

## MDxHealth's Prostate Cancer Test Approved by New York State Department of Health

IRVINE, CA, and LIEGE, BELGIUM – 8:00 AM, July 10, 2013 – MDxHealth SA (NYSE Euronext: MDXH), a leading molecular diagnostic company that develops and commercializes epigenetic tests to support the diagnosis and treatment of cancer patients, today announced that the New York State Department of Health (NYSDOH) has certified and granted approval for the ConfirmMDx™ for Prostate Cancer test. This approval by NYSDOH completes MDxHealth's list of state licensures, allowing the Company to offer the test in all 50 states. The ConfirmMDx for Prostate Cancer test is performed on tissue obtained from a previous negative prostate biopsy to help distinguish patients who have a true-negative result and may forego an unnecessary repeat biopsy from those at high risk for missed cancer.

"The NYSDOH approval of the ConfirmMDx for Prostate Cancer test is a major milestone for MDxHealth. The Department's independent technology assessment for laboratory developed tests, which are also regulated at the federal level, is widely regarded as the most rigorous review process due to stringent quality standards. With the New York State approval and clinical laboratory license, ConfirmMDx for Prostate Cancer is now available to patients and urologists throughout the U.S. This licensure opens one of our largest potential domestic markets within the U.S., with an estimated 65,000 prostate biopsy procedures performed annually." said Dr. Jan Groen, MDxHealth's CEO. "The NYSDOH approval completes our state licensing requirements and allows us to fully execute on our U.S. commercialization strategy for this clinically significant prostate cancer test."

## **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 3<sup>rd</sup> and 4<sup>th</sup> 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.

## About MDxHealth®

MDxHealth is a molecular diagnostics company that develops and commercializes advanced epigenetic tests for cancer assessment and the personalized treatment of patients. The company has a proprietary platform and a strong epigenetic product pipeline focused on the development of products for prostate, brain and lung cancers. The company is based in Irvine,

California with a European headquarters in Liege, Belgium. For more information visit MDxHealth's website at <a href="https://www.mdxhealth.com">www.mdxhealth.com</a>.

## For more information:

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