



PROSTATE HEALTH INDEX

The latest advance in prostate health testing



The original test

PSA

55% diagnostic accuracy

The PSA test is a good starting point, but an elevated result does not differentiate between benign prostate enlargement and prostate cancer.

A better test

Free/Total PSA Ratio

65% diagnostic accuracy

The ratio of Free to Total PSA is lower in cancer than in benign prostate disease, so this test can be a more accurate detector of cancer, but is still a suboptimal test.

The new generation test

Prostate Health Index

75% diagnostic accuracy

A better indicator of whether a patient should proceed to biopsy.

A new blood test for prostate cancer, the Prostate Health Index (*phi*) is now available through Melbourne Pathology. This new test has significantly improved accuracy in prostate cancer risk prediction over currently available tests. (Catalona et al, Journal of Urology 2011, see references)

What is the basis of the *phi* test?

A new marker for prostate cancer has been identified – truncated proPSA (p2PSA). This molecule circulates as part of the Free PSA fraction, and is present as a higher proportion of the Free PSA fraction in patients with prostate cancer. A greater specificity for cancer detection was found when proPSA was combined with Free PSA and Total PSA, as a calculation known as the Prostate Health Index (*phi*).

When is it indicated?

phi is likely to be most useful in men where the Total PSA result is mildly elevated (2–10 µg/L). Determining the cancer risk in this range can be difficult, with up to 25% of new prostate cancer patients having a relatively normal PSA (< 4 µg/L); on the other hand, 60–70% of men with a PSA value > 4 µg/L have a benign biopsy result. Because of this uncertainty, a prostate biopsy is often considered to clarify the diagnosis.

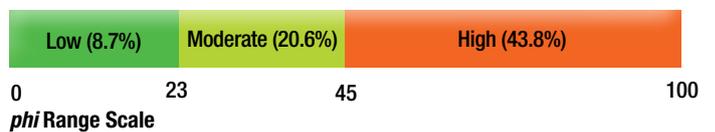
Advantages of the *phi*

- phi* can assist patients and doctors to make a decision about proceeding with a prostate biopsy.
- phi* is minimally influenced by the age of an individual.

It is envisaged that this test may assist in reducing the number of unnecessary biopsies in patients with a mildly elevated Total PSA result (2–10 µg/L).

The role of *phi* in other clinical situations, such as follow-up of radical prostatectomy, has not yet been established.

phi and Prostate Cancer (% probability of positive biopsy) (for Total PSA of 2–10 µg/L)



What to request?

Prostate health index or *phi*.

phi cannot be bulk billed as there is no Medicare rebate. The patient will receive an account for \$95*.

MELBOURNE PATHOLOGY		REFERRAL	
Patient Mr Citizen John		Dr's ID Code	Doctor name
123 Main Street Melbourne VIC 3000		Dr's MBS No.	Address
03/10/1963		Provider No.	Copy to: Dr Name and Address
Recent PSA 1.2		Copy ID No.	Physician name
Tests Requested		Urgent	Tel. Fax By
<i>phi</i>		Yes	Contains Collected
Cervical Cytology		Patient Status at Date of Service or Specimen Collection	
Pre Menstrual, Mid Menstrual, Post Menstrual, Pregnant		Private patient in a private hospital or approved day hospital, Hospital patient in a recognised hospital, Private patient in a recognised hospital, Outpatient patient of a recognised hospital	

I certify that the pathology specimen accompanying the request was collected from the patient stated above as established by direct inquiry and/or inspection of wrist band. Signed: _____ Person identifying patient: _____ Specimen Date: _____ Specimen Time: _____ 103 Victoria Parade, Collingwood, Victoria 3068 Central Laboratory Phone (03) 9057 7700 Melbourne Pathology ABN 63 074 699 139. A subsidiary of Sonic Healthcare Ltd APA www.mps.com.au

PROSTATE HEALTH INDEX cont...

Patient Management

The question about the adoption of widespread screening for prostate cancer is currently the topic of debate, as is the best management protocol for dealing with patients with mild PSA elevations. Other factors, such as patient age and co-morbidities, are very relevant in the approach to each case.

The use of PSA medians for risk stratification was recognised in the changes made to the Medicare Benefits Schedule in May, 2009 (see cost information to the right).

As the *phi* test is most useful where the Total PSA result is above the median (2–10 µg/L), it may help determine, with more confidence, whether the elevated PSA is more likely to be associated with prostate cancer than due to non-cancerous changes, potentially avoiding unnecessary biopsy.

