Test Definition: CA153

Cancer Antigen 15-3 (CA 15-3), Serum

Overview

Useful For

Managing breast cancer patients when used in conjunction with clinical information and other diagnostic procedures

Serial testing to assist in early detection of disease recurrence in previously treated stage II and III breast cancer patients

Monitoring response to therapy in metastatic breast cancer patients

This test is **not useful as** a cancer screening test.

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Supplies: Sarstedt 5 mL Aliquot Tube (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions: Centrifuge and aliquot serum into a plastic vial.

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	Reject

hemolysis	
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	90 days	

Clinical & Interpretive

Clinical Information

Carcinoma of the breast is the most prevalent form of cancer in women. These tumors often produce mucinous antigens, which are large molecular weight glycoproteins with O-linked oligosaccharide chains. Tumor-associated antigens encoded by the human *MUC-1* gene are known by several names, including MAM6, milk mucin antigen, cancer antigen (CA) 27.29, and CA 15-3.

CA 15-3 assay values are not elevated in most normal individuals and are frequently elevated in sera from breast cancer patients.

Nonmammary malignancies in which elevated CA 15-3 assay values have been reported include: lung, colon, pancreas, primary liver, ovary, cervix, and endometrium.

Reference Values

Males: <30 U/mL (use not defined)
Females: <30 U/mL

Interpretation

Increasing and decreasing values show correlation with disease progression and regression, respectively.(1) Increasing cancer antigen 15-3 (CA 15-3) assay values in patients at risk for breast cancer recurrence after primary therapy may be indicative of recurrent disease before it can be detected clinically (2,3) and may be used as an indication that additional tests or procedures should be performed.

Cautions

Testing for cancer antigen 15-3 (CA 15-3) should be performed in conjunction with other clinical methods used for the early detection of recurrence.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. The presence of antibodies to streptavidin or ruthenium can also rarely occur and may also interfere in this assay. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Molina R, Zanon G, Filella X, et al. Use of serial carcinoembryonic antigen and CA 15-3 assays in detecting relapses in breast cancer patients. Breast Cancer Res Treat. 1995;36(1):41-48
2. Geraghty JG, Coveney EC, Sherry F, O'Higgins NJ, Duffy MJ. CA 15-3 in patients with locoregional and metastatic breast carcinoma. Cancer. 1992;70(12):2831-2834
3. Kallioniemi OP, Oksa H, Aaran RK, Hietanen T, Lehtinen M, Koivula T. Serum CA 15-3 assay in the diagnosis and follow-up of breast cancer. Br J Cancer. 1988;58(2):213-215
4. Lin DC, Genzen JR. Concordance analysis of paired cancer antigen (CA) 15-3 and 27.29 testing. Breast Cancer Research and Treatment. 2018;167:269-276

Performance

Method Description
The Roche CA 15-3 (cancer antigen 15-3) method is a sandwich electrochemiluminescence immunoassay that employs a biotinylated monoclonal CA 15-3-specific antibody and a monoclonal CA 15-3-specific antibody. CA 15-3 in the automatically prediluted specimen reacts with both the biotinylated monoclonal CA 15-3-specific antibody (mouse) and the monoclonal CA 15-3-specific antibody (mouse) labeled with a ruthenium complex, 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.(Package insert: Elecsys CA 15-3 II. Roche Diagnostics; V 4.0, 07/2024)

PDF Report
No

Day(s) Performed
Monday through Saturday

Report Available
1 to 3 days

Specimen Retention Time
2 weeks

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

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Test Classification

This test has been cleared, approved, or is exempt by the US 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

86300

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CA153	Cancer Ag 15-3, (CA 15-3), S	83083-6

Result ID	Test Result Name	Result LOINC® Value
CA153	Cancer Ag 15-3, (CA 15-3), S	83083-6