MAYO CLINIC LABORATORIES

Test Definition: CA19

Carbohydrate Antigen 19-9 (CA 19-9), Serum

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

No

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).
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 0.6 mL
Collection Instructions:
1. Within 2 hours of collection, serum gel tubes should be centrifuged.
2. Within 2 hours of collection, red-top tubes should be centrifuged, and the serum aliquoted into a plastic vial.

Forms

If not ordering electronically, complete, print, and send 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	
	Ambient	8 hours	
	Frozen	90 days	

Clinical & 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 are usually below 1000 U/mL.

Individuals that are Lewis antigen 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.

Serum CA 19-9 levels should not be interpreted as absolute evidence of the presence or absence of malignant disease. Instead, serum CA 19-9 results should be used 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

and produce unreliable results.

Clinical Reference

1. Torok N, Gores GJ. Cholangiocarcinoma. Semin Gastrointest Dis. 2001;12(2):125-132
2. Scara S, Bottoni P, Scatena R. CA 19-9: Biochemical and clinical aspects. Adv Exp Med Biol. 2015;867:247-260. 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; U83873h, 04/2020)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Mayo Clinic Jacksonville Clinical Lab

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

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