Overview

Useful For
An adjunct to cytology to differentiate between malignancy-related and benign causes of ascites formation

Method Name
Immunoenzymatic Assay

NY State Available
Yes

Specimen

Specimen Type
Peritoneal

Specimen Required
Container/Tube: Plain, plastic, screw top tube

Specimen Volume: 2mL

Forms
If not ordering electronically, complete, print, and send an Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
0.5 mL (Samples <0.5 mL may be rejected)

Reject Due To

<table>
<thead>
<tr>
<th>Gross hemolysis</th>
<th>Reject</th>
</tr>
</thead>
</table>

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>Peritoneal</td>
<td>Frozen (preferred)</td>
<td>90 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>7 days</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information
Malignancy accounts for approximately 7% of cases of ascites formation. Malignant disease can cause ascites by various mechanisms including: peritoneal carcinomatosis (53%), massive liver metastasis causing portal hypertension (13%), peritoneal carcinomatosis plus massive liver metastasis (13%), hepatocellular carcinoma plus cirrhosis (7%), and chylous ascites due to lymphoma (7%). The evaluation and diagnosis of malignancy-related...
ascites is based on the patient clinical history, ascites fluid analysis, and imaging tests.

The overall sensitivity of cytology for the detection of malignancy-related ascites ranges from 58% to 75%. Cytology examination is most successful in patients with ascites related to peritoneal carcinomatosis as viable malignant cells are exfoliated into the ascitic fluid. However, only approximately 53% of patients with malignancy-related ascites have peritoneal carcinomatosis. Patients with other causes of malignancy-related ascites almost always have a negative cytology.

Carcinoembryonic antigen (CEA) is a glycoprotein that is shed from the surface of malignant cells. Measurement of CEA in ascitic fluid has been proposed as a helpful test in detecting malignancy-related ascites given the limited sensitivity of cytology.

Reference Values
An interpretive report will be provided.

Interpretation
A peritoneal fluid carcinoembryonic antigen (CEA) concentration >6.0 ng/mL is suspicious but not diagnostic of malignancy-related ascites. This clinical decision limit cutoff yielded 48% sensitivity and 99% specificity in a study of 137 patients presenting with ascites. CEA concentrations were significantly higher in ascites caused by malignancies known to be associated with elevated serum CEA levels including lung, breast, ovarian, gastrointestinal, and colorectal cancers. However, ascites caused by other malignancies such as lymphoma, mesothelioma, leukemia, and melanoma and hepatocellular carcinoma, routinely had CEA concentrations <6.0 ng/mL. Therefore, negative results should be interpreted with caution, especially in patients who have or are suspected of having a malignancy not associated with elevated CEA levels in serum.

Cautions
Do not use peritoneal fluid carcinoembryonic antigen (CEA) concentration as absolute evidence of the presence or the absence of malignant disease. The CEA result should be interpreted in conjunction with information from the clinical evaluation of the patient and other diagnostic procedures.

Immunometric assays can, in rare occasions, be subject to interferences such as "hooking" at very high analyte concentrations (false-low results) and heterophilic antibody interference (false-high results). If the clinical picture does not fit the laboratory result, these possibilities should be considered.

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

Clinical Reference


Performance

Method Description
The instrument used is Beckman Coulter UniCel DXI 800. The Access CEA assay is a 2-site immunoenzymatic sandwich assay using mouse monoclonal anti-carcinoembryonic antigen (CEA) antibodies that react with different epitopes of CEA. A sample is added to a reaction vessel, along with the first anti-CEA monoclonal antibodies-alkaline phosphatase conjugate and the second anti-CEA monoclonal antibodies bound to paramagnetic particles. The incubation is followed by a magnetic separation and washing. The chemiluminescent substrate Lumi-Phos 530 is
Test Definition: CEAPT
CEA, Peritoneal Fluid

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 Assay, Beckman Coulter, Inc, Fullerton, CA, 2007)

For all samples with CEA concentrations >3 ng/mL, a dilution series is performed. A linear dilution excludes hooking and most major interferences. Samples that contain CEA concentrations ≤3 ng/mL are spiked with exogenous CEA to identify possible interferences that may cause a false-low result.

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
Same day/1 to 3 days

Specimen Retention Time
14 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information
82378

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAPT</td>
<td>CEA, Peritoneal Fluid</td>
<td>40622-3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEAPN</td>
<td>CEA, Peritoneal Fluid</td>
<td>40622-3</td>
</tr>
<tr>
<td>SITED</td>
<td>Site</td>
<td>39111-0</td>
</tr>
</tbody>
</table>