**Overview**

**Useful For**
Monitoring colorectal cancer and selected other cancers such as medullary thyroid carcinoma

May be useful in assessing the effectiveness of chemotherapy or radiation treatment

Carcinoembryonic antigen levels are **not useful** in screening the general population for undetected cancers.

**Method Name**
Immunoenzymatic Assay

**NY State Available**
Yes

**Specimen**

**Specimen Type**
Serum

**Specimen Required**

**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 an [Oncology Test Request](#) (T729) with the specimen.

**Specimen Minimum Volume**
0.5 mL

**Reject Due To**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Acceptance</th>
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</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
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</table>
Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>90 days</td>
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</tbody>
</table>

Clinical and Interpretive

Clinical Information
Carcinoembryonic antigen (CEA) is a glycoprotein normally found in embryonic entodermal epithelium.

Increased levels may be found in patients with primary colorectal cancer or other malignancies including medullary thyroid carcinoma and breast, gastrointestinal tract, liver, lung, ovarian, pancreatic, and prostatic cancers.

Serial monitoring of CEA should begin prior to therapy to verify post therapy decrease in concentration and to establish a baseline for evaluating possible recurrence. Levels generally return to normal within 1 to 4 months after removal of cancerous tissue.

Reference Values
Nonsmokers: ≤ 3.0 ng/mL

Some smokers may have elevated CEA, usually < 5.0 ng/mL.

Interpretation
Grossly elevated carcinoembryonic antigen (CEA) concentrations (>20 ng/mL) in a patient with compatible symptoms are strongly suggestive of the presence of cancer and also suggest metastasis.

Most healthy subjects (97%) have values ≤ 3.0 ng/mL.

After removal of a colorectal tumor, the serum CEA concentration should return to normal by 6 weeks, unless there is residual tumor.

Increases in test values over time in a patient with a history of cancer suggest tumor recurrence.

Cautions
The concentration of carcinoembryonic antigen (CEA) in serum should not be used to screen asymptomatic individuals for neoplastic disease, and the diagnostic efficacy of CEA measurements in high-risk groups has not been established.

Single values of CEA are less informative than changes assessed over time.

CEA values are method-dependent; therefore, the same method should be used to serially monitor patients.

Do not interpret serum CEA levels as absolute evidence of the presence or the absence of malignant disease. Use serum CEA 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
Instrument used is Beckman Coulter UniCel DXI 800. The Access carcinoembryonic antigen (CEA) assay is a 2-site immunoenzymatic sandwich assay using 2 mouse monoclonal anti-CEA antibodies (MAb) that react with different epitopes of CEA. A sample is added to a reaction vessel, along with the first anti-CEA MAb-alkaline phosphatase conjugate and the second anti-CEA Mab bound to paramagnetic particles. The incubation is followed by a magnetic separation and washing. 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 proportional to the concentration of CEA in the sample. The amount of analyte in the sample is determined by means of a stored, multipoint calibrator curve.(Package insert: Beckman Coulter, Fullerton CA, 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 or approved 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
82378

LOINC® Information

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<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
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<tbody>
<tr>
<td>CEA</td>
<td>Carcinoembryonic Ag (CEA), S</td>
<td>83085-1</td>
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<table>
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<tr>
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