

PROSTATE HEALTH INDEX *(phi)*

A SIMPLE BLOOD TEST FOR BETTER
PROSTATE CANCER DETECTION



3X More Specific Than PSA
More Confidence Before You Biopsy



Prostate Health Index

A simple blood test for better prostate cancer detection.

WHAT IS *phi*? ➤

The Prostate Health Index (*phi*) is a new blood test that results in a score, or “*phi* score”. This score gives you more accurate information about what an elevated PSA level might mean and the probability of finding prostate cancer on biopsy.*

phi is:

- a simple, non-invasive blood test
- 3X more specific for prostate cancer than PSA
- a tool to reduce negative biopsies and provide more confidence in your biopsy decisions

THE POWER OF *phi* ➤

phi is a powerful combination of three Beckman Coulter assays:

- Access Hybritech PSA
- Access Hybritech free PSA
- Access Hybritech p2PSA

The new and novel 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 p2PSA results are combined with PSA and free PSA test results by an algorithm in the Beckman Coulter Access instrument, providing a probability of prostate cancer.

Studies have demonstrated that when p2PSA measurements are combined with Access Hybritech PSA and free PSA measurements, the resulting index demonstrates a significant improvement in clinical specificity for prostate cancer detection, relative to PSA detection rates.*

3X BETTER THAN PSA ➤

Results from a prospective, multi-center clinical trial found that *phi* significantly enhanced clinical specificity relative to PSA for prostate cancer detection.¹ This improved specificity allows for a substantial decrease in the number of prostate biopsies that are negative for cancer.

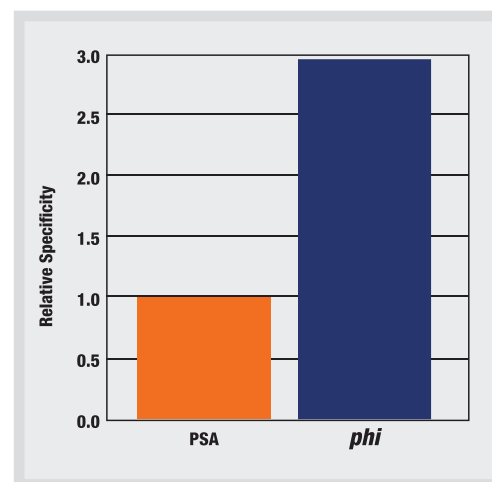


Figure A: The Prostate Health Index (*phi*) is a new blood test that is three times more specific in detecting prostate cancer than PSA testing alone.

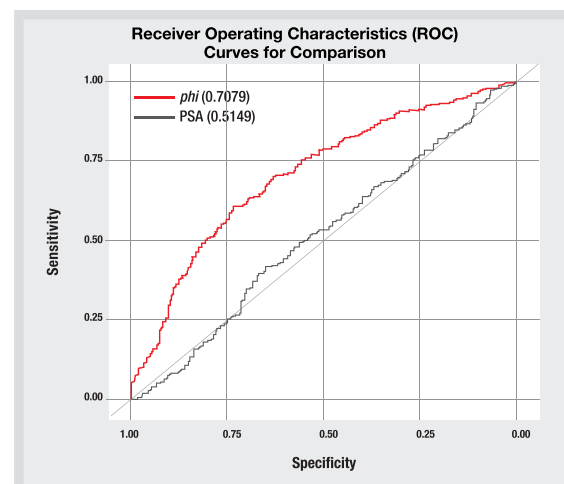


Figure B: Sensitivity and Specificity comparison of *phi* to PSA.

* The *phi* results are intended to be used as an aid in distinguishing prostate cancer from benign prostatic conditions in men 50 years of age and older with total PSA results in the 4 - 10 ng/mL range and negative digital rectal examination (DRE) findings.



BETTER DETECTION TO REDUCE NEGATIVE BIOPSIES ➤

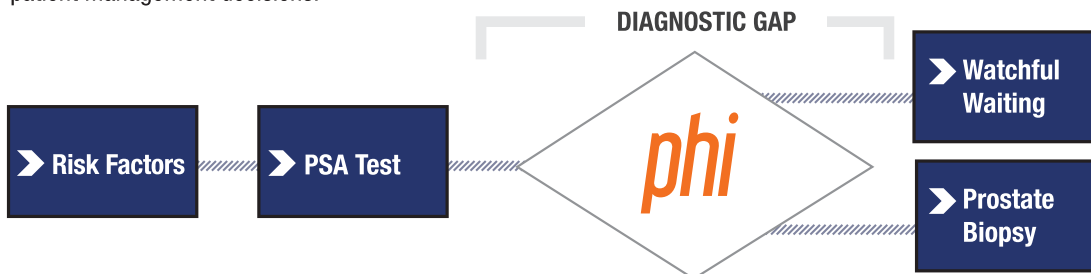
PSA is a widely used screening tool for prostate cancer. However, with PSA's limited specificity, a more precise tool is needed for prostate cancer detection. That tool was found in the discovery of *phi*.

The significantly higher specificity of *phi* means a greater probability of detecting those patients that actually need a biopsy, allowing for a substantial decrease in the number of prostate biopsies that are reported as negative for cancer.

USING *phi* IN YOUR CLINICAL PRACTICE ➤

Because *phi* is three times more specific than PSA for detecting prostate cancer, **it fills the diagnostic gap between PSA screening and a prostate biopsy.**

Combined with family and patient history, the *phi* results can be used to determine the best individualized patient management decisions.



WHAT DOES THE *phi* SCORE MEAN? ➤

Table 1 represents clinical study data analyzed to estimate an individual patient's probability of having detectable prostate cancer based on Beckman Coulter *phi* results, when that patient has a PSA between 4 and 10 ng/mL.

<i>phi</i> Range*	Probability of Cancer	95% Confidence Interval
0-26.9	9.8%	5.2%-15.4%
27.0-35.9	16.8%	11.3%-22.2%
36.0-54.9	33.3%	26.8%-39.9%
55.0+	50.1%	39.8%-61.0%
*Hybritech Calibration		

Table 1: Probability of Prostate Cancer Based *phi* Results

For more information about *phi* visit: www.accureference.com/phi

COMMUNICATION + INFORMATION = CONFIDENCE >

Learning as much information as possible about your patient is an important first step when assessing prostate health. To help encourage open communication about a subject that many patients find confusing, we offer a brochure for patients designed to inform on PSA and *phi* testing. The brochure includes a **Prostate Health Discussion Guide** to ease conversations about prostate health warning signs and prostate cancer risk factors.

Indications for PHI test:

Men 50 years old and over with PSA rate 4 to 10 (Hybertech calibration).

Specimen requirements:

SST Tube

Minimum volume – 1ml

Transit temperature – Refrigerated

Stability time – 7 days

ACCU Reference's ordering code: 123P

MOVING MEN'S HEALTH FORWARD > www.accureference.com/phi

References

1. Catalona WJ, Partin AW, Sanda MG, et al. A multicenter study of [-2]pro-prostate-specific antigen combined with prostate-specific antigen and free prostate-specific antigen for prostate cancer detection in the 2.0 to 10.0 ng/mL prostate-specific antigen range. J Urology 2011 May;185:1650-55.
2. Mikolajczyk SD., Millar LS., Wang TJ., et al. A precursor form of prostate-specific antigen is more highly elevated in prostate cancer compared with benign transition zone prostate tissue. Cancer Res 2000 Feb 1;60:756-759.
3. Beckman Coulter Access Hybritech p2PSA Instructions for Use

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