Test Definition: PSAFT

PSA Total and Free, S

Overview

Useful For

Assessing the risk of prostate cancer in patients with borderline or moderately increased total PSA (4.0-10.0 ng/mL)

Determining which patients should have follow-up prostate biopsy

Highlights

In individuals with a total PSA between 4.0 and 10.0 ng/mL, free:total PSA ratio could help determine the relative risk of prostate cancer. The lower the free:total PSA ratio, the higher the risk of prostate cancer.

Method Name

ElectrochemiluminescentImmunoassay(ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Advisory Information

This test should be ordered only in patients with a total PSA between 4-10 ng/mL.

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.

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions: Centrifuge and aliquot serum within 3 hours of collection.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Oncology Test Request (T729)

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen	90 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.

PSA exists in serum in multiple forms: complexed to alpha-1-anti-chymotrypsin (PSA-ACT complex), unbound (free PSA), and enveloped by alpha-2-macroglobulin (not detected by immunoassays).

Higher total PSA levels and lower percentages of free PSA are associated with higher risks of prostate cancer.

Most prostate cancers are slow growing, so the utility of prostate cancer screening is marginal in most men with a life expectancy of less than 10 years.

Interpretation

When total prostate-specific antigen (PSA) concentration is below 2.0 ng/mL, the probability of prostate cancer in asymptomatic men is low, further testing and free PSA may provide little additional information. When total PSA concentration is above 10.0 ng/mL, the probability of cancer is high and prostate biopsy is generally recommended.

The total PSA range of 4.0 to 10.0 ng/mL has been described as a diagnostic "gray zone," in which the free:total PSA ratio helps to determine the relative risk of prostate cancer (see table below). Therefore, some urologists recommend using the free:total ratio to help select which men should undergo biopsy. However, even a negative result of prostate biopsy does not rule-out prostate cancer. Up to 20% of men with negative biopsy results have subsequently been found to have cancer.

Based on free:total PSA ratio: the percent probability of finding prostate cancer on a needle biopsy by age in years:

Free:total PSA ratio	50-59 years	60-69 years	70 years and older
< or =0.10	49%	58%	65%
0.11-0.18	27%	34%	41%
0.19-0.25	18%	24%	30%
>0.25	9%	12%	16%

Cautions

Normal results do not eliminate the possibility of prostate cancer.

Values obtained with different assay methods or kits may be different and cannot be used interchangeably.

Tumor markers are not specific for malignancy. Test results cannot be interpreted as absolute evidence for the presence or absence of malignant disease.

Specimens collected from patients undergoing prostate manipulation, especially needle biopsy and transurethral resection, may show erroneously high prostate-specific antigen (PSA) results. Care should be taken that specimens are obtained before these procedures are performed.

Prostate cancer patients receiving treatment with antiandrogens and luteinizing hormone-releasing factor agonists may exhibit markedly decreased levels of PSA. Also, men treated for benign prostatic hyperplasia with inhibitors of 5-alpha-reductase (finasteride) may demonstrate a significant reduction in PSA levels compared to values before treatment. Care should be taken in interpreting values for these individuals.

In rare cases, interference due to extremely high titers of antibodies to ruthenium or streptavidin can occur.

Clinical Reference

1. Catalona WJ, Smith DS, Wolfert RL, et al: Evaluation of percentage of free serum prostate-specific antigen to improve specificity of prostate cancer screening. JAMA 1995:274(15);214-1220

2. Oesterling JE, Jacobsen SJ, Klee GG, et al: Free, complexed and total serum prostate specific antigen: the establishment of appropriate reference ranges for their concentrations and ratios. J Urol 1995;154:1090-1095

3. Duffy MJ. Biomarkers for prostate cancer: prostate-specific antigen and beyond. Clin Chem Lab Med. 2020 Feb 25;58(3):326-339

4. Catalona WJ: Prostate Cancer Screening. Med Clin North Am. 2018 Mar;102(2):199-214

Performance

Method Description

Total prostate-specific antigen:

The Roche Elecsys Total prostate-specific antigen (PSA) assay is a sandwich electrochemiluminescent 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)

Free PSA:

The Roche Elecsys Free PSA assay is a sandwich electrochemiluminescent immunoassay that employs a biotinylated monoclonal PSA-specific antibody and a monoclonal PSA-specific antibody labeled with ruthenium complex. Free 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 free PSA in the patient specimen. This method has been standardized against the Reference Standard/WHO 96/668.(Package insert: Elecsys Free PSA reagent, Roche Diagnostics, V 2.0, 10/2018)

The free PSA concentration is divided by the total PSA to derive the free:total ratio. The PSA, total and free test provides a free PSA measurement on every specimen, however, because very high or low total PSA measurements are predictive in themselves, a ratio is provided only when the total PSA is in the range of 4.0 to 10.0 ng/mL.

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 8 a.m.-10 p.m.

Saturday; 8 a.m.-5 p.m.

Analytic Time

1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

12 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

84154

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PSAFT	PSA Total and Free, S	53764-7

Result ID	Test Result Name	Result LOINC Value
TPSA	Total PSA	83112-3
FPSA	Free PSA	83113-1
PSA_R	Free PSA/PSA Ratio	12841-3