

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 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 into 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 hemolysis	Reject
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Gross lipemia	OK
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Specimen Stability Information

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

Clinical and 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.

Some patients who have been exposed to mouse antigens, whether in the environment or as part of treatment or imaging procedures, may have circulating antimouse antibodies. These antibodies may interfere with the assay reagents to produce unreliable CA 15-3 assay results.

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

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 Jan;36:41-48](#)

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 Dec 15;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 Aug;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 cancer antigen 15-3 (CA 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: Roche CA 15-3 reagent. Roche Diagnostics; V14 09/2010)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 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 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