Test Definition: C2729

Breast Carcinoma Assoc Ag(CA 27.29)

Overview

Useful For

Serial testing in women with prior stage II or III breast cancer who are clinically free of disease

Predicting early recurrence of disease in women with treated carcinoma of the breast

Indicating that additional tests or procedures should be performed to confirm recurrence of breast cancer

This test is **not useful for** screening women for carcinoma of the breast.

Method Name

ChemiluminometricImmunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection and the serum aliquoted into a plastic vial prior to sending (aliquot does not need to be within 2 hours).

2. Red-top tubes should be centrifuged and the serum aliquoted into a plastic vial within 2 hours of collection.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-General Request (T239)

-Oncology Test Request (T729)

Specimen Minimum Volume

0.25 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	90 days	
	Refrigerated	7 days	
	Ambient	4 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.

Monoclonal antibodies directed against these antigens have been developed, and several immunoassays are available to quantitate the levels of tumor-associated mucinous antigens in serum. The antibodies recognize epitopes of a breast cancer-associated antigen encoded by the human mucin 1 (*MUC-1*) gene, which is known by several names including MAM6, milk mucin antigen, cancer antigen (CA) 27.29, and CA 15-3.

While CA 27.29 is expressed at the apical surface of normal epithelial cells, it is present throughout malignant epithelial cells of the breast, lung, ovary, pancreas, and other sites. The cancer-associated form of the antigen is less extensively glycosylated than the normal form and more specific for tumor cells.

Reference Values

Males

> or =18 years: < or =38.0 U/mL (use not defined)

Females

> or =18 years: < or =38.0 U/mL

Reference values have not been established for patients who are <18 years of age.

Serum markers are not specific for malignancy, and values may vary by method.

Interpretation

Increased levels of cancer-associated antigen (CA 27.29) (>38 U/mL) may indicate recurrent disease in a woman with treated breast carcinoma.

Cautions

At this time, this test provides results for female patients only.

The use of cancer-associated antigen (CA 27.29) has not been demonstrated to provide clinical benefit to these patients, which has led some Mayo clinical investigators to conclude there is insufficient justification for routine clinical use of this new marker.

Some patients who have been exposed to mouse antigens, either in the environment or as part of treatment or imaging procedure, may have circulating antimouse antibodies present. These antibodies may interfere with the assay reagents to produce unreliable CA 27.29 results.

Clinical Reference

1. Bon GG, Von Mensdorff-Pouilly S, Kenemans P, et al: Clinical and technical evaluation of ACS BR serum assay of *MUC1* gene-derived glycoprotein in breast cancer, and comparison with CA 15-3 assays. Clin Chem. 1997;43:585-593

2. Chan DW, Beveridge RA, Muss H, et al: Use of Truquant BR radioimmunoassay for early detection of breast cancer recurrence in patients with stage II and stage III disease. J Clin Oncol. 1997;15:2322-2328

3. 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

Cancer antigen (CA) 27.29 is measured using an automated, competitive, chemiluminescent immunoassay. The signal (Lite) reagent is a monoclonal antibody specific for CA 27.29, which is labeled with acridinium ester. Purified CA 27.29 antigen attached to paramagnetic particles (solid phase) competes with the antigen in the specimen for binding to the monoclonal antibody. An inverse relationship exists between the amount of CA 27.29 in the patient specimen and the amount of relative light units detected by the system.(Package insert: Siemens Advia Centaur XPT CA 27.29. Siemens Assay Systems; 10630988_EN Rev. T, 02/2020)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 6 a.m.-3 p.m.

Analytic Time

Same day/1 day

Maximum Laboratory Time

3 days

Specimen Retention Time

7 days

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

86300

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
C2729	Breast Carcinoma Assoc Ag(CA 27.29)	17842-6

Result ID	Test Result Name	Result LOINC Value
C2729	Breast Carcinoma Assoc Ag(CA 27.29)	17842-6