# The Laboratory Services Reform Programme

## ADVICE NOTE

## Prostate Specific Antigen Testing

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# Clinical Practice Guidance Document Cover Sheet

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| Document Owner/Author | Author: Marie Culliton Dr Shari Srinivasan |
| National Service/Area | Office of the Chief Clinical Officer |
| Approved by: | Professor Martin Cormican |
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The Laboratory Services Reform Programme offers the following advice:

## 1 Advice for Laboratory Users

1. Prostate assessments includes **both** a Digital Rectal Examination (DRE) and measurement of serum Prostate Specific Antigen (PSA)
2. When men present with clinical features that suggest a lower urinary tract infection (UTI) the patient should be assessed in the first instance for UTI. If UTI is confirmed this should be managed. If testing for PSA is appropriate in this context it should be deferred for 6 weeks.
3. PSA is not a routine test for men **who do not have** symptoms that require investigation for prostate cancer.
4. A decision to perform a test for PSA on a man with no clinical features that suggest prostate cancer requires informed consent of the person tested. Informed consent requires that the person making the request has established that the man is informed of the benefits and risks of testing (see below).
5. PSA testing is valuable in men who present with clinical features that suggest prostate cancer
6. Testing for PSA is valuable in follow up of men with prostate cancer
7. PSA is labile. Specimens should be transported to the laboratory promptly, ideally within 4 hours. PSA testing should not be performed on an un-centrifuged blood specimen received more than 48 hours after it was drawn.
8. Samples for PSA should ideally be drawn before DRE. With respect to activities that can raise PSA please see National Cancer Control Programme Advice[4]
9. With respect to interpretation of result of DRE and PSA
    a. With normal age appropriate PSA and no suspicious findings on DRE no further immediate action is normally required. Clinical review is based on established risk stratification protocols.
    b. If the PSA is raised for the age of the man but with no suspicious findings on DRE the PSA analysis should be repeated in 6-12 weeks at the same laboratory.

10. The National Cancer Control Programme recommends referral to specialist services based on the following levels of PSA[1].

| Age | Raised Age Related PSA Value (ug/L) |
|---|---|
| Less than50 | Equal to or greater than 2 |
| 50 – 59 | Equal to or greater than 3 |
| 60 – 69 | Equal to or greater than 4 |
| 70 and older | Equal to or greater than 5 |

11. 5α reductase inhibitors reduce PSA levels by approximately 50%. A baseline PSA should be established 6 months post treatment. An increase in PSA while on treatment should prompt referral to specialist services.
12. Post treatment for prostate cancer surveillance of PSA should be undertaken at intervals according to evidence based guidelines as indicated by the National Cancer Control Programme (NCCP). PSA levels being used for surveillance should be tested by the same laboratory using the same method and platform.

## 2 Advice for Laboratories

13. To the greatest extent practical, within the limits of the information systems and other resources available, laboratories should require relevant clinical details on requests for testing for PSA
14. Laboratories should advise users that one of more of the following clinical details are required on requests for testing for PSA
    - Clinical features suggest prostate cancer
    - Follow up of prostate cancer
    - Informed consent for testing in an asymptomatic patient
    - Other specific legible clinical details
15. To the greatest extent practical laboratories should decline to process requests for testing for PSA that do not provide relevant clinical details. The validity of consent for testing in an asymptomatic man is the responsibility of the requestor and not of the laboratory.
16. Whole blood specimens for PSA measurement should be drawn, transported, logged-in, and serum / plasma separated and ready for analysis in less than 24 hours. Requesting doctors should be advised of this requirement.
17. If testing is performed on samples that are not ready for analysis in 24 hours, laboratories should advise users of the limitations of such a result. This should be by a statement of limitations on each such report if this can be implemented on the laboratory information system.

18. PSA testing should not be performed on an un-centrifuged blood specimen received more than 48 hours after it was drawn
19. Only PSA assays calibrated to the WHO International Standard for Prostate-Specific Antigen (NIBSC Code 96/670) shall be used
20. Internal Quality Control material used must span all clinical decision points and reporting ranges including those used in surveillance.
21. The unit of measurement of PSA concentration in serum or plasma shall be µg/L and at least one decimal point is required.
22. Assay details (calibration followed by manufacturer) shall be specified with the test name on PSA reports
23. Laboratories should ensure that their assays are aligned with the decision levels referred to in 9 above.
24. To the greatest extent possible laboratories should include comments based on these levels reports to guide interpretation.

## 3 Background

The NCCP notes that Prostate cancer is the leading cause of cancer in men (excluding Non Melanoma Skin Cancer). Over 3,300 men are diagnosed with prostate cancer in Ireland each year[1].

Testing for PSA has an established role in assessment of men with clinical features suspicious for and/or suggestive prostate cancer and in follow up of men with a diagnosis of prostate cancer.

PSA is not recommended as a routine screening test for men with no clinical features suggestive of prostate cancer. While there is evidence to demonstrate that PSA testing of asymptomatic men is associated with increased detection of prostate cancer debate continues about the benefits of increased detection as many men with nonlethal cancers undergo radical treatments that compromise quality of life. Screening based on risk stratification to identify those at risk of developing high grade prostate cancer is the subject of investigation. If testing of PSA in men with no clinical features of prostate cancer is considered the clinician should discuss patient's concerns, benefits/harms/risks of prostate assessment and provide patient information leaflet. This provides the patient with a basis for making an informed decision to consent to testing.

Potential benefits: Prostate assessment may lead to early detection of treatable cancer

Potential harms/risk: Potential false positive and false negative results, Risk of side effects from investigations and treatment, Un-necessary anxiety for the patient and their family

Patient groups at higher risk of prostate cancer include:

- African ethnicity
- Increased risk with number of family members and early age of onset (age less than 50 years)
- Increased risk of aggressive disease in patients with BRCA1/2 mutations

Informed consent of the patient is required to support testing for PSA in men with no clinical features of prostate cancer. It is the responsibility of the requestor to ensure that the patient has been appropriately informed and agreed to have the test. The informed consent should be noted on the request form to assure the laboratory service that the request conforms to national guidance. The laboratory does not have a role in verifying the validity of the consent for testing.

## 4 References


1. Master NCCP Prostate Cancer GP Referral Guideline Introduction TABS- Alt Cover.indd (hse.ie)
2. prostate-surveillance-published-v1-pca-f2.pdf (hse.ie)
3. Prostate Specific Antigen (PSA) Test Harmonisation Outcomes Agreed at the National Cancer Control Program PSA Harmonisation Board Workshop 2014. Previously published in the National Laboratory Handbook Vol 1
4. having-your-prostate-checked-a-guide.pdf



**Authors:** Developed by the Laboratory Services Reform Programme incorporating The National Clinical Pathology Programme.

**Approved By:** Martin Cormican MCRN 011105, HSE Clinical Lead for Laboratory Services Reform Programme.


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