



# DEAR DOCTOR

LABORATORY INFORMATION



## Prostate Health Index (phi).

A new blood test for prostate cancer is now available. This has 75 % diagnostic accuracy compared with 50 % for Total PSA and 65 % for FPSA/ Total PSA ratio.

The determination of this index involves the use of a new prostate marker known as proPSA (p2PSA)

This molecule circulates in the blood as part of the Free PSA fraction, its proportion of the Free PSA increases in patients with prostate cancer. Prostate Health Index appears to have a greater diagnostic sensitivity in men where the Total PSA result is mildly elevated (4-10ng/ml). It is envisaged that this test may assist in reducing the number of unnecessary biopsies in patients with a mildly elevated Total PSA result. (4-10ng/ml)

The Prostate Health Index (phi) was approved by the US FDA in 2012 for use as an aid in the diagnosis of prostate cancer for men presenting with total PSA levels from 4 to 10 ng/ml and non-suspicious Digital Rectal Examination (DRE) findings.

## Clinical Information

Normally, very little PSA is secreted in the blood, however in conditions of increase glandular size and/or tissue damage, PSA is released into circulation.

It follows therefore that while an elevated serum PSA is associated with prostate cancer, other conditions, such as benign prostatic hyperplasia (BPH) and prostatitis might lead to elevated serum PSA concentrations. Consequently, PSA lacks specificity for prostate cancer detection.

In a multicenter study that compared the performance of PSA, free PSA, p2PSA, and phi in men undergoing prostate biopsy due to a serum PSA concentration between 4 and 10 ng/mL, phi was the best predictor of prostate cancer.

At 95% clinical sensitivity, the clinical specificity of phi was 16.0%, compared to 8.4% for free PSA and 6.5% for PSA.

**PROSTATIC BIOPSY IS HOWEVER REQUIRED FOR DIAGNOSIS OF CANCER.**



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## Reference Values

TOTAL PROSTATE-SPECIFIC ANTIGEN (PSA)

## FOR MALES

## PERCENT FREE PSA

When total PSA is in the range of 4-10 ng/mL

## PROSTATE HEALTH INDEX (phi)

When total PSA is in the range of 4-10 ng/mL

Age	Reference Range
<40 years	< / = 2.0 ng/mL
40-49 years	< / = 2.5 ng/mL
50-59 years	< / = 3.5 ng/mL
60-69 years	< / = 4.5 ng/mL
70-79 years	< / = 6.5 ng/mL
> / = 80 years	< / = 7.2 ng/mL

If the % Free PSA	Is: The probability of Cancer
< / =<10%	56%
11-15%	28%
16-20%	20%
21-25%	16%
>25%	8%

Phi Range	Probability of cancer	Probability of cancer
0-26.9	9.8%	5.2-15.4%
27.0-35.9	16.8%	11.3-22.2%
36.0-54.9	33.3%	26.8-39.9%
> / = 55.0	50.1%	39.8-61.0%

## Interpretation

Based on available clinical data Prostate health index (phi) may be used to determine the probability of prostate cancer on biopsy in men with total PSA in the 4 to 10 ng/mL range.

Low phi scores are associated with a lower probability of finding prostate cancer on biopsy and higher phi scores are associated with an increased probability of finding prostate cancer on biopsy.

## Cautions

**Specimens for** [-2] ProPSA (p2PSA) testing should be drawn prior to prostate manipulations such as digital rectal examination (DRE), prostatic massage, transrectal ultrasound (TRUS), and prostatic biopsy. DRE may cause a transient increase in p2PSA, free PSA, and PSA. Transrectal needle biopsy has also been shown to cause transient increases in p2PSA, free PSA, and PSA elevations, thus a 6-week waiting period between needle biopsy and p2PSA, free PSA, and PSA sampling is recommended.

The prostate health index (phi) results should be interpreted considering the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information. phi should not be interpreted as absolute evidence for the presence or absence of prostate cancer. Elevated PSA concentrations, increased phi, or decreased free PSA may be observed in patients with nonmalignant disorders, as well as those with prostate cancer.

Routine use of 5 alpha-reductase inhibitor drugs typically lower PSA, free PSA, and p2PSA levels in patients. Other drugs used to treat benign prostatic hyperplasia (BPH) may also affect PSA levels. Care should be taken in interpreting results from patients taking these drugs.