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:

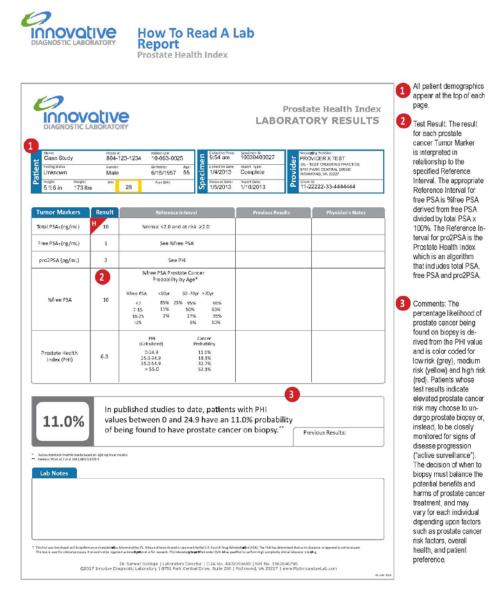
- While an elevated serum PSA is associated with prostate cancer, a number of benign conditions such as benign prostatic hyperplasia (BPH) and prostatitis might lead to elevated serum PSA concentrations.
- The Prostate Health Index is indicated for use as an aid in distinguishing prostate cancer from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

- 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.
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- 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
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