



PAML Changes Testing Method for Cancer Antigen CA 19-9

Method Change Effective December 4, 2000

THE TUMOR MARKER CA 19-9 is used primarily in the diagnosis and management of patients with pancreatic cancer. CA 19-9 has been shown to be a more sensitive and specific marker of pancreatic cancer than other serologic markers. Very little of the antigen is found in the blood of normal patients or those with benign disorders, but most patients with pancreatic cancer have elevated levels of CA 19-9. CA 19-9 can also be used in patients with other types of cancer, such as bile duct, hepatocellular, gastric, colon, esophageal, and nongastrointestinal cancer.

The PAML R&D department has completed validation on a new analysis method for the tumor marker CA19-9. The change to the new method was necessary because the old method was discontinued by the vendor. The new method uses an automated chemiluminescence system and is a marked improvement over the old manual radioimmunoassay procedure.

As a part of the validation protocol, results from the chemiluminescence method were compared statistically with paired sample results from the old procedure. The comparison studies show that although some patients show close correlations, other patients show remarkably different results from the old method to the new. There is no consistent pattern to the discrepant results, so physicians should not track patient results from the old method to the new.

The usual protocol for a change in tumor marker methods is to re-baseline all patients with the new method by running parallel analyses with the old method. Unfortunately, the manufacturer of the old reagents abruptly discontinued production and reagents are no longer available. PAML regrets that we will not be able to re-baseline patients for CA 19-9. The new method gives reliable results that will allow physicians to again monitor their patients with CA 19-9.

Test Information

DESCRIPTION **CA 19-9**

METHOD Chemiluminescence

ORDER CODE CA 19-9

CPT CODE 86316

SPECIMEN 1 mL frozen serum (red top tube). Separate serum from cells and put in separate plastic tube. Store and transport frozen.

COMMENTS *Minimum amount: 0.5 mL*

Unacceptable conditions: Plasma, grossly hemolyzed or grossly turbid samples.

Stability: 8 hours at room temperature, 2 days refrigerated, 3 months frozen.

This test is for research use only.

SCHEDULE Monday – Friday nights

TURNAROUND 1-3 days

RANGES Normal: 0-37 U/mL

Features

- ▶ **More accurate and consistent results**
- ▶ **Reliable supplier of reagents**
- ▶ **New method does not compare directly with old method**

Usage Recommendations

- ▶ **Can be used to evaluate the success of pancreatic resection.**
- ▶ **Prognosis following surgery may be evaluated.**
- ▶ **Serial levels of CA 19-9 can predict recurrence of disease prior to radiographic or clinical findings.**
- ▶ **Physicians should not track patient results from the old method to the new.**
- ▶ **CA 19-9 also detects bile duct, hepatocellular, gastric, colonic, esophageal, and nongastrointestinal cancer.**

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