



The Prostate Health Index (*phi*)

A more reliable method for screening prostate cancer,
aiding in biopsy candidate selection



What is *phi*?

The Prostate Health Index (*phi*) is a prostate cancer risk assessment that is intended to help reduce unnecessary, painful and potentially risky prostate biopsies. Although prostate biopsies are a common procedure, they do carry the risks associated with any invasive medical procedure, and they can also be uncomfortable for the patient. *phi* incorporates the results of three blood tests—PSA, free PSA and p2PSA—to calculate a *phi* score. The *phi* score provides key information about the likelihood that patients with elevated PSA have cancer, as opposed to other, more benign conditions that can also cause elevated PSA scores.



Who is *phi* for?

phi is designed to aid in distinguishing prostate cancer from benign prostatic conditions in patients aged 50 years and older. In particular, for those with elevated PSA levels or other risk factors, such as a family history of prostate cancer, *phi* provides valuable insights into disease progression that can guide patient management.



Did you know?

phi is FDA-approved and included in the 2023 National Comprehensive Cancer Network NCCN Guidelines for the early detection of prostate cancer¹

A smarter way to assess prostate health

The PSA test is a widely used screening tool for prostate cancer. However, because of its limited cancer specificity (i.e., limited ability to correctly identify those without the disease), an additional assessment tool such as *phi* is preferable to using just a PSA score.

Key benefits of using *phi* include:

Greater accuracy and specificity:

- *phi* combines multiple prostate-specific biomarkers, providing a more accurate, specific and reliable indication of prostate health compared to traditional PSA tests¹

Fewer unnecessary biopsies:

- By minimizing false positives, *phi* helps patients avoid unnecessary prostate biopsies, promoting patient comfort and minimizing risk while helping to reduce healthcare costs.² If used in the correct population, *phi* can reduce the number of biopsies by up to 30%

Early detection:

- *phi* aids in the early detection of prostate cancer, contributing to timely intervention, increased options for treatment and improved patient outcomes.³ When prostate cancer is detected early, a patient's 5-year survival rate is more than 99%⁴

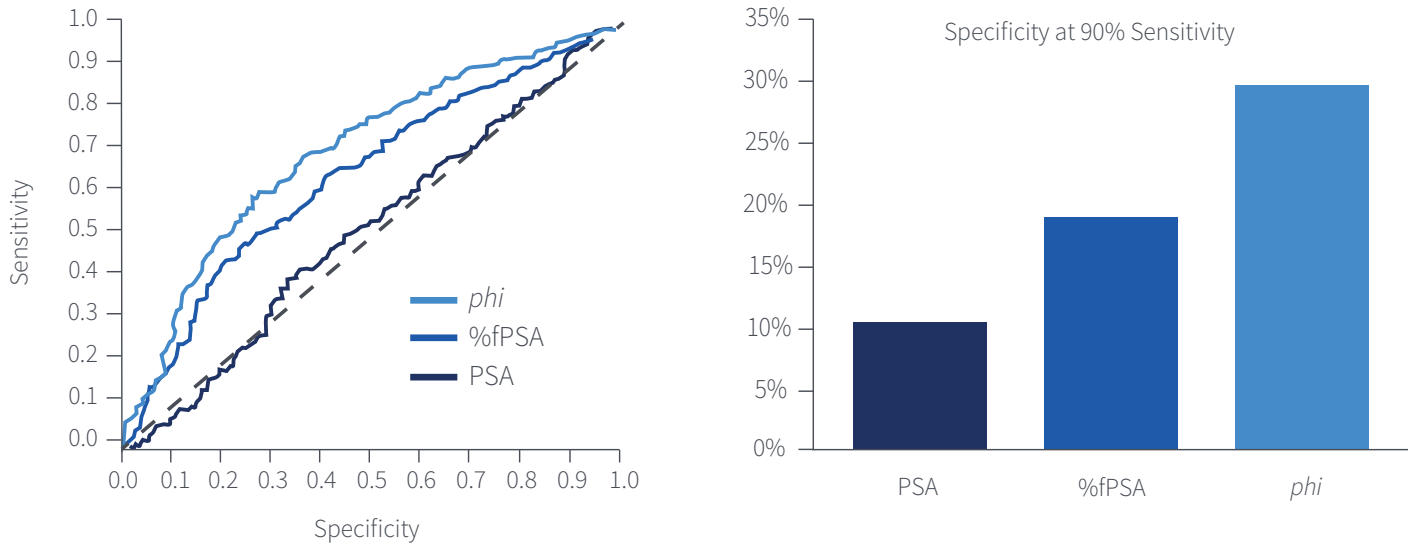
Improved patient experience:

- With its precision and reliability, *phi* fosters trust and satisfaction among those seeking clear answers about their prostate health

Bringing precision to prostate testing

Because *phi* improves specificity for prostate cancer, it fills the diagnostic gap between PSA screening and prostate biopsy for men whose total PSA falls within the gray zone (e.g., those with a total PSA level between 4 and 10 ng/mL). Combined with family and patient history, *phi* can help determine the best individualized patient-management decisions.

