

## **PROSTATE HEALTH INDEX (*phi*)**

**FDA-APPROVED MULTI-ANALYTE BLOOD TEST FOR BETTER PROSTATE CANCER DETECTION**



## WHAT IS *phi*?

The prostate health index (*phi*) is a mathematical formula that provides a probability of prostate cancer (PCa) by combining three tests (prostate-specific antigen [PSA], free PSA, and p2PSA) into a single score.

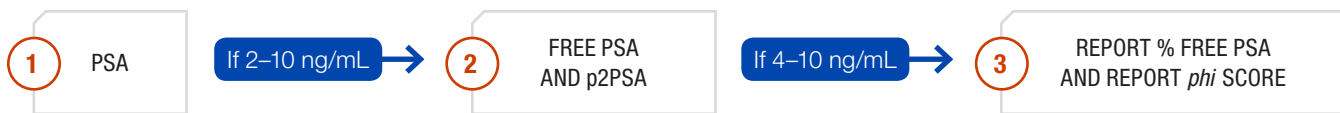
Calculated by using an algorithm in the Beckman Coulter Access instrument, the *phi* score can provide more accurate information about the meaning of an elevated PSA level and the probability of finding prostate cancer on a biopsy.

## BETTER PROSTATE CANCER DETECTION

While PSA is a widely used screening tool for prostate cancer, its limited specificity for cancer necessitates a more precise tool for prostate cancer detection. *Phi* is intended to fill the diagnostic “gap” between PSA screening and a prostate biopsy. Combined with family and patient history, the *phi* can be used to determine the best individualized patient-management decisions for those diagnosed with prostate cancer.

The higher specificity of *phi* means a greater probability of identifying those patients who actually need a biopsy, allowing for a substantial decrease in the current number of prostate biopsies being ordered and reported as negative for cancer.

## HOW DOES *phi* PROGRESS THROUGH THESE 3 TESTS?



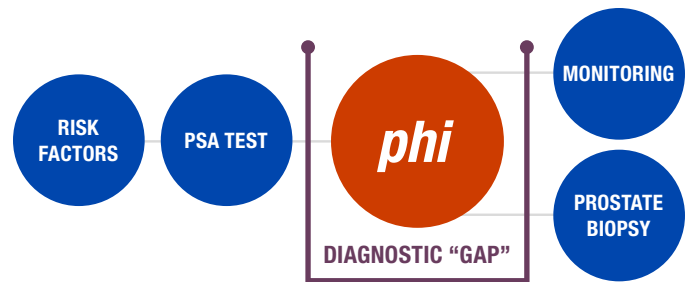
## HOW IS *phi* REIMBURSED?

The calculation of *phi* is similar to the calculation of %fPSA. From a coding and reimbursement perspective, the difference is that for *phi*, the American Urological Association (AUA) recommends using CPT code 86316 for the new test of p2PSA. There currently is no separate CPT code for the calculation of the *phi* value.

The AUA Coding and Reimbursement Committee recommends that if each of the prostate cancer blood tests is performed, then CPT codes 84153 (PSA Total), 84154 (Free PSA), and 86316 (p2PSA) should be reported.

The *phi* test is also:

- ▶ FDA-approved.
- ▶ Recommended in the guidelines from the National Comprehensive Cancer Network for PCa early detection.



## HOW DOES THE *phi* SCORE GUIDE CLINICAL DECISION MAKING?

The *phi* score is used to estimate an individual patient's probability of having detectable prostate cancer, when that patient has a PSA between 4 and 10 ng/mL. At *phi* cutoffs ranging from 27–55, the probability of cancer ranged from 16.8% to 50.1%.

