Test Definition: SPSA

Prostate-Specific Ag Screen, S

Overview

Useful For

Monitoring patients with a history of prostate cancer as an early indicator of recurrence and response to treatment

Prostate cancer screening

Method Name

Electrochemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Free prostate-specific antigen (PSA) can only be added to previously-submitted specimen within 12 hours of performing total PSA. Specimen must have been shipped frozen. If both free and total PSA are requested, order PSAFT / Prostate-Specific Antigen (PSA), Total and Free, Serum.

Necessary Information

Include patient's age.

Specimen Required

Patient Preparation: For 12 hours before specimen collection do not take multivitamins or dietary supplements containing biotin (vitamin B7), which is commonly found in hair, skin, and nail supplements and multivitamins.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume:1 mL

Collection Instructions:

1. Red-top tube must be centrifuged and aliquoted within 2 hours of collection.

2. Serum gel tube must be centrifuged within 2 hours of collection.

Forms

If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	180 days	
	Refrigerated	5 days	

Clinical and Interpretive

Clinical Information

Prostate-specific antigen (PSA) is a glycoprotein that is produced by the prostate gland, the lining of the urethra, and the bulbourethral gland. Normally, very little PSA is secreted in the blood. Increases in glandular size and tissue damage caused by benign prostatic hypertrophy, prostatitis, or prostate cancer may increase circulating PSA levels.

In patients with previously diagnosed prostate cancer, PSA testing is advocated as an early indicator of tumor recurrence and as an indicator of response to therapy. The role of PSA in early detection of prostate cancer is controversial. The American Cancer Society recommends annual examination with digital rectal examination and serum PSA beginning at age 50, and for those men with a life expectancy of at least 10 years after detection of prostate cancer. For men in high-risk groups, such as African Americans or men with a first-degree relative diagnosed at a younger age, testing should begin at a younger age. It is generally recommended that information be provided to patients about the benefits and limitations of testing and treatment so they can make informed decisions.

Reference Values

Males:

Age (years)	**PSA upper limit (ng/mL)**
<40	< or =2.0
40-49	< or =2.5
50-59	< or =3.5
60-69	< or =4.5
70-79	< or =6.5
> or =80	< or =7.2

Females: not applicable

Interpretation

Prostate-specific antigen (PSA) values are reported with the 95th percentile limits by decade of age.

These reference limits include men with benign prostatic hyperplasia. They exclude all cases with proven cancer.

PSA values exceeding the age-specific limits are suspicious for prostate disease, but additional testing, such as prostate biopsy, is needed to diagnose prostate pathology.

The minimal reporting value is 0.1 ng/mL. Values above 0.2 ng/mL are considered evidence of biochemical recurrence of cancer in men after prostatectomy.

Cautions

Serum markers are not specific for malignancy, and values may vary by method. When age is not supplied, the results cannot be flagged as high or low.

Digital rectal examination generally does not increase normal prostate-specific antigen (PSA) values. However, cystoscopy, urethral instrumentation, and prostate biopsy may increase PSA levels.

Some patients who have been exposed to animal antigens, either in the environment or as part of treatment or imaging procedure, may have circulating anti-animal antibodies present. These antibodies may interfere with the assay reagents to produce unreliable results.

Clinical Reference

1. Oesterling JE, Jacobsen SJ, Chute CG, et al: Serum prostate-specific antigen in a community-based population of healthy men. JAMA. 1993 Aug 18;270:860-864

2. Smith RA, Cokkinides V, von Eschenbach A, et al: American Cancer Society guidelines for the early detection of cancer. CA Cancer J Clin. 2002 Jan-Feb;52(1):8-22

3. Barry MJ, Albertsen PC, Bagshaw MA, et al: Outcomes for men with clinically nonmetastatic prostate carcinoma managed with radical prostatectomy, external beam radiotherapy, or expectant management: a retrospective analysis. Cancer. 2001 June 15;91(12):2302-2314

4. Blute ML, Bergstralh EJ, Iocca A, Scherer B, Zincke H: Use of Gleason score, prostate specific antigen, seminal vesicle and margin status to predict biochemical failure after radical prostatectomy. J Urol. 2001 Jan;165(1):119-125

5. Netto GJ, Epstein JI: Immunohistology of the prostate. In: Dabbs DJ, ed. Diagnostic Immunohistochemistry. 5th ed. Elsevier; 2019:588-623

Performance

Method Description

The Elecsys cobas Total PSA (prostate-specific antigen) assay is a sandwich electrochemiluminescence immunoassay that employs a biotinylated monoclonal PSA-specific antibody and a monoclonal PSA-specific antibody labeled with ruthenium complex. PSA in the specimen reacts with both the biotinylated monoclonal PSA-specific antibody (mouse) and the monoclonal PSA-specific antibody (mouse) labeled with a ruthenium, forming a sandwich complex. Streptavidin-coated microparticles are added and the mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell. Application of voltage to the electrode induces the chemiluminescent emission, which is then measured against a calibration curve to determine the amount of PSA in the patient specimen. This method has

been standardized against the Reference Standard/WHO 96/670.(Package insert: Elecsys total PSA reagent. Roche Diagnostics; V 1.0 07/2018)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

Same day/1 to 3 days

Specimen Retention Time

14 months

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

84153

G0103 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
SPSA	Prostate-Specific Ag Screen, S	83112-3

Result ID	Test Result Name	Result LOINC Value
SPSA	Prostate-Specific Ag Screen, S	83112-3