The flowchart shows one possible approach. Earlier referral to a urologist may be desirable for patients with specific symptoms or concerns including a rapidly rising PSA.

How much does prostate testing cost?

Prostate Specific Antigen (PSA): Total

Medicare rebate is available under the following conditions:

- Monitoring of previously diagnosed prostatic disease – unrestricted
- 1 PSA test per year for all other men.

Prostate Specific Antigen (PSA): Free/Total Ratio

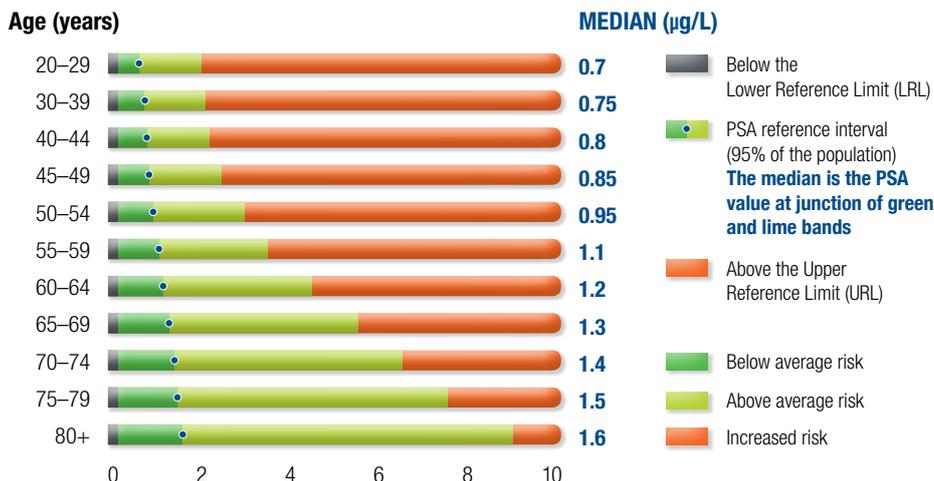
Medicare rebate is available under the following conditions:

Follow-up of a PSA result that:

- 1) lies at or above the age-related median, but below the age-related, method-specific 97.5% reference limit – 1 test per 12 month period, or
- 2) lies at or above the age-related, method-specific 97.5% reference limit, but below a value of 10 µg/L – 4 tests per 12 month period.

Prostate Health Index (*phi*)

phi tests cannot be bulk billed as Medicare Australia does not provide a rebate for *phi*. Patients will receive an account. The fee for *phi* is \$95* and patients will not be able to claim a Medicare rebate for this service.



Dr Ken Sikaris
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Director Of Chemical Pathology

A graduate of the University of Melbourne, Dr Sikaris trained at the Royal Melbourne, Queen Victoria, and Prince Henry's Heidelberg Repatriation Hospitals. He obtained fellowships from the Royal College of Pathologists of Australasia and the Australasian Association of Clinical Biochemists in 1992 and 1997 respectively.

Dr Sikaris was Director of Chemical Pathology at St Vincent's Hospital in Melbourne between 1993 and 1996. A NATA-accredited laboratory assessor, Dr Sikaris specialises in Prostate Specific Antigen, cholesterol and quality assurance and is Chair of the RCPA Key Incident Monitoring Program for Australasia. Dr Sikaris is a prolific lecturer to undergraduate and postgraduate, medical and allied health students including GP's and a variety of specialist groups across Australia and overseas.

For further information, please contact Dr Ken Sikaris on 9287 7847.

References

Australian Institute of Health and Welfare (AIHW) 2010. ACIM (Australian Cancer Incidence and Mortality) Books. AIHW: Canberra (2007 data). Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level ≤ 4.0 ng per Milliliter. Thompson IM et al. N Engl J Med 2004;350:2239-46. Baseline prostate-specific antigen compared with median prostate-specific antigen for age group as predictor of prostate cancer risk in men younger than 60 years old. Loeb S et al. Urology 2006;67:316-320. Long-term prediction of prostate cancer up to 25 years before diagnosis of prostate cancer using prostate kallikreins measured at age 44 to 50 years. Lijia H et al. J Clin Oncol 2007;25:431-6. A multicenter study of [-2]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. Catalonia WJ et al. J Urol. 2011 May;185(5):1650-5. Epub 2011 Mar 17. Free prostate-specific antigen test utilization. Consistency with guidelines. Jackson BR et al. J Gen Intern Med. 2005 September; 20(9): 859-861.

*Correct at the time of printing.
Fees are subject to change without notice.

