Test Definition: CA25

Cancer Ag 125 (CA 125), S

Overview

Useful For

Evaluating patients' response to ovarian cancer therapy

Predicting recurrent ovarian cancer

This test is **not useful for** cancer detection screening in the normal population.

Method Name

Electrochemiluminescent Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

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.

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Forms

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

Specimen Minimum Volume

0.75 mL

Reject Due To

Gross hemolysis	OK
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	5 days	
	Frozen	180 days	

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

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

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 1200 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

1. Sturgeon CM, Duffy MJ, Stenman UH, et al: National Academy of Clinical Biochemistry laboratory medicine practice guidelines for use of tumor markers in testicular, prostate colorectal, breast, and ovarian cancers. Clin Chem. 2008 Dec;54(12):11-79

2. Salani R, Backles FJ, Fung MFK, et al: Posttreatment surveillance and diagnosis of recurrence in women with gynecologic malignancies: Society of Gynecologic Oncologists recommendations. Am J Obstet Gynecol.2011 Jun;204(6):466-478

3. The Role of the Obstetrician-Gynecologist in the Early Detection of Epithelial Ovarian Cancer. American College of Obstetricians and Gynecologists. 2011. Committee Opinion Number 477

Performance

Method Description

The Roche Elecsys cancer antigen (CA) 125 assay 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 radioimmunoassay (RIA) from Fujirebio Diagnostics, Inc..(Package insert: Elecsys CA 125 II reagent. Roche Diagnostics; V 1.0, 05/2017)

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, 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

86304

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CA25	Cancer Ag 125 (CA 125), S	83082-8

Result ID	Test Result Name	Result LOINC Value
CA25	Cancer Ag 125 (CA 125), S	83082-8