

# CA 19-9

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## Reference Range

Cancer antigen 19-9 (CA 19-9) is used to help differentiate between cancer of the pancreas and other conditions, as well as to monitor treatment response and recurrence.

The reference range of serum CA 19-9 is less than 37 U/mL.

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## Interpretation

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of CA 19-9 for the diagnosis of pancreatic cancer is dependent on the cutoff level (see the table below). A normal level is less than 37 U/mL, which corresponds to a sensitivity of 81% (68%-93%), a specificity of 90% (76%-100%), a PPV of 72%, and a NPV of 96%. <sup>[1, 2]</sup> However, when CA 19-9 levels are greater than 1000 U/mL, sensitivity is 41%, specificity is 99.8%, PPV is 97%, and NPV is 89%.

**Table. Cutoff levels of CA 19-9 for the Diagnosis of Pancreatic Cancer** <sup>[2]</sup>

Table. (Open Table in a new window)

Cutoff (U/mL)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
37	81	90	72	96
100	68	98	87	94

300	54	99	92	91
1000	41	99.8	97	89

Elevated levels of CA 19-9 can be seen in healthy individuals. Elevated levels can also be seen in benign conditions, such as the following:

- Biliary tract obstruction [3]
- Cholangitis [4]
- Inflammatory bowel disease [5]
- Acute or chronic pancreatitis [6]
- Liver cirrhosis [7]
- Cystic fibrosis [8]
- Thyroid disease

Elevated levels of CA 19-9 can be seen in the following malignant conditions as well:

- Bile duct cancers [9]
- Colorectal cancers [10]
- Gastric cancers [11, 12]
- Ovarian cancers [13]
- Hepatocellular cancers [14]
- Esophageal cancers [15]
- Pancreatic cancers [16, 17, 18, 19]

Additionally, at least 5% of the population is unable to produce the CA 19-9 antigen. The overall low specificity and sensitivity of this assay precludes its use as a screening tool for pancreatic cancer. An elevated tumor marker level needs to be interpreted within the context of the patient's history, physical examination, diagnostic imaging, and laboratory work-up findings.

High CA 19-9 levels (ie, greater than 1000 U/mL) correlate with unresectable or more advanced tumors, although this preoperative evaluation of CA 19-9 has not been widely used to establish inoperability. [20] High marker levels may also be used to predict patient outcomes. [21, 22] A decrease or normalization of CA 19-9 levels postoperatively correlates with a longer duration of survival. Conversely, rising marker levels postoperatively have been correlated with shorter duration of survival and increased disease recurrence.

Finally, CA 19-9 levels can be used to monitor tumor response to active treatment with surgery, with or without chemotherapy, radiation therapy, and/or other targeted or biological therapies. A decrease in CA 19-9 levels confirms the effectiveness of the therapeutic regimen, while a stable or rising level may indicate the need to change therapies.

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## Collection and Panels

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### Collection

Specimen: Serum

Container: Red-top tube (see the first image below), tiger-top tube (see the second image below), or gold-top tube (see the third image below). Discuss collection methods with your laboratory prior to collecting the specimen.



Red top tube



Tiger top tube



Gold top tube

Collection method: Venipuncture

## Panels

Serum CA 19-9 is not part of a panel.

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## Background

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### Description

Cancer antigen 19-9 (CA 19-9) is a tumor-associated mucin glycoprotein antigen that is related to the Lewis blood group protein. This antigen is present in epithelial tissues of the pancreas, biliary ductular cells, stomach, gall bladder, colon, endometrium, salivary glands, and prostate. <sup>[2]</sup> Normal pancreatic juice, bile (in benign conditions), and even seminal fluid contain CA 19-9. <sup>[2]</sup> Blood levels may be elevated in healthy patients as well as in patients with benign and malignant conditions. <sup>[23]</sup>

CA 19-9 was originally identified by a monoclonal antibody in a colorectal cancer cell line <sup>[24, 25]</sup> but has proven more useful in the management of pancreatic cancer. This sialylated Lewis A blood group antigen is identified by a radioimmunometric assay. <sup>[17, 24]</sup> However, approximately 5% of the

population are Lewis antigen A- B- and do not produce the CA 19-9 antigen. This assay cannot be used in these patients. [23, 24]

## Indications/Applications

### *CA 19-9 for pancreatic cancer, as a screening test*

CA 19-9 is not recommended for use as a screening test for pancreatic cancer. [19] Its sensitivity (68-93%) and specificity (76-100%) are inadequate for accurate diagnosis. [2] The test may be falsely normal or inappropriately elevated in people who do not have cancer, since increased levels can be seen in healthy individuals, in benign conditions, and in other malignant conditions. [17, 18, 19] Conversely, CA 19-9 levels may not be elevated in patients with small pancreatic tumors or with early-stage tumors. Approximately 5% of the population does not produce the CA 19-9 antigen. [23]

