

# Patient/Physician Discussion Guide

## THE PROSTATE HEALTH INDEX

SHARE THIS GUIDE WITH YOUR PHYSICIAN TO DETERMINE  
IF THE PROSTATE HEALTH INDEX IS RIGHT FOR YOU



Finding Cancer in the  
Earliest Possible Stages



# ABOUT THE PROSTATE HEALTH INDEX

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.(2-5)

## ABOUT THE TEST

- *phi* combines total PSA, free PSA, and pro2PSA via a sophisticated algorithm, into a single score.
- a *phi* score of less than 27 indicates a higher likelihood of a benign condition.
- a *phi* score that is greater than 36 indicates the increased possibility of prostate cancer.

## IS THE PROSTATE HEALTH INDEX RIGHT FOR ME?

Men may be a candidate for the Prostate Index Test if you are age 50 years and older with an elevated PSA between 4ng/ml and 10ng/ml. Peer-reviewed published studies support the use of Prostate Health Index in men with total PSA values as low as 2 ng/ml. (2-5)



## CLINICAL BENEFITS OF THE PROSTATE HEALTH INDEX

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. Elevated PSA can also indicate common conditions such as prostatitis and benign prostatic hyperplasia (BPH).

## 70% OF MEN WITH ELEVATED PSA DO NOT HAVE CANCER

Studies have shown that approximately **70%** of men with an elevated PSA who have a biopsy do not have cancer. (7) The higher specificity of *phi* means a greater probability of identifying those patients who actually need a biopsy.

## ORDERING THE TEST

The Prostate Health Index needs to be ordered by a physician. If you would like to order this test online through our telehealth network of physicians please visit [www.mycancerrisk.info/phi](http://www.mycancerrisk.info/phi)

Physicians can order this test by visiting [StageZeroLifeSciences.com](http://StageZeroLifeSciences.com).

The Prostate Health Index can help men with elevated PSA <10 ng/ml and their physicians decide if a prostate biopsy is indicated.

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. (6)

## FINDING PROSTATE CANCER EARLY SAVES LIVES

- When Prostate Cancer is found early, the five-year survival rate is 100%. (1)
- When Prostate Cancer is found late, the five-year survival rate drops to 29%. (1)

Using the Prostate Health Index to stratify men with PSA < 10 ng/ml may reduce unnecessary prostate biopsies.



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### References

1. American Cancer Society. Prostate Cancer Prevention and Early Detection. Last revised April 14, 2018.
2. 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.
3. 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.
4. Huang YQ, Sun T, Zhong WD, et al. Clinical performance of serum [-2]proPSA derivatives, %p2PSA and PHI, in the detection and management of prostate cancer. Am J Clin Exp Urol 2014;2(4):343-350.
5. Lepor A, Catalona WJ, Loeb S. The Prostate Health Index: Its Utility In Prostate Cancer Detection. The Urologic Clinics of North America. 2016;43(1):1-6.
6. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection. Version 2.2018 – April 5, 2018
7. 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.

# TEST INTERPRETATION



## 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:		

Tumor Markers	Results	Reference Interval	Prev. Results	Physician's Notes																		
PSA, Total (ng/mL)	<b>H</b> 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 4.0 ng/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.

- 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)

## 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 when that patient has a PSA in the diagnostic gray zone between 4 and 10 ng/mL. (8) At *phi* cutoffs between 27 to 55, the probability of cancer ranged from 16.8 to 50.1%

Table 1

Phi Range*	Probability of Cancer
0-26.9	9.8%
27.0-35.9	16.8%
36.0-54.9	33.3%
55.0+	50.1%

### References

1. American Cancer Society. Prostate Cancer Prevention and Early Detection. Last revised April 14, 2018.
2. 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.
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6. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer Early Detection. Version 2.2018 – April 5, 2018
7. 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.
8. Beckman Coulter Access Hybritech p2PSA Instructions for Use.



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