



## THE CHALLENGE

While Prostate Specific Antigen (PSA) is currently the most used screening test for prostate cancer, it is widely recognized that PSA results can indicate the possibility of prostate cancer when none is present. Studies have shown that approximately 70% of men with an elevated PSA who have a biopsy do not have cancer.(1)

## THE PROSTATE HEALTH INDEX SOLUTION

- The Prostate Health Index (*phi*) is an FDA approved blood test that can help differentiate prostate cancer from benign conditions in men with elevated PSA. (2)
- The Prostate Health Index utilizes three different PSA markers (PSA, freePSA, and p2PSA) as part of a sophisticated algorithm to more reliably determine the probability of cancer in patients with elevated PSA levels and can help men and their physicians decide if a prostate biopsy is indicated.(3)
- The Prostate Health Index is included in the National Comprehensive Cancer Network (NCCN) Guideline for Prostate Cancer Early Detection as a blood test to improve specificity for prostate cancer detection.(4)

## INDICATIONS FOR USE

- The Prostate Health Index is indicated for use as an aid in distinguishing prostate cancer from benign prostatic conditions in men aged 50 years and older with elevated PSA between 4 ng/ml and 10ng/ml (5).
- Peer-reviewed published studies support the use of Prostate Health Index in men with total PSA values as low as 2ng/ml. (6)

## PATIENT SELECTION CRITERIA

- Patients with elevated PSA between 4ng/ml and 10ng/ml .
- Specimens for testing should be drawn prior to prostate manipulations such as digital rectal examination (DRE), prostatic massage, transrectal ultrasound (TRUS), or prostatic biopsy.

## WHY USE THIS TEST IN MY PRACTICE?

- When Prostate Cancer is found early, the five-year survival rate is nearly 100%. Found late, the five-year survival rate drops to 29%.(7)
- Prostate Health Index helps male patients and their physicians decide if prostate biopsy, an invasive procedure, is indicated.(3)
- Using the Prostate Health Index to stratify patients with elevated PSA may reduce exposure to complications of prostate biopsy including pain, bleeding and infection.

**Contact Us Today to Get Started**

**1-855-420-7150**

[clientrelations@stagezerols.com](mailto:clientrelations@stagezerols.com)



## Prostate Cancer LABORATORY RESULTS

Patient	Name:	Phone #:	Patient ID #:	Specimen	Collection Time:	Specimen ID:	Provider	Requesting Provider	
	Fasting Status:	Gender:	Birthdate:		Age:	Collection Date:		Report Type:	
	Height:	Weight:	BMI:		Prev. BMI:	Received Date:		Report Date:	Client ID:

Tumor Markers	Results	Reference Interval	Prev. Results	Physician's Notes																		
PSA, Total (ng/mL)	4.7	Normal < 4.0 At Risk ≥ 4.0																				
PSA, Free (ng/mL)	0.47	See % Free PSA																				
Pro2PSA (pg/mL)	14.29	See PHI																				
% Free PSA	13	% free PSA Prostate Cancer Probability by Age* <table border="1"> <tr> <th>% Free PSA</th> <th>50-64 Yrs</th> <th>65-75 Yrs</th> </tr> <tr> <td>0.00 to 10.00%</td> <td>56%</td> <td>55%</td> </tr> <tr> <td>10.01 to 15.00%</td> <td>24%</td> <td>35%</td> </tr> <tr> <td>15.01 to 20.00%</td> <td>17%</td> <td>23%</td> </tr> <tr> <td>20.01 to 25.00%</td> <td>10%</td> <td>20%</td> </tr> <tr> <td>≥ 25.01%</td> <td>5%</td> <td>9%</td> </tr> </table>	% Free PSA	50-64 Yrs	65-75 Yrs	0.00 to 10.00%	56%	55%	10.01 to 15.00%	24%	35%	15.01 to 20.00%	17%	23%	20.01 to 25.00%	10%	20%	≥ 25.01%	5%	9%		
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Prostate Health Index (PHI)‡	58.7	<table border="1"> <tr> <th>PHI Range</th> <th>Prob. of Cancer</th> <th>95% CI</th> </tr> <tr> <td>0 - 26.9</td> <td>9.8%</td> <td>5.2% - 15.4%</td> </tr> <tr> <td>27.0 - 35.9</td> <td>16.8%</td> <td>11.3% - 22.2%</td> </tr> <tr> <td>36.0 - 54.9</td> <td>33.3%</td> <td>26.8% - 39.9%</td> </tr> <tr> <td>≥ 55.0</td> <td>50.1%</td> <td>39.8% - 61.0%</td> </tr> </table>	PHI Range	Prob. of Cancer	95% CI	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%					
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**50.1%**

