

ConfirmMDx included in EAU guidelines

June 2018—MDxHealth announced that its ConfirmMDx is included in the 2018 European Association of Urology guidelines. Inclusion in the guidelines will facilitate adoption of the test in EU member state-specific guidelines, and the company will pursue CE marking of the test.

MDxHealth completed a multicenter validation study demonstrating the utility of ConfirmMDx in African American men at risk of aggressive cancer missed by prostate biopsy (Waterhouse RL Jr., et al. *Urology*. Epub ahead of print April 13, 2018. doi:10.1016/j.urology.2018.04.001). In the study of 211 African American men from seven urology centers across the U.S., the test was shown to identify African American men who had received false-negative biopsy results. Upon repeat biopsy, 38 percent of men with a previous negative diagnosis were diagnosed with prostate cancer, 33 percent of whom were harboring high-grade disease (Gleason score >7). The test's clinical performance was equivalent to published studies that were conducted in primarily Caucasian populations. When the test was negative, it yielded a 94 percent negative predictive value for ruling out aggressive prostate cancer, consistent with previously reported results.

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