

Study finds more than 40 percent of prostate biopsies could be avoided with new blood test

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A multi-center study that validates the clinical performance of IsoPSA—a new blood test that has proven to be more accurate in predicting overall risk of prostate cancer than standard prostate-specific antigen (PSA) - will be presented during a special press conference at the 13th Annual Meeting of the American Urological Association (AUA) on May 18 in San Francisco.

Results showed that more than 40 percent of biopsies could have been avoided in both the preliminary study (45.1 percent) and validation study (47 percent), suggesting that use of IsoPSA may substantially reduce the need for <u>biopsy</u>, and may thus lower the likelihood of overdetection and overtreatment of nonlethal <u>prostate</u> cancer.

The study, Prospective Validation of the IsoPSA Assay for Detection of High Grade Prostate Cancer, was conducted as a follow-up to early studies which demonstrated that IsoPSA, a structure-focused protein biomarker, may be an effective means of discriminating between high-grade prostate cancer (Gleason≥7) and low-grade/benign disease (Gleason=6).

The research team, led by Cleveland Clinic's Eric Klein, M.D., conducted a multicenter validation trial and evaluated performance data with a new cohort, including cutoff parameters derived from a preliminary study, using the detection of cancer by biopsy as the endpoint.



"To be clinically useful, a biomarker must be both tissue-specific and cancer-specific. While PSA is prostate-specific, it is not specific for prostate cancer, leading to diagnostic inaccuracy and too many unneeded biopsies," said Dr. Klein, chair of Cleveland Clinic's Glickman Urological & Kidney Institute. "IsoPSA fulfills both the tissue- and cancer-specificity needed for a useful biomarker, and this validation study shows that it can more accurately detect high-grade cancer and reduce the rate of unneeded biopsies in patients at low risk of this disease."

More information: Eric Klein et al, PD60-05 PROSPECTIVE VALIDATION OF THE ISOPSA TM ASSAY FOR DETECTION OF HIGH GRADE PROSTATE CANCER, *The Journal of Urology* (2018). DOI: 10.1016/j.juro.2018.02.2817

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