



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.
- 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 25 indicates a higher likelihood of a benign condition.
- a *phi* score that is greater than 35 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	Case Study Name: Case Study Phone #: 804-123-1234 Patient ID #: 10-063-0025 Gender: Male Birthdate: 6/15/1957 Age: 55 Height: 5'11.6 in Weight: 173 lbs BMI: 28 Free BMT: <input type="checkbox"/>	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 DRONOVSKI PRACTICE 8751 PARK CENTRAL DRIVE RICHMOND, VA 23227 Clinic ID: 11-22222-33-4444444
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Tumor Markers	Result	Reference Interval	Previous Results	Physician's Notes
Total PSA ^a (ng/ml)	10	Normal <2.0 and at risk ≥2.0		
Free PSA ^a (ng/ml)	1	See %Free PSA		
pro2PSA (ng/ml)	2	See PHI		
%Free PSA	10	%Free PSA Prostate Cancer Probability by Age* %Free PSA <50yr 60-70yr >70yr <7 85% 25% 95% 98% 7-15 11% 50% 60% 16-25 2% 27% 35% >25 6% 6% 10%		
Prostate Health Index (PHI)	6.3	PHI (Calculated) 0-24.9 11.0% 25.0-34.9 18.1% 35.0-54.9 32.7% >55.0 52.1%		

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.**

Previous Results:

Lab Notes

* This test was developed and its performance characteristics determined by IDL. It has not been cleared or approved by the U.S. Food & Drug Administration (FDA). The USA has determined that each clinician or approved is not accurate. This test is used for clinical purposes. It should not be reported as Investigational or for research. This laboratory is not CLIA certified to perform high complexity clinical laboratory testing.

Dr. Suresh Sridhara | Laboratory Director | CLIA No. 48202056888 | NPI No. 11426846790
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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
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- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Prostate Cancer Early Detection. Version 2.2018 – April 5, 2018