MAYO CLINIC LABORATORIES

Test Definition: PSAU

Prostate-Specific Antigen (PSA) Ultrasensitive, Serum

Overview

Useful For

As an aid in the detection of prostate cancer when used in conjunction with a digital rectal exam in men ages 50 years and older

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

Monitoring disease after radical prostatectomy

This test **should not be used** for initial prostate cancer screening.

Method Name

Electrochemiluminescent Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

Free prostate-specific antigen (PSA) can be added on within 72 hours of performing this test. 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

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions:
1. Serum gel tubes should be centrifuged within 2 hours of collection.

2. Red-top tubes should be centrifuged, and the serum aliquoted into a plastic vial within 2 hours of collection.

Specimen Minimum Volume

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	14 days	
	Ambient	7 days	

Clinical & Interpretive

Clinical Information

Prostate-specific antigen (PSA) is the most widely used method to detect prostate cancer recurrence after radical prostatectomy (RP). Approximately 20% to 35% of patients develop a rising PSA following RP for clinically localized prostate cancer. Biochemical recurrence (BCR) is defined as an increase in PSA after curative therapy without clinical or radiological evidence of disease. The median time to BCR could vary between 2 to 3 years. A standard PSA cutpoint to indicate BCR has yet to be established. For example, the American Urological Association and the American Society for Radiation Oncology defined BCR after surgery as initial and confirmatory PSA concentrations of 0.2 ng/mL or greater. However, a BCR definition of 0.4 ng/mL PSA has also been proposed.

Assays that measure PSA to concentrations below 0.1 ng/mL are denoted ultrasensitive PSA (USPSA). The use of USPSA cutpoints below currently recommended PSA thresholds may be helpful in identifying cases of early biochemical recurrence and for selecting patients with adverse clinicopathologic risk factors for secondary therapy. However, some authors believe that USPSA assays offers minimal advantages and could lead to increased anxiety in patients who have clinically meaningless rises of PSA and might lead to overtreatment.

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

An undetectable (<0.01 ng/mL) ultrasensitive prostate-specific antigen (USPSA) concentration after radical prostatectomy is reassuring and may aid in postoperative risk stratification of patients.

A detectable USPSA concentration (> or =0.01 ng/mL) after radical prostatectomy (RP) does not necessarily translate into disease progression or recurrence. Interpretation of a detectable USPSA needs to be made in conjunction with other clinicopathologic risk factors. The cutpoint for interpretation of USPSA assays remains controversial and has ranged from 0.01 to 0.05 ng/mL. For example, in a study that included 754 men after RP, a cutpoint of 0.01 ng/mL was an independent predictor of biochemical recurrence (BCR). BCR-free survival at 5 years was 92.4% for patients with an USPSA post-RP of less than 0.01 ng/mL and 56.8% for patients with an USPSA post-RP of 0.01 ng/mL or higher.(1) In the same study a cutoff of 0.03 ng/ml also predicted BCR independent of clinicopathological factors and BCR-free survival at 5 yrs was 90.8% for patients with an USPSA post-RP of less than 0.03 ng/mL and 26.9% for patients with a PSA post-RP of greater or equal to 0.03 ng/mL.(1)

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.

No interference was observed from rheumatoid factors up to a concentration of 1500 IU/mL.

There is no high-dose hook effect at total PSA concentrations up to 17,000 ng/mL.

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.(2) 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.(3)

Clinical Reference

1. Sokoll LJ, Zhang Z, Chan DW, et al. Do ultrasensitive prostate specific antigen measurements have a role in predicting long-term biochemical recurrence-free survival in men after radical prostatectomy? J Urol. 2016;195(2):330-336.

doi:10.1016/j.juro.2015.08.080
2. 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
3. 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 Sept;2(4):247-256. doi:10.4155/ipk-2017-0013
4. Thompson IM, Valicenti RK, Albertsen P, et al. Adjuvant and salvage radiotherapy after prostatectomy: AUA/ASTRO guideline. J Urol. 2013;190(2):441-449. doi:10.1016/j.juro.2013.05.032
5. Mir MC, Li J, Klink JC, Kattan Mw, Klein EA, Stephenson A. Optimal definition of biochemical recurrence after radical prostatectomy depends on pathologic risk factors: Identifying candidates for early salvage therapy. Eur Urol. 2014;66(2):204-210. doi:10.1016/j.eururo.2013.08.022

Performance

Method Description

The Roche Elecsys 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. Roche Diagnostics; V 2.0, 06/2023)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 3 days

Specimen Retention Time

3 months

Performing Laboratory Location

Rochester

Test Definition: PSAU

Prostate-Specific Antigen (PSA) Ultrasensitive, Serum

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

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PSAU	PSA, Ultrasensitive, S	35741-8

Result ID	Test Result Name	Result LOINC® Value
PSAU	PSA, Ultrasensitive, S	35741-8