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
This test is not useful for 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.

Reject Due To

Gross hemolysis Reject
Gross lipemia OK

Specimen Minimum Volume
0.5 mL

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<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 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.
Serum markers are not specific for malignancy, and values may vary by method.

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 suggest metastasis.
Most healthy subjects (97%) have values less than or equal to 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: Access CEA. Beckman Coulter; 05/2020)

**PDF Report**

No

**Specimen Retention Time**

3 months

**Performing Laboratory Location**

Rochester

**Fees & Codes**

**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**

82378