

**TEST ID: PHIND**  
**PROSTATE HEALTH INDEX (PHI), SERUM**

**USEFUL FOR**

Aids in distinguishing prostate cancer from benign prostate conditions in men 50 years of age and older with total PSA results in the 4 to 10 ng/mL range and digital rectal examination (DRE) findings that are not suspicious for cancer

**CLINICAL INFORMATION**

Prostate-specific antigen (PSA) is a glycoprotein produced by the prostate gland, the lining of the urethra, and the bulbourethral gland. Normally, very little PSA is secreted in the blood. In conditions of increased glandular size and/or tissue damage, PSA is released into circulation. Measurement of serum PSA is useful for determining the extent of prostate cancer and assessing the response to prostate cancer treatment. PSA is also used as a screening tool for prostate cancer detection, although its use in screening has become controversial in recent years. 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. As a consequence, PSA lacks specificity for prostate cancer detection.

Several PSA isoforms have been identified that can further increase the specificity of PSA for prostate cancer. In particular, the [-2] form of proPSA (p2PSA) shows improved performance over either total or free PSA for prostate cancer detection on biopsy. The prostate health index (phi) is a formula that combines all 3 PSA forms (total PSA, free PSA, and p2PSA) into a single score. phi is calculated using the following formula:  $(p2PSA/free\ PSA) \times \text{square root (PSA)}$ .

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 any prostate cancer, high-grade cancer, and clinically significant 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 required for diagnosis of cancer.

**ANALYTIC TIME**

1 day

**REFERENCE VALUES**

**Total PSA Males**

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

**% Free PSA Males**

**When total PSA is in the range of 4–10 ng/mL:**

% FREE PSA	PROBABILITY OF CANCER
≤10%	56%
11-15%	28%
16-20%	20%
21-25%	16%
>25%	8%

**Prostate Health Index (phi) Males**

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

PHI RANGE	PROBABILITY OF CANCER	95% CONFIDENCE INTERVAL
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

The prostate health index (phi) may be used to determine the probability of prostate cancer on biopsy in men 50 years of age and older with total prostate-specific antigen (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. The choice of an appropriate phi score to be used in guiding clinical decision making may vary for each patient and may depend on other clinical factors or family history. The table below indicates the probability of finding prostate cancer on biopsy when PSA is in the range of 4 to 10 ng/mL and may be used as guidance for interpreting the phi score.

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36.0–54.9	33.3%	26.8–39.9%
≥55.0	50.1%	39.8–61.0%

## CLINICAL REFERENCE

1. Catalona WJ, Partin AW, Sanda MG, et al: A multicenter study of [-2]pro-prostate-specific antigen combined with prostate-specific antigen and free prostate-specific antigen for prostate cancer detection in the 2.0 to 10.0 ng/mL prostate-specific antigen range. *J Urology* 2011 May;185:1650-1655
2. Pecoraro V, Roli L, Plebani M, et al: Clinical utility of the (-2)proPSA and evaluation of the evidence: a systematic review. *Clin Chem Lab Med*. 2015 Nov 26. pii available at: [/j/cclm.ahead-of-print/cclm-2015-0876/cclm-2015-0876.xml](#). doi: 10.1515/cclm-2015-0876
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