### *CA 19-9 for pancreatic cancer, to determine surgical resectability and postoperative outcomes*

CA 19-9 should not be used alone to determine surgical resectability or outcomes after surgical resection. In the evaluation of patients for surgical intervention, preoperative CA 19-9 levels have been used to predict patient outcomes. When blood levels of CA 19-9 were greater than 1000 U/mL, 96% of tumors were found to be unresectable. [2] However, this preoperative evaluation alone has yet to be widely used to establish inoperability. [24] Furthermore, several studies have shown a correlation between a postoperative decline in CA 19-9 levels and the increased duration of patient survival. [24] Patients whose CA 19-9 normalized postoperatively may live longer, [2] whereas rising CA 19-9 levels may correlate with shorter survival times.

### *CA 19-9 for pancreatic cancer, to detect recurrence*

CA 19-9 may predict recurrence of pancreatic cancer before the clinical examination or radiographic findings. However, CA 19-9 determinations alone cannot provide definitive evidence of disease recurrence and must be confirmed with imaging studies or biopsy. Serial assay measurements may be helpful in the management of patients following surgical resection with adjuvant chemotherapy and/or radiation therapy or surgical resection alone without adjuvant therapy. [24] Elevation of CA 19-9 above certain levels may also correlate with disease recurrence early in the postoperative period.

### *CA 19-9 for pancreatic cancer, to monitor treatment response*

Currently, insufficient data exists to recommend routine use of CA 19-9 alone to monitor treatment response. CA 19-9 can be measured at the start of treatment for locally advanced and metastatic disease and every 1-3 months during active treatment with chemotherapy, radiation therapy, and/or other targeted or biological therapies. A fall in CA 19-9 levels could help confirm the effectiveness of a particular treatment regimen.

Conversely, a rise in CA 19-9 levels could indicate a need to change the treatment regimen. If CA 19-9 rises during surveillance, disease progression needs to be confirmed with clinical examination,

diagnostic imaging, and/or biopsy. However, no agreement exists regarding the frequency with which the CA 19-9 assay should be performed or the magnitude of change or time period of change of CA 19-9 levels that is considered significant. [24]

### *CA 19-9 for colon cancer*

Currently, insufficient data exists to recommend CA 19-9 for screening, diagnosis, staging, surveillance, or monitoring the treatment of patients with colorectal cancer. [24]

## Considerations

Pancreatic cancer is just one of several conditions that may cause elevated levels of CA 19-9. Increased levels can be seen in healthy individuals, in benign conditions, and in other malignant conditions. [17, 18] In particular, cholestasis and jaundice, such as from bile duct disease, cirrhosis, or pancreatitis, can falsely elevate CA 19-9 levels and cause diagnostic uncertainty. CA 19-9 levels correlate with alkaline phosphatase levels, which further associates the 2 mechanisms of CA 19-9 elevation by secretion from pancreatic cancer cells and cholestasis. Serial determination of levels after relief of jaundice and/or the use of higher cut-off levels in patients with jaundice could be necessary to exclude pancreatic cancer in patients with normal imaging and clinical studies. [1] Since this marker cannot be synthesized in approximately 5% of the population (ie, those who lack the Lewis antigen or are Lewis A-B-), CA 19-9 levels may be falsely low even in the presence of pancreatic cancer.

Because of the low prevalence of pancreatic cancer in the general population and the possibility of elevated tumor marker levels in conditions other than pancreatic cancer, the CA 19-9 assay is not accurate enough to be used as a screening tool in the asymptomatic population. [2, 19, 24] CA 19-9 levels are increased in only about 40% of stage I pancreatic cancers, and levels may be normal even up to several months prior to clinical signs of pancreatic cancer. [19] However, the higher the levels of CA 19-9, the greater the PPV and specificity in diagnosing pancreatic cancer. When CA 19-9 levels were greater than 1000 U/mL, the PPV and specificity approached 100% and were correlated with unresectable tumors. [2] Studies also show that CA 19-9 levels may correlate with tumor burden, disease recurrence, and response to treatment. Thus, CA 19-9 is a better marker for advanced pancreatic neoplasms than for early-stage disease.

Low sensitivity in early-stage pancreatic cancer and low overall specificity are important limitations of CA 19-9 that preclude the use of this assay as a screening tool for pancreatic cancer. Although not yet standardized, CA 19-9 may also be used to determine surgical resectability and predict postoperative outcomes. Future studies are needed to detail the use of this marker in patients with jaundice and/or cholestasis.

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