Test Definition: CA19

Carbohydrate Ag 19-9, S

Overview

Useful For

As a potential adjunct for diagnosis and monitoring of pancreatic cancer

Potentially differentiating patients with cholangiocarcinoma and primary sclerosing cholangitis (PSC) from those with PSC alone

Method Name

Immunoenzymatic Assay

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.

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume:0.6 mL

Collection Instructions:

1. Serum gel tubes should be centrifuged within 2 hours of collection.

2. Red-top tubes should be centrifuged and aliquoted 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

0.5 mL

Reject Due To

Gross hemolysis	Reject

Gross lipemia	OK
Gross Icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	90 days	
	Ambient	8 hours	

Clinical and Interpretive

Clinical Information

Carbohydrate antigen 19-9 (CA 19-9) is a modified Lewis(a) blood group antigen. CA 19-9 may be elevated in patients with gastrointestinal malignancies such as cholangiocarcinoma, pancreatic cancer, or colon cancer.

Benign conditions such as cirrhosis, cholestasis, and pancreatitis also result in elevated serum CA 19-9 concentrations but in these cases values usually are below 1000 U/mL.

Individuals that are Lewis negative (5%-7% of the population) do not express CA 19-9 due to the lack of the enzyme fucosyltransferase needed for CA 19-9 production. In these individuals, a low or undetectable serum CA 19-9 concentration is not informative regarding cancer recurrence.

Reference Values

<35 U/mL

Interpretation

Serial monitoring of carbohydrate antigen 19-9 (CA 19-9) should begin prior to therapy to verify post-therapy decreases in CA 19-9 and to establish a baseline for evaluating possible recurrence. Single values of CA 19-9 are less informative.

Elevated values may be caused by a variety of malignant and nonmalignant conditions including cholangiocarcinoma, pancreatic cancer, and colon cancer.

Cautions

Carbohydrate antigen 19-9 (CA 19-9) is neither specific nor sensitive enough to be used as a cancer screen.

Some individuals do not express CA 19-9. Consequently low values in these individuals are not informative regarding cancer recurrence.

Do not interpret serum CA 19-9 levels as absolute evidence of the presence or the absence of malignant disease. Use serum CA 19-9 in conjunction with information from the clinical evaluation of the patient and other diagnostic procedures.

Some patients who have been exposed to animal antigens, either in the environment or as part of treatment or imaging procedures, may have circulating anti-animal antibodies present. These antibodies may interfere with the

assay reagents to produce unreliable results.

Clinical Reference

1. Torok N, Gores GJ: Cholangiocarcinoma. Semin Gastrointest Dis. 2001 Apr;12(2):125-132

2. Scara S, Bottoni P, Scatena R: CA 19-9: Biochemical and clinical aspects. Adv Exp Med Biol. 2015;867:247-60. doi: 10.1007/978-94-017-7215-0_15

Performance

Method Description

The Access GI Monitor assay is a 2-site immunoenzymatic sandwich assay. A sample is added to a reaction vessel along with paramagnetic particles coated with polyclonal goat-antibiotin antibody, mouse monoclonal-biotin conjugate, and a buffered protein solution. After incubation in a reaction vessel, separation in a magnetic field and washing remove materials not bound to the solid phase. A monoclonal-alkaline phosphatase conjugate is then added. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field, while unbound materials are washed away. The chemiluminescent substrate is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of carbohydrate antigen 19-9 in the sample. The amount of analyte in the sample is determined from a stored, multipoint calibration curve.(Package insert: Access GI Monitor. Beckman Coulter; 04/2020)

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

Same day/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

86301

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CA19	Carbohydrate Ag 19-9, S	83084-4

Result ID	Test Result Name	Result LOINC Value
CA19	Carbohydrate Ag 19-9, S	83084-4