

Overview

Useful For

An adjuvant to cytology and imaging studies to differentiate between nonmalignant and malignant causes of pleural effusions

Method Name

Immunoenzymatic Assay

NY State Available

Yes

Specimen

Specimen Type

Pleural Fluid

Specimen Required

Container/Tube: Plain, plastic, screw-top tube

Specimen Volume: 2 mL

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

Gross hemolysis	Reject
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Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Pleural Fluid	Ambient	7 days	
	Refrigerated	14 days	
	Frozen (preferred)	90 days	

Clinical & Interpretive

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**Clinical Information**

Pleural effusions occur as a consequence of either nonmalignant conditions (including congestive heart failure, pneumonia, pulmonary embolism, and liver cirrhosis) or malignant conditions (including lung, breast, and lymphoma cancers). Diagnosing the cause of an effusion can be difficult, often requiring cytological examination of the pleural fluid and imaging studies of the pleural tissue. Analysis of various tumor markers in pleural fluid has shown that these markers can differentiate between effusions caused by nonmalignant and malignant conditions and can enhance cytology and imaging findings.

Carcinoembryonic antigen (CEA) is a glycoprotein produced during fetal development. Nonsmoking, healthy adults typically produce low to undetectable levels of CEA. Serum concentrations of CEA may be elevated in patients with certain malignancies that secrete CEA into circulation, including medullary thyroid carcinoma and breast, gastrointestinal tract, colorectal, liver, lung, ovarian, pancreatic, and prostate cancers.

Pleural fluid concentrations of CEA have been reported to be elevated in patients with certain malignancies. Malignancies that can secrete CEA and elevate serum CEA concentrations, including lung, breast, ovarian, gastrointestinal, and colorectal cancers, typically also elevate CEA in pleural fluid. In contrast, malignancies that do not secrete CEA, including mesothelioma, lymphoma, leukemia, and melanoma, have low concentrations of CEA in pleural fluid comparable to concentrations observed in non-malignant effusions.

Elevated CEA concentrations in pleural fluid have also been reported with certain nonmalignant conditions, including liver cirrhosis, pancreatitis, complicated parapneumonic effusions and empyemas, and rarely with tuberculosis.

CEA results should be used in conjunction with cytological analysis of pleural fluid, imaging studies, and other clinical findings.

**Reference Values**

An interpretive report will be provided.

**Interpretation**

A pleural fluid carcinoembryonic antigen (CEA) concentration of 3.5 ng/mL or higher is suspicious but not diagnostic of a malignant source of the effusion. This cutoff yielded a sensitivity of 52%, specificity of 95%, and part per volume of 93% in a study of 200 patients presenting with effusion. CEA concentrations were significantly higher in effusions caused by CEA-secreting malignancies, including lung, breast, ovarian, gastrointestinal, and colorectal cancers. However, effusions caused by non-CEA-secreting malignancies, including lymphoma, mesothelioma, leukemia, and melanoma, routinely had CEA concentrations below 3.5 ng/mL. Therefore, negative results should be interpreted with caution, especially in patients who have or are suspected of having a non-CEA-secreting malignancy.

Correlation of all tumor marker results with cytology and imaging is highly recommended.

**Cautions**

This test result should not be the sole basis for diagnosis. Carcinoembryonic antigen (CEA) and other tumor markers are not specific for malignancy and CEA testing has limited utility when used as the sole diagnostic test. Test results should always be correlated with cytology, imaging, and other clinical findings.

A low or negative CEA result may be misleading, as certain malignancies do not secrete CEA and will not produce elevated CEA concentrations in pleural effusions. Negative results should be interpreted with caution in patients who

have, or are suspected of having, a non-CEA-secreting malignancy or who have a cancer of unknown primary origin. Alternative methodologies, including cytology, imaging, and other tumor markers should be considered.

CEA concentrations have been reported to be elevated in pleural fluid as a consequence of certain nonmalignant conditions, including liver cirrhosis, pancreatitis, complicated parapneumonic effusions and empyemas, and rarely with tuberculosis. Results should be interpreted with caution in patients with those conditions.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results and the laboratory should be alerted if the result does not correlate with the clinical presentation.

### Clinical Reference

1. Shitrit D, Zingerman B, Shitrit ABG, Shlomi D, Kramer MR: Diagnostic value of CYFRA 21-1, CEA, CA 19-9, CA 15-3, and CA 125 assays in pleural effusions: analysis of 116 cases and review of the literature. *Oncologist*. 2005 Aug;10(7):501-507
2. Hackbarth JS, Murata K, Reilly WM, Algeciras-Schimnich A: Performance of CEA and CA19-9 in identifying pleural effusions caused by specific malignancies. *Clin Biochem*. 2010 Sep;43(13-14):1051-1055
3. Garcia-Pachon E, Padilla-Navas I, Dosda MD, Miralles-Llopis A: Elevated level of carcinoembryonic antigen in nonmalignant pleural effusions. *Chest*. 1997 Mar;111(3):643-647
4. Hackner K, Errhalt P, Handzhiev S: Ratio of carcinoembryonic antigen in pleural fluid and serum for the diagnosis of malignant pleural effusion. *Ther Adv Med Oncol*. 2019 May 22;11:1758835919850341. doi: 10.1177/1758835919850341
5. Tozzoli R, Basso SMM, D'Aurizio F, Metus P, Lumachi F: Evaluation of predictive value of pleural CEA in patients with pleural effusions and histological findings: A prospective study and literature review. *Clin Biochem*. 2016 Nov;49(16-17):1227-1231. doi: 10.1016/j.clinbiochem.2016.08.006

### 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 carcinoembryonic antigen (CEA) antibodies that react with different epitopes of CEA. A sample is added to a reaction vessel, along with the first CEA monoclonal antibody-alkaline phosphatase conjugate and the second CEA monoclonal antibody bound to paramagnetic particles. The incubation is followed by a magnetic separation and washing. A chemiluminescent substrate is added to the vessel, and the 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; 2020)

#### PDF Report

No

#### Day(s) Performed

Monday through Saturday

#### Report Available

1 to 3 days

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

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](#).

Test Classification

This test has been modified from the manufacturer's instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

82378

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
PFCEA	CEA, Pleural Fluid	19169-2

Result ID	Test Result Name	Result LOINC® Value
PCEA	CEA, Pleural Fluid	19169-2
SITE9	Site	39111-0