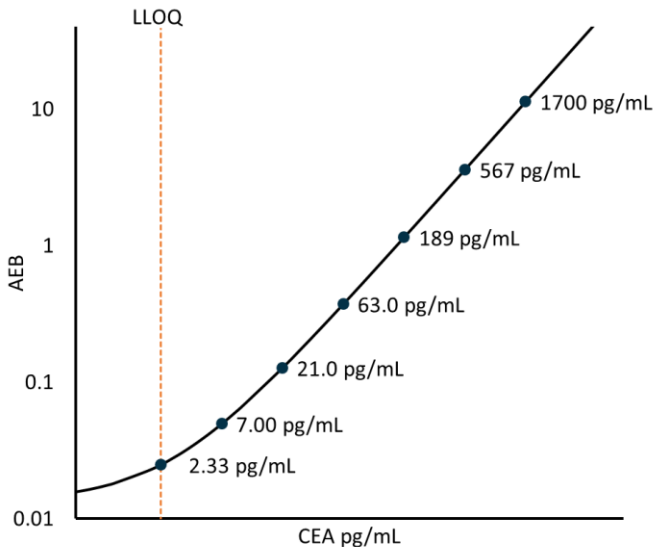


Description

Carcinoembryonic antigen (CEA) is a 180 kDa glycosylphosphatidylinositol-anchored cell surface glycoprotein that belongs to the immunoglobulin superfamily. CEA is found in many types of cells but is associated with tumors and the developing fetus. Benign conditions that can increase CEA include smoking, infection, inflammatory bowel disease, pancreatitis, cirrhosis of the liver, and some benign tumors. Benign disease does not usually cause a CEA increase over 10 ng/mL whereas levels over 20 ng/mL before therapy are associated with cancer that has already metastasized. CEA is produced by 90% of colorectal cancers and contributes to the malignant characteristics of the tumor. Serum CEA level is the most widely used tumor marker for colorectal cancer as rising concentrations of CEA precede other clinical indicators by several months and are associated with an increased risk of relapse and poor patient outcome. If CEA is high before treatment, it should fall to normal after successful therapy. CEA levels are also elevated in many other cancers such as thyroid, pancreas, liver, cervix, and bladder.

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



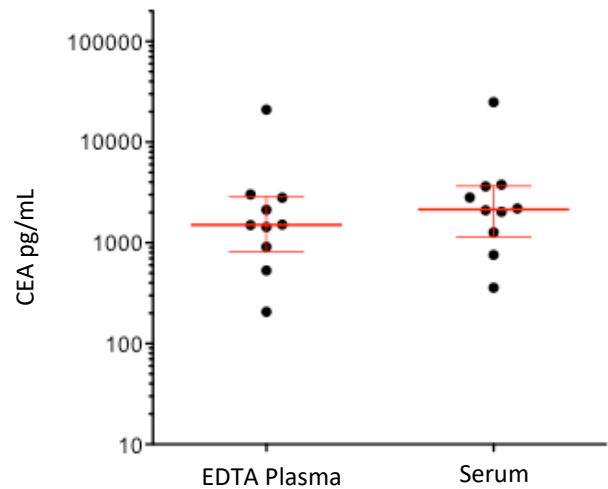
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

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

LLOQ	2.33 pg/mL pooled CV 9.9% mean recovery 107.6%
LOD	0.486 pg/mL range 0.107–1.015 pg/mL
Dynamic range (serum and plasma)	0–85 ng/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median with interquartile range.



Sample Type	Median CEA pg/mL	% Above LOD
Serum	2153.9	100%
Plasma	1511.5	100%

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

Sample	Mean (pg/mL)	Within run CV	Between run CV
Serum Panel 1	22,841	3.0%	9.0%
Serum Panel 2	38,934	4.3%	9.0%
Plasma Panel 3	35,473	4.7%	10.9%

Spike and Recovery: CEA spiked into 2 serum and 2 plasma samples at 2 levels.

Dilution Linearity: Spiked, diluted 2x serially from MRD (50x) to 3,200x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 95.9% Range: 87.4–105.4%
Dilution Linearity (3,200x)	Mean = 93.9% Range: 87.7–94.9%