MAYO CLINIC LABORATORIES

Test Definition: SPSA

Prostate-Specific Antigen (PSA) Screen, Serum

Overview

Useful For

As a screening aid in the detection of prostate cancer when used in conjunction with a digital rectal exam in men aged 50 years or older

Screening to aid in the prognosis and management of individuals diagnosed with prostate cancer

Method Name

Electrochemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Free prostate-specific antigen (PSA) can be added to previously-submitted PSA screen specimen within 72 hours of performing the total PSA. Specimen must have been shipped frozen.

If both free and total PSA results are desired, order PSAFT / Prostate-Specific Antigen (PSA), Total and Free, Serum.

Necessary Information

Include patient's age.

Specimen Required

Supplies: Sarstedt Aliquot Tube 5mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL serum
Collection Instructions:
1. Red-top tube must be centrifuged, and the serum aliquoted into a plastic vial 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

Serum: 0.75 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

Prostate-specific antigen (PSA) is a glycoprotein 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 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:
<40 years: < or =2.0 ng/mL
40-49 years:< or =2.5 ng/mL
50-59 years: < or =3.5 ng/mL
60-69 years: < or =4.5 ng/mL
70-79 years: < or =6.5 ng/mL
> or =80 years: < or =7.2 ng/mL

Females: Not applicable

Interpretation

Prostate-specific antigen 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.

Prostate-specific antigen 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.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium can also rarely occur and may interfere in this assay. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Serum biotin concentrations up to 1200 ng/mL do not interfere with this assay. Concentrations up to 1200 ng/mL may be present in specimens collected from patients taking extremely high doses of biotin up to 300 mg per day.(1) In a study among 54 healthy volunteers, supplementation with 20 mg/day biotin resulted in a maximum serum biotin concentration of 355 ng/mL 1-hour post-dose.(2)

Clinical Reference

1. Grimsey P, Frey N, Bendig G, et al. Population pharmacokinetics of exogenous biotin and the relationship between biotin serum levels and in vitro immunoassay interference. J Pharmacokinet Pharmacodyn. 2017;2(4):247-256. doi:10.4155/ipk-2017-0013
2. Oesterling JE, Jacobsen SJ, Chute CG, et al. Serum prostate-specific antigen in a community-based population of healthy men. Establishment of age-specific reference ranges. JAMA. 1993;270(7):860-864
3. Saint Paul LP, Debruyne D, Bernard D, Mock DM, Defer GL. Pharmacokinetics and pharmacodynamics of MD1003 (high-dose biotin) in the treatment of progressive multiple sclerosis. Expert Opin Drug Metab Toxicol. 2016;12(3):324-344. doi:10.1517/17425255.2016.1136288
4. Smith RA, Cokkinides V, von Eschenbach A, et al. American Cancer Society guidelines for the early detection of cancer. CA Cancer J Clin. 2002;52(1):8-22. doi:10.3322/canjclin.52.1.8
5. 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;91(12):2302-2314. doi:10.1002/1097-0142(20010615)91:12<2302::aid-cncr1262>3.3.co;2-g
6. 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;165(1):119-125. doi:10.1097/00005392-200101000-00030
7. Netto GJ, Epstein JI. Immunohistology of the prostate. In: Dabbs DJ, ed. Diagnostic Immunohistochemistry. 5th ed. Elsevier; 2019:588-623

8. Ilic D, Djulbegovic M, Jung JH, et al. Prostate cancer screening with prostate-specific antigen (PSA) test: a systematic review and meta-analysis. BMJ. 2018;362:k3519. doi:10.1136/bmj.k3519

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 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 3.0, 07/2024)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US 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