Test Definition: C2729

Breast Carcinoma-Associated Antigen, Serum

Overview

Useful For

Aiding in the management of breast cancer in patients with metastatic disease by monitoring the progression or regression of disease in response to treatment

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

M**ay be useful for** predicting early recurrence of disease in women with treated carcinoma of the breast

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

Highlights

The US Food and Drug Administration has approved CA 27.29 for serial testing in women with prior stage II or III breast cancer who are clinically free of disease.

Method Name

Chemiluminometric Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.5 mL
Collection Instructions:
1. Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial. **Specimens that have not been aliquoted will be canceled**.
2. Send refrigerated.

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	Refrigerated (preferred)	7 days	
	Ambient	4 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.

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 younger than 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 and may be useful as an indication that additional tests or procedures should be performed to confirm recurrence.

Cautions

Measurement of CA 27.29 is not useful to screen women for carcinoma of the breast. It is **not intended** as a screening test or for diagnosis.

Testing for CA 27.29 should be performed in conjunction with other clinical methods used for the early detection of recurrence.

Normal concentrations of CA 27.29 do not always preclude the presence of disease. Do not interpret concentrations of CA 27.29 as absolute evidence of the presence or the absence of malignant disease. Before treatment, patients with confirmed breast carcinoma frequently have concentrations of CA 27.29 within the range observed in healthy individuals. Additionally, elevated concentrations of CA 27.29 can be observed in patients with nonmalignant diseases. Measurements of CA 27.29 should always be used in conjunction with other diagnostic procedures, including information from the patient's clinical evaluation.

This test provides results on female patients only at this time.

Exercise caution when interpreting ADVIA Centaur BR 27.29 concentrations during pregnancy.

Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. 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.

The testing method is a chemiluminometric immunoassay manufactured by Siemens and performed on the Siemen's Advia Centaur. Values obtained with different assay methods or kits may be different and cannot be used interchangeably. Test results cannot be interpreted as absolute evidence for the presence or absence of malignant disease.

Clinical Reference

1. Bon GG, von Mensdorff-Pouilly S, Kenemans P, van Kamp GJ, Verstraeten RA, Hilgers J. 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(4):585-593
2. Chan DW, Beveridge RA, Muss H. 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(6):2322-2328
3. Lin DC, Genzen JR. Concordance analysis of paired cancer antigen (CA) 15-3 and 27.29 testing. Breast Cancer Res Treat. 2018;167(1):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: Advia Centaur XPT CA 27.29. Siemens Healthcare Diagnostics Inc.; 11206409_EN Rev. 22, 10/2022)

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
Same day/1 to 3 days

Specimen Retention Time
3 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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.

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
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