THE PROSTATE HEALTH INDEX *(phi)*
SUPERIOR PERFORMANCE DEMONSTRATED THROUGH MULTIPLE PEER-REVIEWED PUBLICATIONS

Prostate cancer continues to be a leading cause of cancer mortality in men. The American Cancer Society estimates that approximately 161,360 new cases will be diagnosed and 26,730 men will die from prostate cancer in 2017 in the United States. Approximately 1 man in 7 will be diagnosed with prostate cancer during his lifetime.¹

Early detection of prostate cancer is an important health care issue. The PSA test is a prostate cancer screening test administered by primary care physicians and urologists around the world. However, approximately 75% of prostate biopsies performed are negative for cancer, which calls out the need for a more specific test to help reduce unnecessary biopsies. In a patient with an elevated PSA test result in the 4-10 ng/mL range, the Prostate Health Index *(phi)* test is an option to determine the risk of prostate cancer and whether or not a biopsy is warranted.

The *(phi)* test utilizes a calculation that combines the results of three quantitative blood serum immunoassays (PSA, free PSA and p2PSA) into a single numerical result (the “*phi* score”). This score gives more accurate information about what an elevated PSA level might mean and the probability of finding prostate cancer with a biopsy. The p2PSA assay is specific to measuring [-2]proPSA. The [-2] proPSA biomarker is an isoform of free PSA that was identified as the most prostate cancer-specific form found in tumor extracts.²

THE PROSTATE HEALTH INDEX: FILLING THE DIAGNOSTIC GAP

Results of the multi-center pivotal clinical trial showed that Beckman Coulter *(phi)* values significantly enhanced the clinical specificity for prostate cancer detection in men with PSA in the the 4 to 10 ng/mL PSA range.³ A Beckman Coulter *(phi)* value of 27.0 corresponds to 90% clinical sensitivity and 31.1% clinical specificity. Therefore, nearly 1 in 3 men may avoid prostate biopsy while detecting 90% of cancers if their Beckman Coulter *(phi)* value is less than 27.0.⁴
The following peer-reviewed publications highlight the clinical value of the Prostate Health Index (phi)

THE PROSTATE HEALTH INDEX: ITS UTILITY IN PROSTATE CANCER DETECTION

Publication/Authors:
Urology Clinics of North America 2016: 43:1–6
Lepor A, Catalona WJ, Loeb S

Key Points:
- This is a review of the major studies on phi in prostate cancer detection and risk stratification.
- Numerous large, prospective studies from geographically diverse regions have consistently demonstrated that phi is more specific for prostate cancer detection than existing standard reference tests of total and free PSA.
- Increasing phi scores predict a greater risk of clinically significant disease on biopsy and adverse prostatectomy outcomes.

THE PERCENTAGE OF PROSTATE-SPECIFIC ANTIGEN (PSA) ISOFORM [-2] PROPSA AND THE PROSTATE HEALTH INDEX IMPROVE THE DIAGNOSTIC ACCURACY FOR CLINICALLY RELEVANT PROSTATE CANCER AT INITIAL AND REPEAT BIOPSY COMPARED WITH TOTAL PSA AND PERCENTAGE FREE PSA IN MEN AGED ≤ 65 YEARS

Publication/Authors:

Key Points:
- A prospective multi-center study that assessed 769 men aged ≤ 65 years with a PSA concentration of 2.0–10.0 ng/mL scheduled for initial or repeat prostate biopsy.
- The diagnostic accuracy of %p2PSA and phi for discrimination between significant and insignificant prostate cancer was evaluated.
- phi was the best predictor of prostate cancer at initial and repeat biopsy with an ROC area under the curve (AUC) of 0.73.
- %p2PSA and phi have a superior diagnostic performance for detecting prostate cancer in the PSA range of 2.0–10.0 ng/mL compared with total PSA and %free PSA at initial and repeat biopsy.
THE PROSTATE HEALTH INDEX \( (\phi) \) SELECTIVELY IDENTIFIES CLINICALLY-SIGNIFICANT PROSTATE CANCER

**Publication/Authors:**
Loeb S, Sanda MG, Broyles DL, Shin SS, Bangma CH, Wei JT, Partin AW, Klee GG, Slawin KM, Marks LS, van Schaik RHN, Chan DW, Sokoll LJ, Cruz AB, Mizrahi IA, Catalona WJ

**Key Points:**
- Multi-center prospective trial that included 658 men aged 50 years or older who underwent prostate biopsy.
- In this population, the performance of PSA, % free PSA, p2PSA and \( \phi \) were compared to predict biopsy results and, specifically, the presence of clinically-significant prostate cancer using multiple criteria.
- Results showed that \( \phi \) was significantly higher in men with Gleason 7 or greater.
- On ROC analysis, \( \phi \) had the highest AUC for overall cancer, and Gleason 7 or greater.
- At the 90% sensitivity cut off point for \( \phi \) (a score of 28.6) 30.1% of patients could have been spared an unnecessary biopsy for benign disease or insignificant.

CLINICAL PERFORMANCE OF SERUM [-2]PROPSA DERIVATIVES, %P2PSA AND \( \phi \) IN THE DETECTION AND MANAGEMENT OF PROSTATE CANCER

**Publication/Authors:**
Huang Y, Sun T, Zhong W, Wu C

**Key Points:**
- A systematic review of the available scientific evidence to evaluate %p2PSA and \( \phi \) in clinical application.
- Increased \( \phi \) levels were associated with patients harboring more aggressive diseases.
- Studies showed that if \( \phi \) was added to the current prostate cancer screening strategies, overall reductions in cost can be achieved due to the reduction in the total number of office visits, laboratory tests and unnecessary biopsies.
- Studies suggest that \( \phi \) enhances the accuracy of detection, reduces the number of unnecessary biopsies and helps predict the aggressiveness of prostate cancer when compared to total PSA and free PSA.
2015

2014
Loeb S, Catalona W. The Prostate Health Index: a new test for the detection of prostate cancer. Therapeutic Advances in Urology 2014; 6(2) 74-77.

2013


2012


2011


2010


References


4. p2PSA IFU