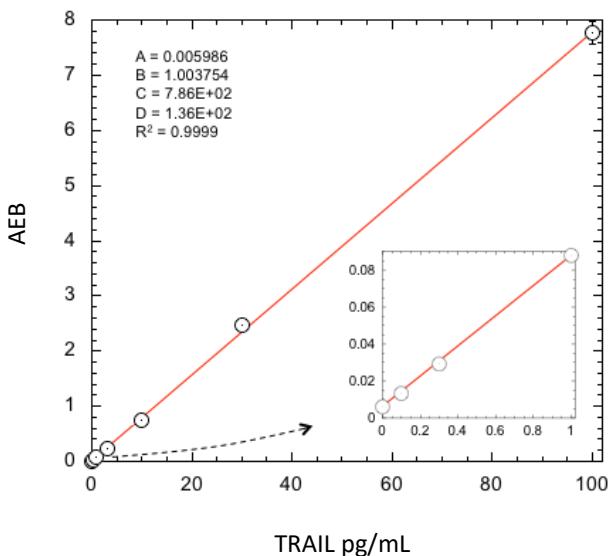


Description

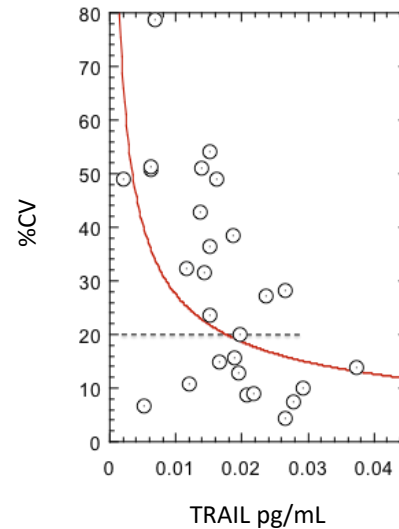
TNF-related apoptosis-inducing ligand or TRAIL is a 281 amino acid cytokine that initiates apoptosis by binding to specific death receptors on the cell surface. Both full-length cell surface expressed TRAIL and picomolar concentrations of soluble TRAIL rapidly induce apoptosis in a wide variety of transformed cell lines of diverse origin. Serum TRAIL levels are significantly lower in patients with coronary artery disease than in normal patients. Plasma TRAIL levels are significantly higher in patients with HIV-1 than in normal patients and correlate positively with viral load. This protein has generated excitement as a potential tumor-specific cancer therapeutic because, as a stable soluble trimer, it selectively induces apoptosis in many transformed cells but not in normal cells. Transcriptional activation of Apo2L/TRAIL by interferons (IFNs) through specific regulatory elements in its promoter, and possibly by a number of other cytokines, reveals its possible involvement in the activation of natural killer cells, cytotoxic T lymphocytes, and dendritic cells.

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



Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 10 runs.

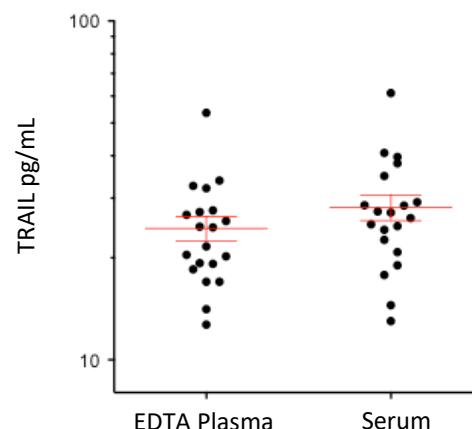
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (27 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



LLOQ	0.0177 pg/mL
LOD	0.0083 pg/mL SD 0.00574 pg/mL
Dynamic range (serum and plasma)	0–400 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=20) and serum (n=20) were measured. Error bars depict mean and SEM.



Sample Type	Median TRAIL pg/mL	% Above LOD
Serum	26.7	100%
EDTA Plasma	23.1	100%

Precision: Five samples consisting of 2 serum-based panels, one plasma-based panel, and two TRAIL controls were assayed in replicates of three at two separate times per day for five days using a single lot of reagents and calibrators. Analysis of variance (fully nested ANOVA) results are summarized in the following table.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between day CV
Control 1	0.962	6.9%	4.9%	0.0%
Control 2	22.5	4.6%	3.8%	0.0%
Panel 1	17.9	6.2%	3.7%	0.0%
Panel 2*	38.0	4.7%	8.7%	0.0%
Panel 3	104	6.7%	6.0%	0.0%

*Plasma

Spike and Recovery: TRAIL spiked into 4 serum samples at 2 levels.

Admixture Linearity: High TRAIL serum sample admixed with low TRAIL sample, mean of 10 levels.

Dilution Linearity: Spiked serum and endogenous plasma diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (Serum)	Mean = 81.5% Range: 74.6–92.3%
Admixture Linearity	Mean = 97.8%
Dilution Linearity (128x)	Mean = 111% Range: 85.9–143%