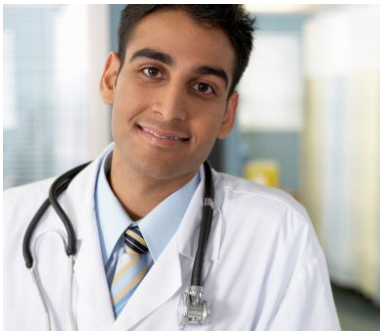
# The Prostate Health Index

Bridging the Diagnostic Gap Between PSA and Prostate Biopsy



## THE CHALLENGE

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. Studies have shown that approximately 70% of men with an elevated PSA who have a biopsy do not have cancer.(1)

## THE PROSTATE HEALTH INDEX SOLUTION

- 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)
- The Prostate Health Index utilizes three different PSA markers (PSA, freePSA, and p2PSA) as part of a sophisticated algorithm to more reliably determine the probability of cancer in patients with elevated PSA levels and can help men and their physicians decide if a prostate biopsy is indicated.(3)
- 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.(4)

## INDICATIONS FOR USE

- 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 between 4 ng/ml and 10ng/ml (5).
- Peer-reviewed published studies support the use of Prostate Health Index in men with total PSA values as low as 2ng/ml. (6)

## PATIENT SELECTION CRITERIA

- Patients with elevated PSA between 4ng/ml and 10ng/ml .
- Specimens for testing should be drawn prior to prostate manipulations such as digital rectal examination (DRE), prostatic massage, transrectal ultrasound (TRUS), or prostatic biopsy.

## WHY USE THIS TEST IN MY PRACTICE?

- When Prostate Cancer is found early, the five-year survival rate is nearly100%. Found late, the five-year survival rate drops to 29%.(7)
- Prostate Health Index helps male patients and their physicians decide if prostate biopsy, an invasive procedure, is indicated.(3)
- Using the Prostate Health Index to stratify patients with elevated PSA may reduce exposure to complications of prostate biopsy including pain, bleeding and infection.

**Contact Us Today to Get Started**

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# The Prostate Health Index

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STAGE ZERO LIFE SCIENCES

Prostate Cancer
LABORATORY RESULTS

| Patient | | | | Specimen | | | Provider | |
|---|---|---|---|---|---|---|---|---|
| Name: | Phone #: | Patient ID #: | | Collection Time: | Specimen ID: | | Requesting Provider | |
| Fasting Status: | Gender | Birthdate: | Age: | Collection Date: | Report Type: | | | |
| Height: Weight: | BMI: | Prev. BMI: | | Received Date: | Report Date: | | Client ID: | |

| Tumor Markers | Results | Reference Interval | Prev. Results | Physician's Notes |
|---|---|---|---|---|
| PSA, Total (ng/mL) | H 4.7 | Normal < 4.0<br>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*<br>% Free PSA / 50-64 Yrs / 65-75 Yrs<br>0.00 to 10.00% / 56% / 55%<br>10.01 to 15.00% / 24% / 35%<br>15.01 to 20.00% / 17% / 23%<br>20.01 to 25.00% / 10% / 20%<br>≥ 25.01% / 5% / 9% | | |
| Prostate Health Index (PHI)‡ | 58.7 | PHI Range / Prob. of Cancer / 95% CI<br>0 - 26.9 / 9.8% / 5.2% - 15.4%<br>27.0 - 35.9 / 16.8% / 11.3% - 22.2%<br>36.0 - 54.9 / 33.3% / 26.8% - 39.9%<br>≥ 55.0 / 50.1% / 39.8% - 61.0% | | |

**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 4.0ng/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.

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Rpt ver: SZLS 1.0
Ref ver: 2.0
Source:

## TEST INTERPRETATION

The percentage likelihood of prostate cancer being found on biopsy is derived from the *phi* value.

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%

| Phi Range* | Probability of Cancer |
|---|---|
| 0–26.9 | 9.8% |
| 27.0–35.9 | 16.8% |
| 36.0–54.9 | 33.3% |
| 55.0+ | 50.1% |

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