

Test predicts prostate cancer aggressiveness, 7/15

July 2015—MDxHealth revealed data with the aim of demonstrating the prognostic value of its ConfirmMDx for Prostate Cancer test. The data, offered in two presentations at the American Urology Association's annual meeting in May, show the test's ability to identify patients likely to harbor clinically significant prostate cancer from negative biopsy tissue.

In histopathology-positive biopsies, the test showed a better separation between men with aggressive prostate cancer from those with indolent disease. Previous diagnostic studies have established the utility of ConfirmMDx as a significant, independent predictor of prostate cancer, with a negative predictive value of 90 percent for all cancers and an NPV of 96 percent for significant cancers.

In the first study, on 269 men with histopathologically negative biopsy results and ConfirmMDx-positive, DNA-methylation levels of the standard 12-core biopsies combined with clinical risk factors were used to develop an epigenetic health index, or EHI. The EHI was significantly higher in patients with an aggressive cancer detected upon repeat biopsy. The EHI of patients showed a strong correlation with the National Comprehensive Cancer Network score obtained on a second biopsy taken between three and 15 months later. These findings confirm the results from previous studies that ConfirmMDx is able to segregate aggressive from non-aggressive prostate cancer in histopathological negative biopsies.

In the second study, the newly developed EHI was validated in 12-core biopsies from 102 men with either no cancer, insignificant or significant cancer detected upon biopsy. The EHI was significantly higher in those men with high-grade cancer versus those with low-grade cancer. Also in this study, a strong correlation between the EHI and the NCCN risk stratification for prostate cancer was observed.

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