pstate*Dx*™
FOR PROSTATE HEALTH
by BPGbio

- Non-PSA Based
- Serum Based Test
- Provides A Risk Score For Prostate Cancer
- Differentiates BPH From Aggressive Prostate Cancer

Executive Summary

Prevention of unnecessary prostate biopsies is a clear clinical unmet need in men at risk for prostate cancer. Data indicates that 79% of prostate cancer biopsies yield negative results but lead to 18% of men facing complications and 3% hospitalization. Benign Prostatic Hyperplasia (BPH) is a common condition that increases with age, generates a false positive signal utilizing prostate specific antigen (PSA) as a diagnostic tool, and is a dominant condition in men at risk for prostate cancer leading to over recommendation of prostate biopsies in this population.

Using BPGbio's AI-powered Interrogative Biology® platform, BPGbio identified, developed and validated a biomarker diagnostic that demonstrated promising clinical utility in stratifying BPH from prostate cancer. This diagnostic test is branded and commercialized as pstate*Dx*™.

pstate*Dx*™ is capable of differentiating BPH from Prostate Cancer

- A Non-Invasive Serum Blood Test – *Novel mechanism to distinguish between BPH and Prostate Cancer*
- Measures Filamin A, a key biological driver of prostate cancer
- A Non-PSA Based Test – *Reduces the need for prostate biopsies*
- Effectively Rules Out Aggressive Prostate Cancers

Retrospective and Prospective Cohort Design For Validation

- CPDR - Caucasian and African American cohort of retrospective serum samples from patients undergoing radical prostatectomy
- Cleveland Clinic - Prospective study of individuals undergoing biopsy due to elevated PSA
- US Department of Veteran Affairs - Retrospective collection of men undergoing biopsy with AUA scores 8-21, negative DRE, PSA 4-10 ng/mL
- UHN Toronto - Large confirmed BPH population with negative biopsy and matched AUA scores, prostate size, and PSA ranges
- In combined studies, more than 1000 samples have been analyzed to demonstrate the value

Clinical Evidence

- Detection of Prostate Cancer in Symptomatic Men Where PSA Does Not Provide Any Informed Guidance - Test demonstrated an AUC 0.75, PPV 0.72, NPV 0.73, and Odds Ratio 7.0; [PSA AUC 0.55]
- Avoidance of Unnecessary Biopsies in BPH/LUTS Men who Underwent Multiple Biopsies -BPH/LUTS men who subsequently underwent between 2-4 negative biopsies and demonstrated an AUC 0.87, PPV 0.93, NPV 0.58, and OR 18.9; [PSA AUC 0.52]
- Identification of Men Not at Risk for Aggressive Prostate Cancers (Gleason 8-10) - BPGbio panel demonstrated an AUC 0.74, PPV 0.18, and NPV 0.97, OR 7.5 for identification of risk for high gleason cancers; [PSA AUC 0.47]

Publications

- Clinical Utility of a Serum Biomarker Panel in Distinguishing Prostate Cancer from Benign Prostate Hyperplasia
  - *Scientific Reports*. 2021 Jul 23;11(1):15052 [weblink]
- Multi omic serum biomarkers for prognosis of disease progression in prostate cancer
  - *Journal of Translational Medicine*. 2020 Jan 7;18(1): 10 [weblink]
- Clinical Validation of a Serum Protein Panel (FLNA, FLNB and KRT19) for Diagnosis of Prostate Cancer
  - *J Mol Biomark Diagn. 2017;8(2):323. doi: 10.4172/2155-9929.1000323. Epub 2017 Feb 8.* [weblink]
- AACR 2023 Poster - Prostate Cancer [PDF Download]

Recent News

- BPGbio Announces Oncology Drug Pipeline and Prostate Cancer Biomarker Developments at AACR
- BPGbio Announces New Partnership with DoD Focused on AI-Guided Breast Cancer Diagnostics
- CEO Niven Narain Sheds Light on New Prostate Cancer Diagnostic Test Developed for DoD
- Using AI-Driven Testing for Prostate Cancer

BPGbio is currently exploring commercial opportunities globally for this technology.

The pstate*Dx*® test is currently not commercially available in the United States.

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Reimagining Biology for Humanity