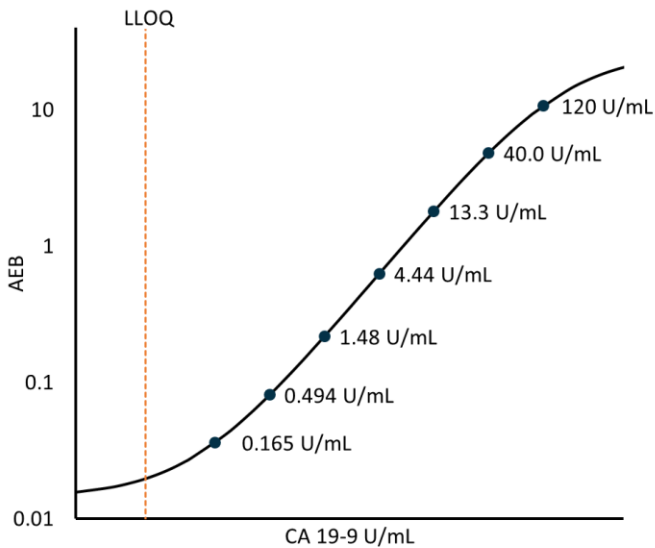


Description

CA 19-9, also known as Cancer Antigen 19-9 and Carbohydrate Antigen 19-9, is a sialylated derivative of Lewis A blood group antigen. CA 19-9 is currently recognized as one of the most common tumor markers for colorectal, gastric, and hepatocellular cancers. Increases in levels of biomarkers CA 19-9, CA242, and CEA inversely correlate with survival time in pancreatic adenocarcinoma patients. Serum levels of CA 19-9 are elevated in 70–80% of pancreatic cancer patients and may also be elevated in a variety of other cancers and benign conditions like biliary tract obstruction. Elevated levels are associated with advanced disease at presentation and disease progression during follow-up. High CA 19-9 levels correlate with unresectable or more advanced tumors, although this evaluation has not been widely used to establish inoperability. High marker levels may also be used to predict patient outcomes and are used to monitor treatment response and recurrence.

Calibration Curve: Four-parameter curve fit parameters are depicted.



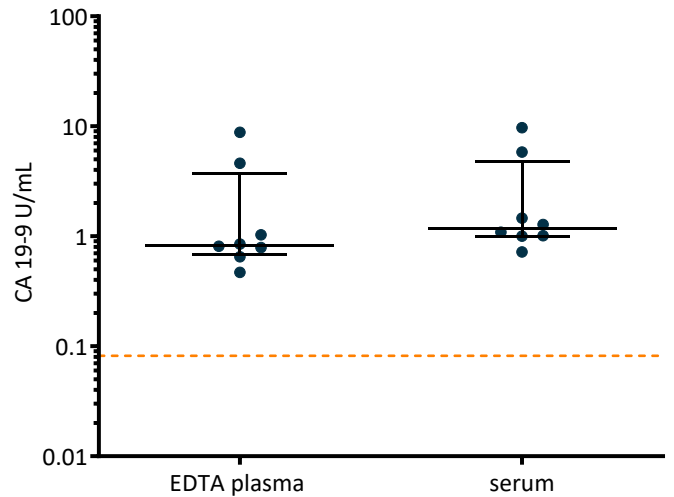
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve for 1 reagent lot on 1 instrument (5 runs total).

LLOQ	0.041 U/mL pooled CV 19.0% mean recovery 109.2%
LOD	0.023 U/mL range 0.01–0.03 U/mL
Dynamic range (serum and plasma)	0–240 U/mL
Diluted Sample volume*	152 µL per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=8) and serum (n=8) were measured. Error bars depict median with interquartile range. Two samples of each type were below the LOD.



Sample Type	Median CA 19-9 pg/mL	% Above LOD
Serum	1.19	80%
Plasma	0.83	80%

Precision: Representative precision was estimated with repeated assay of serum panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect CVs across 5 experiments of 3 replicates each.

Sample	Mean (U/mL)	Within run CV	Between run CV
Panel 1	3.09	3.5%	10.5%
Panel 2	113	4.3%	7.8%
Panel 3	19.8	3.5%	3.5%

Spike and Recovery: CA 19-9 spiked into 2 plasma and 2 serum samples at 6.0 and 60 U/mL.

Dilution Linearity: Spiked serum diluted 2x serially from MRD (2x) to 128x with Sample Diluent.

Specificity: 1 plasma and 1 serum sample depleted with capture antibody.

Spike and Recovery (Serum/Plasma)	Mean = 86.3% Range: 74.9–103.8%
Dilution Linearity (128x)	Mean = 108.3% Range: 102.7–113.0%
Specificity	Mean = 94.7%