# 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.<sup>2</sup>

#### 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 detection<sup>6</sup>

#### **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:**

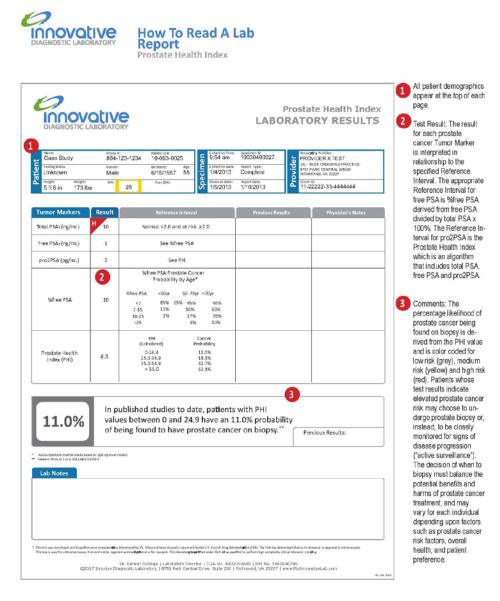
- While an elevated serum PSA is associated with prostate cancer, a number of benign conditions such as benign prostatic hyperplasia (BPH) and prostatitis might lead to elevated serum PSA concentrations.
- The Prostate Health Index is indicated for use as an aid in distinguishing prostate cancer from 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.<sup>2-5</sup>

#### The Patient Benefit:

- Finding Prostate Cancer early saves lives.
  - When Prostate Cancer is found early, the five-year survival rate is 100%.<sup>1</sup>
  - When Prostate Cancer is found late, the five-year survival rate drops to 29%.<sup>1</sup>
- 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?

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



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

#### References

- 1. American Cancer Society. Prostate Cancer Prevention and Early Detection. Last revised April 14, 2018.
- 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.
- 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
- Huang YQ, Sun T, Zhong WD, et al. Clinical performance of serum [-2]proPSA derivatives, %p2PSA and PHJ, 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

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### **New Account Form**

Please fax this completed form to: 1-804-515-7291 or email to clientrelations@myinnovativelab.com

PROVIDER INFORMATION	PROVIDER ADDRESS	
Healthcare Organization:	Location Address:	
Provider Name:	City, State, Zip:	
NPI#:	Phone Number:	
Practice Manager:	Secure Fax Number*:	
Email Address:	*To receive results for this order, please provide secure FAX number only	
SHIP SUPPLIES TO (IF DIFFERENT FROM ABOVE)	TESTS BEING ORDERED	
Location Address: City, State, Zip: Phone Number:	<ul> <li>ColonSentry<sup>®</sup></li> <li>EarlyCDT<sup>®</sup>-Lung</li> <li>Prostate Health Index</li> <li>BreastSentry<sup>™</sup></li> </ul>	
HOW TO RECEIVE TEST RESULTS	PICK UP INSTRUCTIONS	
HOW TO RECEIVE TEST RESULTS	PICK UP INSTRUCTIONS         *Please complete this section only if you would like IDL to create a pick up schedule with FedEx for your practice         FedEx Pickup Schedule         Daily       Specific Days: M_T_W_TH_F_	
Fax Email     Online Access (need below to send instructions & log-in information)     First & Last Name: Email:	*Please complete this section <u>only</u> if you would like IDL to create a pick up schedule with FedEx for your practice FedEx Pickup Schedule	

ADDITIONAL ORDERING PROVIDERS:	DESIGNATION (MD, DO, NP):	NPI #:	EMAIL ADDRESS:
	•	•	