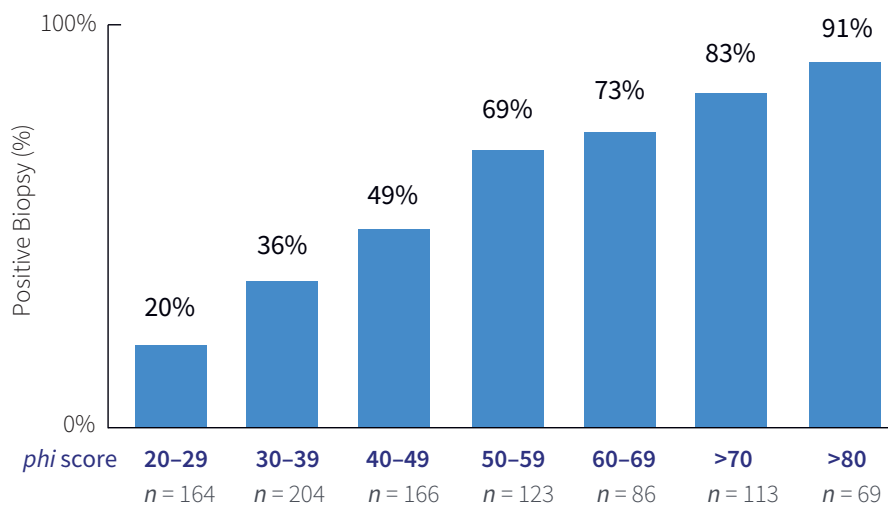
Figure 1. Comparison of specificities of total PSA, %fPSA and *phi*³



Know the risks: Understanding *phi* efficacy

phi assesses the likelihood of prostate cancer in men who meet PSA standards for consideration of a biopsy, similar to percentage of free PSA (%fPSA). The higher diagnostic performance of *phi* is supported by over 70 published clinical studies demonstrating its benefits and economic value. As shown in Figure 2, an increasing *phi* score indicates an increasing probability that your patient may have prostate cancer.

Figure 2. Percent of positive biopsies in relation to *phi* score⁵

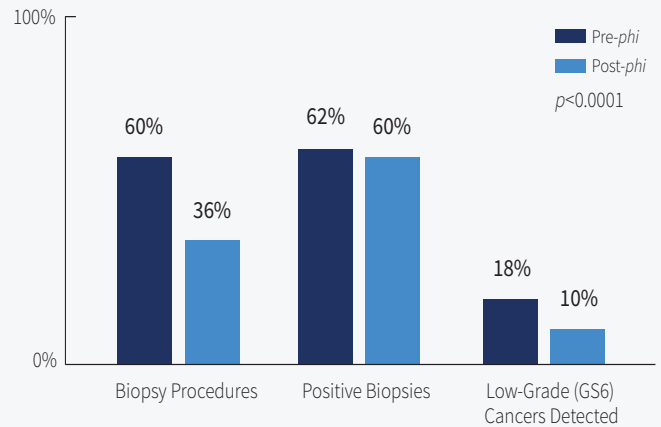


phi in action: Defer biopsies when introduced in routine clinical practice

A clinical study (Figure 3) comparing the treatment course of over 500 men assessed with *phi* to a historical control group—seen by the same urologists within the previous 24 months—showed:

- ✓ The *phi* score significantly impacted the **patient management plan in over 73% of cases**, including biopsy deferrals when the *phi* score was low, and decisions to perform biopsies when the *phi* score indicated an intermediate or high probability of prostate cancer ($\phi \geq 36$)
- ✓ Men receiving a *phi* test showed nearly a **24% reduction in the number of biopsy procedures performed** compared to the historical control group with a decrease in the rates of low-grade (i.e., Gleason score 6) cancers detected. Moreover, the number of high-grade positive biopsies (Gleason score >7) did not change (Figure 3)

Figure 3. Real-world biopsies and pathological findings before and after *phi*⁶



Another study involving a large academic practice at Johns Hopkins University in Baltimore, Maryland, showed, for example, 66% of men with $\phi < 27$ were found to have a negative biopsy, and 91% of those men had either a negative biopsy or Grade Group 1 disease. By contrast, only 16% of men with $\phi > 55$ had a negative biopsy, 8% had Grade Group 1 cancer, and 76% had Grade Group 2 or higher cancers.⁷

Your guide to better prostate cancer detection and management

When you need clear answers to inform the best treatment options for your patient, count on *phi*'s proven track record. Numerous clinical studies support the efficacy and reliability of *phi* in prostate health assessment, and results from a prospective, multicenter clinical trial found that *phi* can provide better risk stratification versus %fPSA to identify patients who need a biopsy.^{6,7}

Aligning seamlessly with a patient-centric approach, *phi* improves the overall healthcare experience for your patient and provides you with the scientific validation you need to guide decision-making.

Test Number	Description
140405	Prostate Health Index (<i>phi</i>). Total PSA measured. Free PSA and p2PSA reflex testing is performed when total PSA is between 4.0 and 10.0 ng/mL.*

*If reflex testing is performed, additional charges/CPT code(s) may apply.

References

1. NCCN Guidelines® insights: prostate cancer early detection, version 1.2023. National Comprehensive Cancer Network. 2023
2. Access p2PSA Instructions for Use. Beckman Coulter
3. Loeb S, Sanda MG, Broyles DL, et al. The Prostate Health Index selectively identifies clinically significant prostate cancer. *J Urol*. 2015;193:1163-1169. doi:10.1016/j.juro.2014.10.121
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5. Stephan C, Vincendeau S, Houlgatte A, Cammann H, Jung K, Semjonow A. Multicenter evaluation of [-2] proprostate-specific antigen and the prostate health index for detecting

6. White J, Shenoy BV, Tutrone RF, et al. Clinical utility of the Prostate Health Index (*phi*) for biopsy decision management in a large group urology practice setting. *Prostate Cancer Prostatic Dis*. 2018;21(1):78-84. doi:10.1038/s41391-017-0008-7
7. Tosoian JJ, Druskin SC, Andreas D, et al. Use of the Prostate Health Index for detection of prostate cancer: results from a large academic practice. *Prostate Cancer Prostatic Dis*. 2017;20(2):228-233. doi:10.1038/pcan.2016.72

Get diagnostic clarity for prostate cancer today.

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