



Prostate Health Index (*phi*)

Bridging the Diagnostic Gap Between PSA and Prostate Biopsy

The Problem:

- Prostate specific antigen (PSA) does not differentiate between prostate cancer and benign prostatic conditions in patients with elevated PSA.

Why Should I Use the Test in My Practice?

- Prostate Health Index is 3 times more specific than PSA alone in identifying prostate neoplasm.
- Up to 26% of men with slightly elevated PSA may undergo unnecessary biopsy. ²

The Prostate Health Index (*phi*) Solution:

- The Prostate Health Index is an FDA approved blood test that can help differentiate prostate cancer from benign conditions in men with elevated PSA.
- 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 detection⁶

Science Behind 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.

Prostate Health Index Patient Profile:

- While an elevated serum PSA is associated with prostate cancer, a number of benign conditions such as benign prostatic hyperplasia (BPH) and prostatitis might lead to elevated serum PSA concentrations.
- 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.
- 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

The Patient Benefit:

- 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
- Prostate Health Index helps male patients and their physicians decide if prostate biopsy, an invasive procedure, is indicated.
- Using the Prostate Health Index to stratify patients with elevated PSA may reduce exposure to complications of prostate biopsy including pain, bleeding and infection.

How Do I Get Started?

- Fill out a new account form and submit it to client relations clientrelations@myinnovativelab.com.
- Upon completion of new account form, a starter kit(s) will be shipped based upon your testing needs.
- Schedule training of your staff through onboarding call with Innovative Diagnostic Laboratory.



Prostate Health Index LABORATORY RESULTS

1 Patient

Name: Case Study	Phone #: 804-123-1234	Patient ID #: 10-063-0025
Gender: Unknown	Sex: Male	Birthdate: 6/15/1957
Age: 55	Height: 5'11.6 in	Weight: 173 lbs

Specimen

Collected on Time: 9:54 am	Specimen ID: 10030400027
Collected on Date: 6/14/2015	Report Type: Complete
Received Date: 6/15/2015	Report Date: 11/10/2013

Provider

PROVIDER X TEST
DR. BESS DRUGGINS PRACTICE
8751 PARK CENTRAL DRIVE
RICHMOND, VA 23227
CLINIC ID: 11-22222-33-4444444

Tumor Markers	Result	Reference Interval	Previous Results	Physician's Notes																			
Total PSA (ng/ml)	10	Normal <2.0 and at risk ≥2.0																					
Free PSA (ng/ml)	1	See %Free PSA																					
pro2PSA (ng/ml)	2	See PHI																					
%Free PSA	10	%Free PSA Prostate Cancer Probability by Age* <table border="1" style="font-size: 8px; width: 100%;"> <tr> <th>%Free PSA</th> <th><50yr</th> <th>60-70yr</th> <th>>70yr</th> </tr> <tr> <td><7</td> <td>85%</td> <td>25%</td> <td>95%</td> </tr> <tr> <td>7-15</td> <td>11%</td> <td>50%</td> <td>60%</td> </tr> <tr> <td>16-25</td> <td>2%</td> <td>27%</td> <td>35%</td> </tr> <tr> <td>>25</td> <td></td> <td>6%</td> <td>13%</td> </tr> </table>	%Free PSA	<50yr	60-70yr	>70yr	<7	85%	25%	95%	7-15	11%	50%	60%	16-25	2%	27%	35%	>25		6%	13%	
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Prostate Health Index (PHI)	6.3	<table border="1" style="font-size: 8px; width: 100%;"> <tr> <th>PHI (Calculated)</th> <th>Cancer Probability</th> </tr> <tr> <td>0-24.9</td> <td>11.0%</td> </tr> <tr> <td>25.0-34.9</td> <td>18.1%</td> </tr> <tr> <td>35.0-54.9</td> <td>32.7%</td> </tr> <tr> <td>>55.0</td> <td>52.1%</td> </tr> </table>	PHI (Calculated)	Cancer Probability	0-24.9	11.0%	25.0-34.9	18.1%	35.0-54.9	32.7%	>55.0	52.1%											
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3 11.0% In published studies to date, patients with PHI values between 0 and 24.9 have an 11.0% probability of being found to have prostate cancer on biopsy.**

Lab Notes

- All patient demographics appear at the top of each page.
- Test Result: The result for each prostate cancer Tumor Marker is interpreted in relationship to the specified Reference Interval. The appropriate Reference Interval for free PSA is %free PSA derived from free PSA divided by total PSA x 100%. The Reference Interval for pro2PSA is the Prostate Health Index which is an algorithm that includes total PSA, free PSA and pro2PSA.
- Comments: The percentage likelihood of prostate cancer being found on biopsy is derived from the PHI value and is color coded for low risk (grey), medium risk (yellow) and high risk (red). Patients whose test results indicate elevated prostate cancer risk may choose to undergo prostate biopsy or, instead, to be closely monitored for signs of disease progression ("active surveillance"). The decision of when to biopsy must balance the potential benefits and harms of prostate cancer treatment, and may vary for each individual depending upon factors such as prostate cancer risk factors, overall health, and patient preference.

What Do I do With the Results?

- 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.
 - for low risk (grey)
 - medium risk (yellow)
 - and high risk (red)

References

- American Cancer Society. Prostate Cancer Prevention and Early Detection. Last revised April 14, 2018.
- Catalona WJ, Partin AW, Sando 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.
- Loeb S, Sando MG, Broyles DL, et al. The Prostate Health Index Selectively Identifies Clinically Significant Prostate Cancer. *The Journal of Urology*. 2015;193(4):1163-1169
- 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
- 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.
- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection. Version 2.2018 – April 5, 2018