Overview

Useful For
Evaluating patients’ response to ovarian cancer therapy

Predicting recurrent ovarian cancer

Method Name
Electrochemiluminescent Immunoassay

NY State Available
Yes

Specimen

Specimen Type
Serum

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.

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 0.6 mL

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

Specimen Minimum Volume
0.5 mL

Reject Due To

| Hemolysis | Mild OK; Gross OK |
| Lipemia   | Mild OK; Gross OK |
| Icterus   | NA               |
| Other     | NA               |

Specimen Stability Information

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

Document generated September 4, 2019 at 6:27pm CDT
Clinical and Interpretive

Clinical Information
Cancer antigen 125 (CA 125) is a glycoprotein antigen normally expressed in tissues derived from coelomic epithelia (ovary, fallopian tube, peritoneum, pleura, pericardium, colon, kidney, stomach).

Serum CA 125 is elevated in approximately 80% of women with advanced epithelial ovarian cancer, but assay sensitivity is suboptimal in early disease stages. The average reported sensitivities are 50% for stage I and 90% for stage II or greater.

Elevated serum CA 125 levels have been reported in individuals with a variety of nonovarian malignancies including cervical, liver, pancreatic, lung, colon, stomach, biliary tract, uterine, fallopian tube, breast, and endometrial carcinomas.

Elevated serum CA 125 levels have been reported in individuals with a variety of benign conditions including: cirrhosis, hepatitis, endometriosis, first trimester pregnancy, ovarian cysts, and pelvic inflammatory disease. Elevated levels during the menstrual cycle also have been reported.

Reference Values
Males: Not applicable
Females: <46 U/mL

Interpretation
In monitoring studies, elevations of cancer antigen 125 (CA 125) above the reference interval after debulking surgery and chemotherapy indicate that residual disease is likely (>95% accuracy). However, normal levels do not rule-out recurrence.

A persistently rising CA 125 value suggests progressive malignant disease and poor therapeutic response.

Physiologic half-life of CA 125 is approximately 5 days.

In patients with advanced disease who have undergone cytoreductive surgery and are on chemotherapy, a prolonged half-life (>20 days) may be associated with a shortened disease-free survival.

Cautions
Not useful as a screening assay for cancer detection in the normal population.

Results cannot be interpreted as absolute evidence of the presence or absence of disease.

Serum markers are not specific for malignancy and values may vary by method. Values obtained with different assay methods cannot be used interchangeably.

Some individuals have antibodies to mouse protein (HAMA), which can cause interference in immunoassays that employ mouse antibodies. In particular, it has been reported that serum specimens from patients who have undergone therapeutic or diagnostic procedures that include infusion of mouse monoclonal antibodies may produce
Test Definition: CA25
Cancer Ag 125 (CA 125), S

erroneous results in such assays. Rerunning the specimen in question after additional blocking treatment may resolve the issue.

No interference was observed from rheumatoid factors up to a concentration of 1,200 IU/mL.

There is no high-dose hook effect at cancer antigen 125 (CA 125) concentrations of up to 50,000 U/mL.

Clinical Reference


Performance

Method Description
The instrument used is the Roche Cobas 6000 e601. The Roche Elecsys CA 125 II (Cancer Antigen 125) method is a sandwich electrochemiluminescence immunoassay that employs a biotinylated monoclonal CA 125-specific antibody and a monoclonal CA 125-specific antibody labeled with a ruthenium complex. CA 125 in the specimen reacts with both the biotinylated monoclonal CA 125-specific antibody (mouse) and the monoclonal CA 125-specific antibody (mouse) labeled with 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 CA 125 in the patient specimen. This method has been standardized against the Enzymun-Test CA 125 II method which has been standardized against the CA 125 II RIA from Fujirebio Diagnostics, Inc.(Package insert: Roche CA 125 II reagent, USAV1.0. Roche Diagnostic Corp., Indianapolis, IN 2015-10)

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
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
3 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
86304

LOINC® Information

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<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>CA25</td>
<td>Cancer Ag 125 (CA 125), S</td>
<td>83082-8</td>
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<table>
<thead>
<tr>
<th>Result ID</th>
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