Overview

Useful For
Evaluating patients with documented prostate problems in whom multiple prostate-specific antigen tests may be necessary per year

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

Method Name
Electrochemiluminescent Immunoassay (ECLIA)

NY State Available
Yes

Specimen

Specimen Type
Serum

Necessary Information
Include patient's age.

Specimen Required

Patient Preparation: For 12 hours before this test 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 aliquoted within 2 hours of collection.

Additional Information: Free prostate-specific antigen (PSA) can only be added on within 12 hours of performing total PSA. Specimen must have been shipped frozen.

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

Specimen Minimum Volume
Test Definition: PSA
Prostate-Specific Ag Diagnostic, S

0.4 mL

Reject Due To

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
</tr>
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</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>180 days</td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>5 days</td>
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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 also 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:

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>PSA Upper Limit (ng/mL)</th>
</tr>
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<tbody>
<tr>
<td>&lt;40</td>
<td>≤2.0</td>
</tr>
<tr>
<td>40-49</td>
<td>≤2.5</td>
</tr>
<tr>
<td>50-59</td>
<td>≤3.5</td>
</tr>
<tr>
<td>60-69</td>
<td>≤4.5</td>
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<tr>
<td>70-79</td>
<td>≤6.5</td>
</tr>
<tr>
<td>&gt; or ≥80</td>
<td>≤7.2</td>
</tr>
</tbody>
</table>

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 further 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


Performance
Method Description
The instrument used is the Roche Cobas 6000 e601. The Roche Elecsys Total PSA (prostate-specific antigen) method 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: Roche total PSA reagent, V5. Roche Diagnostic Corp., Indianapolis, IN 2010-09)
Test Definition: PSA
Prostate-Specific Ag Diagnostic, S

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; 5 a.m.-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 or approved 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

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<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>PSA</td>
<td>Prostate-Specific Ag Diagnostic, S</td>
<td>2857-1</td>
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<table>
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