In published studies to date, patients with PHI values greater than 55.0 have a 50.1% probability of being found to have prostate cancer on biopsy. \*\*

‡ The ordering physician affirms that 1) PHI results are desired and 2) the physician is prepared to proceed with management of the patient based on the results of the PHI test

Previous Results: \_\_\_\_\_  
Date: \_\_\_\_\_

\* Data are based on Hybritech Tandem Calibration with a PSA cutoff of 4.0ng/mL. The corresponding PSA cutoff based on WHO calibration is 3.1 ng/mL. A PSA range of 4-10 ng/mL with Hybritech calibration corresponds to a PSA range of 3.1-7.8 ng/mL with the WHO calibration.  
\*\* Total Prostate Specific Antigen in Serum - NHANES 2001-2002

**Disclaimer**

Prostate Health Index (PHI) is indicated for use as an aid in distinguishing prostate cancer from benign prostatic conditions. The FDA has approved PHI in men aged 50 years and older with Total PSA ≥ 4.0 to ≤ 10.0 ng/mL. Peer-reviewed, published literature addresses the use of PHI in men with Total PSA ≥ 2.0 to ≤ 10.0 ng/mL, and in those younger than age 50.

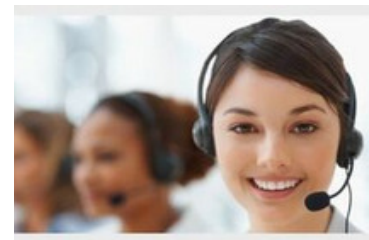
## TEST INTERPRETATION

- If the *phi* score is high, patients may require more extensive evaluation, including referral for prostate biopsy.
- If the *phi* score is medium or low, active surveillance with a repeat phi at a subsequent time may be an option to guide patient care.
- The percentage likelihood of prostate cancer being found on biopsy is derived from the *phi* value and is color coded.
  - low probability (grey)
  - medium probability (yellow)
  - high probability (red)

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- Biddle C, Brasel A, Underwood W 3rd, et al. Experiences of Uncertainty in Men With an Elevated PSA. Am J Mens Health. 2016;11(1):24-34.
- Loeb S, Sanda MG, Broyles DL, et al. The Prostate Health Index Selectively Identifies Clinically Significant Prostate Cancer. The Journal of Urology. 2015;193(4):1163-1169
- White J, Shenoy V, Tutrone RF, et al. Clinical utility of the Prostate Health Index (phi) for biopsy decision management in a large group urology practice setting. Prostate Cancer and Prostatic Diseases. 2018; 21: 78-8
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection.
- Beckman Coulter Access Hybritech p2PSA Instructions for Use.
- Catalona WJ, Partin AW, Sanda MG, et al. A Multi-Center Study of [-2]Pro-Prostate-Specific Antigen (PSA) in Combination with PSA and Free PSA for Prostate Cancer Detection in the 2.0 to 10.0 ng/mL PSA Range. The Journal of Urology. 2011;185(5):1650-1655.
- American Cancer Society. Prostate Cancer Prevention and Early Detection. Last revised April 14, 2018.