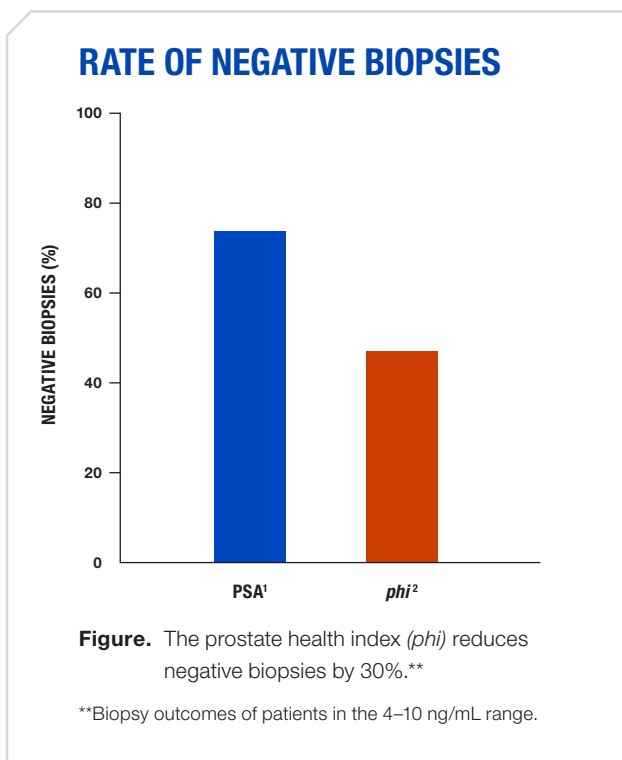
| <i>phi</i> RANGE* | PROBABILITY OF CANCER | 95% CONFIDENCE INTERVAL |
|-------------------|-----------------------|-------------------------|
| 0–26.9            | 9.8%                  | 5.2%–15.4%              |
| 27.0–35.9         | 16.8%                 | 11.3%–22.2%             |
| 36.0–54.9         | 33.3%                 | 26.8%–39.9%             |
| 55.0+             | 50.1%                 | 39.8%–61.0%             |

**Table.** Probability of prostate cancer based on *phi* results.<sup>1</sup>

\*The *phi* results are intended to be used as an aid in distinguishing prostate cancer from benign prostatic conditions in men 50 years of age and older with total PSA results in the 4–10 ng/mL range and negative digital rectal examination (DRE) findings.

## IMPROVED RISK STRATIFICATION

Results from a prospective, multicenter clinical trial found that *phi* provides better risk stratification. It reduces unnecessary biopsies by 30% and reduces medical costs for the patient.



## WHEN SHOULD I ORDER?

*Phi* should be ordered after confirmation that PSA is in the 4–10 ng/mL range. This indication extends to both initial and repeat biopsies.

### FEATURED TEST

- ▶ Prostate Health Index (*phi*), Serum (Mayo ID: PHI11)

## PEER-REVIEWED ARTICLES

The following highlight the clinical value of *phi*:

### THE PROSTATE HEALTH INDEX: ITS UTILITY IN PROSTATE CANCER DETECTION

Lepor A, Catalona WJ, Loeb S. *Urologic Clinics of North America*. 2016;43(1):1–6.

#### KEY POINTS

- ▶ Numerous large, prospective studies from geographically diverse regions have consistently demonstrated that *phi* is more specific for prostate cancer detection than existing standard reference tests of total and free PSA.
- ▶ Increasing *phi* scores predict a greater risk of clinically significant disease on biopsy.

### THE PROSTATE HEALTH INDEX SELECTIVELY IDENTIFIES CLINICALLY SIGNIFICANT PROSTATE CANCER

Loeb S, Sanda MG, Broyles DL, et al. *The Journal of Urology*. 2015;193(4):1163–1169.

#### KEY POINTS

- ▶ Multicenter prospective trial that included 658 men aged 50 years or older were identified with PSA 4 to 10 ng/mL and normal digital rectal examination who underwent prostate biopsy.
- ▶ At the 90% sensitivity cutoff point for *phi*, 30.1% of patients could have been spared an unnecessary biopsy for benign disease or insignificant prostate cancer.

For the full list of more than 80 articles and meeting abstracts, visit:

**[mayomedicallaboratories.com/phitest](http://mayomedicallaboratories.com/phitest)**.

## CITATIONS

1. Beckman Coulter Access Hybritech p2PSA Instructions for Use
2. Loeb S, Martin S, Broyles, D, et al. The Prostate Health Index (*phi*) Selectively Identifies Clinically Significant Prostate Cancer. *J. Urolog.* Jan. 2015

**FOR MORE INFORMATION  
ABOUT PROSTATE HEALTH  
INDEX (*phi*) TESTING, VISIT:**

[MayoMedicalLaboratories.com/phitest](https://MayoMedicalLaboratories.com/phitest)