Test Definition: PSAU

PSA, Ultrasensitive, S

Overview

Useful For

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

Additional Testing Requirements

Free prostate-specific antigen (PSA) can only be added on within 12 hours of performing this test. Specimen must have been shipped frozen. Call 800-533-1710 if wanting to order PSAFT / Prostate-Specific Antigen (PSA), Total and Free, Serum instead.

Necessary Information

Include patient's age.

Specimen Required

Patient Preparation: For the 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: 0.6 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

0.4 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 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.

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

No interference was observed from rheumatoid factors up to a concentration of 1,500 IU/mL.

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

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 Feb;195(2):330-336

2. Thompson IM, Valicenti RK, Albertsen P, et al: Adjuvant and salvage radiotherapy after prostatectomy:AUA/ASTRO Guideline. J Urol 2013 Aug;190(2):441-449

3. Mir MC, Li J, Klink JC, et al: Optimal definition of biochemical recurrence after radical prostatectomy depends on pathologic risk factors: Identifying candidates for early salvage therapy. Eur Urol 2014 Aug;66(2):204-210

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 reagent, Roche Diagnostics,Â V 3.0 English, 02/2020)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 5-12 a.m.

Saturday; 6 a.m.-6 p.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

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

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