Overview

Useful For
Potentially useful adjunct for diagnosis and monitoring of pancreatic cancer

May be used for differentiating patients with cholangiocarcinoma and primary sclerosing cholangitis (PSC) from those with PSC alone

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

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
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<tbody>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>90 days</td>
<td></td>
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</tbody>
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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 1,000 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/or 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 antianimal antibodies present. These antibodies may interfere with the assay reagents to produce unreliable results.

Clinical Reference
**Performance**

**Method Description**

The instrument used is a Beckman Coulter DXI 800. 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 Lumi-Phos 530 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: Beckman Coulter Ireland Inc., Ireland, 2009)

**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

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<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
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<td>Carbohydrate Ag 19-9, S</td>
<td>83084-4</td>
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<table>
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<tr>
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