx for Prostate Cancer is an epigenetic assay to help urologists distinguish patients who have a true-negative biopsy from those at risk for occult cancer. The test is able to detect an epigenetic field effect or "halo" associated with the cancerization process at the DNA level. This molecular "halo" around a cancer lesion can be present despite having a normal appearance under the microscope. The test helps urologists rule out prostate cancer-free men from undergoing unnecessary repeat biopsies and rule in high-risk patients who may require repeat biopsies and potential treatment. Performance of the proprietary ConfirmMDx genes and technology has been published in 42 studies with over 4,100 patients.

About MDxHealth

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. MDxHealth helps to address a large and growing unmet medical need for better cancer diagnosis and treatment information. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain, bladder and lung cancers. For more information visit www.mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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