

A Patient's Guide to the Prostate Health Index

INTRODUCTION

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.



Finding Cancer in the
Earliest Possible Stages



ABOUT PROSTATE CANCER

Prostate cancer begins when cells in the prostate gland start to grow uncontrollably. Early prostate cancer usually causes no symptoms, which is why it's so important to get screened. Signs and symptoms of prostate cancer include changes in urination, painful ejaculation, and erectile dysfunction.(1)

WHAT IS PSA?

PSA stands for Prostate Specific Antigen and is a protein made only by the prostate gland. Very little PSA is found in the blood of a man with a healthy prostate. A low PSA is better for prostate health. A rapid rise in PSA may be a sign that something is wrong.

WHAT IS 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)
- *phi* combines total PSA, free PSA, and pro2PSA via a sophisticated algorithm, into a single score.

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)



WHAT BENIGN CONDITIONS CAN CAUSE ELEVATED PSA?

In addition to prostate cancer, a number of benign (not cancerous) conditions can cause a man's PSA level to rise. The most frequent benign prostate conditions that cause an elevation in PSA level are prostatitis (inflammation of the prostate) and benign prostatic hyperplasia (BPH) (enlargement of the prostate) (1)

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)

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)



WHAT ARE THE BENEFITS OF THE PROSTATE HEALTH INDEX TEST?

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). Studies have shown that approximately 70% of men with an elevated PSA who have a biopsy do not have cancer. (7)

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

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

PROSTATE HEALTH INDEX TEST RESULTS



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)	H 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	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%

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 2.2019 - May 31, 2019
7. Biddle C, Brasel A, Linderwood 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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How Do I Order This 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 or call **855-420-7140** to start your order. Physicians can order this test by visiting StageZeroLifeSciences.com to enroll their practice.

THE ONLINE ORDERING PROCESS IS EASY

✓ 1. Order The Test

Upon receiving your order, a client relations specialist will contact you to walk you through the process and connect you with a telehealth physician to prescribe the test.

✓ 2. Visit the Lab

Once you receive the test order, we will send you the test kit and connect you to our U.S. Lab network for the blood draw.

✓ 3. Get Your Results

You will receive your results via a secure encrypted email and/or by mail. Elevated scores will be reviewed by a physician and you will be contacted.



How Much Does The Test Cost?

The Cost of the Prostate Health Index for Telehealth Orders is **\$299**. This price includes a physician order, test kit, blood draw and test results.

Where do I review my results?

You will receive your results via a secure encrypted email and/or by mail. Elevated scores will be reviewed by a physician and you will be contacted.

What do I do with my results?

We strongly recommend that you share and review your results with your physician and healthcare providers.

Does Insurance Cover The Test?

If your physician orders this test, insurance should cover the test, depending on your plan. However, we do not accept insurance for using our telehealth network. We accept all major credit and debit cards: MasterCard, Visa, American Express and Discover.

Questions?

Call: 1-855-420-7140 Ext 0

Or email: clientrelations@stagezerols.com

You can also visit our frequently asked questions page at www.mycancerrisk.info/faq

Note: StageZero Life Sciences offers testing services to residents of almost all states except the three where direct access testing is prohibited by law. We do not offer direct access testing to residents of New York, New Jersey, and Rhode Island. We do not offer direct access testing at this time in Canada.



FREQUENTLY ASKED QUESTIONS FOR TELEHEALTH ORDERS

Where do I get my Blood Drawn?

- Get your blood drawn at one of our approved patient service centers nationally.
- Client relations will confirm with you the closest patient service center.
- Client relations will send the supplies and test requisition form to you to take to the patient service center.

Do I need an appointment to get my blood drawn?

Yes. Appointments must be scheduled via a toll-free number to access a patient service center.

You should not show up without an appointment.

Do you accept insurance?

We do not accept insurance. We will provide a receipt containing the Current Procedural Terminology (CPT) codes for our tests which you can submit directly to your insurance carrier for reimbursement. As we do not provide diagnostic services, your receipt will not include diagnosis codes. Diagnosis codes must be supplied by an appropriately licensed healthcare provider. Please note that you may not submit any charges for our services for reimbursement from any state, federal or other government funded health plan or program, including without limitation: Medicare, Medicaid, or any subsidized exchange policy.

May I submit a claim for reimbursement under Medicare or Medicaid?

No. You may not submit any charges for Stage Zero Lab Tests services for reimbursement from any state, federal or other government funded health plan or program, including without limitation Medicare, Medicaid, or any subsidized exchange policy.

When will I be able to view my lab results?

You will be notified via phone or email once your results are available. Test results can take between 7-10 business days.

What do I need to do to prepare for my test?

The test does not require any special preparation.

Can I pay by personal check instead of by credit card?

No, at this time we only accept credit cards.

What is your refund and exchange policy?

You may cancel an order if you have not shipped you your test kit in order to have your blood drawn. If the order is cancelled in the first 10 days from the purchase date, the purchase price will be refunded minus a \$50 cancellation fee.