

MDxHealth's ConfirmMDx[®] for Prostate Cancer Epigenetic Test Correctly Identifies Prostate Cancer Missed in Five Previous Biopsies

Multidisciplinary Case Study Published in The Journal of OncoPathology

IRVINE, CA, and HERSTAL, BELGIUM — 8:00 AM, February 12, 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 the ConfirmMDx[®] for Prostate Cancer test was used as part of an multidisciplinary approach to successfully confirm prostate cancer diagnosis missed by five previous biopsies. The case study of a 63-year old man was published online in *The Journal of OncoPathology* (La Rosa FG, Jones C, Arangua P, Crawford ED & Van Neste L (2013). Finding Occult Prostatic Cancer: The Value of Transperineal Mapping Biopsies and Epigenetic Assays - <http://www.ingentaconnect.com/content/oc/tjop/pre-prints/content-tjop100078>) by researchers from the University of Colorado (USA) and Maastricht University Medical Center (Netherlands).

Using a technique called transperineal mapping biopsy (TPMB), which extensively samples the prostate, cancer lesions in this patient were found, which were not detected by conventional biopsies. The epigenetic test, ConfirmMDx for Prostate Cancer, performed on the residual prostate biopsy tissues, was able to confirm all the same areas of cancer lesions and locate additional regions of concern. Those latter regions were confirmed after histopathological re-examination.

“Through perseverance and the availability of new techniques, this patient’s prostate cancer was eventually correctly diagnosed and treated,” explained E. David Crawford, M.D, Professor of Surgery, Urology and Radiation Oncology and head of section of Urologic Oncology at the University of Colorado. “After seeing a continual increase in PSA and five negative, conventional 12-core biopsies, prostate cancer diagnosis, including one region of an aggressive Gleason score 9, was established by TPMB and then confirmed by the ConfirmMDx epigenetic test. Importantly, this test also identified two areas of atypical small acinar proliferations missed during the original histopathology performed on the TPMB cores.”

“This case demonstrates the utility of our ConfirmMDx for Prostate test. As the test uses residual biopsy tissue, it can be carried out immediately to help detect occult prostate cancer,” said Dr. Jan Groen, CEO of MDxHealth. “This rapid turnaround will not only provide clinicians with more objective information for treatment management, it also prevents the need for patients to undergo the stress and pain of unnecessary repeat biopsies.”

Study Details

Over a five-year period, serum levels of prostate-specific antigen (PSA) of a 63-year old Caucasian male increased from 5.20 ng/mL in 2007 up to 23.22 ng/mL in 2012. These values triggered five transrectal ultrasound-guided (TRUS) biopsies, which were all negative for malignancy. In January 2013, an MRI was also performed which failed to show any areas suspicious for prostate cancer.

Using transperineal mapping biopsies (TPMB), ninety-nine biopsy core samples were obtained with a brachytherapy template grid at 5 mm intervals. Nine (9%) were found positive for prostate cancer. One core on the left had a Gleason score (GS) 6 (3+3), two cores at mid and left had GS 7 (3+4), five bilateral cores showed GS 7 (4+3) and one core on the right had GS 9 (4+5).

To investigate the correlation between the histopathology of the biopsies and the DNA-methylation profile of these samples, the ConfirmMDx for Prostate Cancer test was used. A blinded, without corresponding histopathology, evaluation was made of the complete set of TPMB sample cores with the epigenetic assay. The molecular and histopathological correlation was found to be an excellent match. An epigenetic halo surrounded the multiple cancers thus extending the zone of detection.

The epigenetic profile also identified two regions located at the posterior of the prostate, in which no cancer was identified on either the TPMB or the radical prostatectomy specimen. Further pathology re-examination of these regions later revealed high-grade prostatic intraepithelial neoplasia (HGPIN) and atypical small acinar proliferations indicative of cancer.

About ConfirmMDx for Prostate Cancer

Over 975,000 American men have negative prostate biopsies each year; however approximately 25-35% of those men harbor a neoplasm. Under the current standard of care, prostate biopsy procedures consisting of 10-12 needle biopsy cores only sample approximately 1% of a man's prostate. This approach leaves men at risk of cancer, leading to a high rate of repeat biopsies, often on cancer-free men. There is an unmet medical need for a clinically effective diagnostic test to address this dilemma. ConfirmMDx for Prostate Cancer is able to detect an epigenetic field effect or 'halo' associated with the cancerization process at the DNA level. This "halo" around a cancer lesion can be present despite cells having a normal appearance under the microscope. Thus ConfirmMDx for Prostate Cancer aids urologists in identifying truly negative men who may forego an unnecessary repeat biopsy procedure.

About MDxHealth®

MDxHealth is a leading molecular diagnostic company that develops and commercializes epigenetic tests to support cancer treatment. The company's tests are based on proprietary gene methylation (epigenetics) technology and assist physicians with the diagnosis of cancer, prognosis of recurrence risk, and prediction of response to a specific therapy. For more information visit mdxhealth.com and follow us on Twitter at: twitter.com/mdxhealth.

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