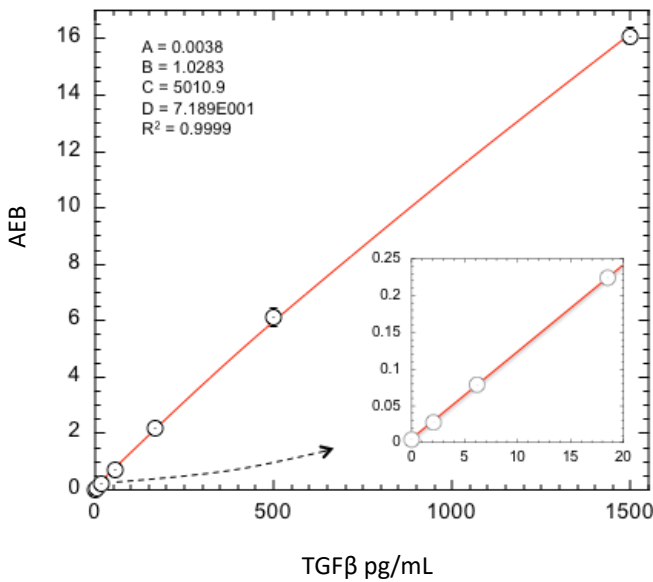


Description

Human TGFβ exists as three isoforms (1,2,3), that are 70-80% homologous; the Simoa Human TGFβ assay recognizes all 3 isoforms. As part of a Kinase complex, TGFβ initiates a signal cascade that upregulates target gene expression. Target genes activated by this cascade impact a wide range of functions including cell invasion, environmental modification, differentiation, proliferation, and immune cell activation. Modification of the normal TGFβ pathway is associated with cancer development. Because TGFβ is secreted by most cell types, dysfunction is associated with many types of cancer. In many such cancers, malignancy correlates with an increased expression of TGFβ and a progressive loss of TGFβ-mediated growth inhibition.

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



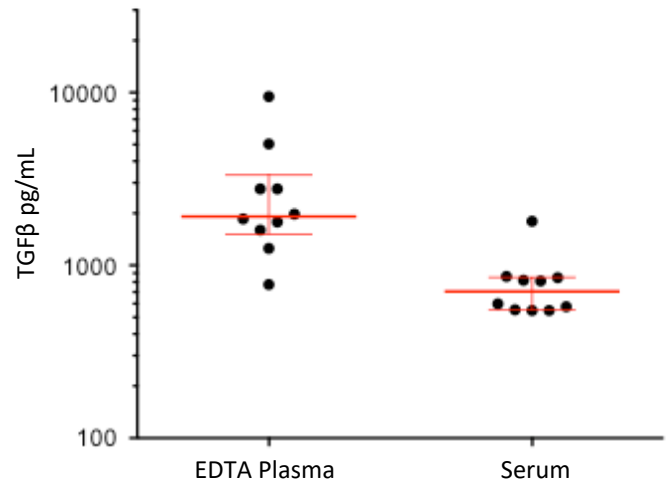
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

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	0.514 pg/mL pooled CV 13% mean recovery 109%
LOD	0.137 pg/mL range 0.075–0.203 pg/mL
Dynamic range (serum and plasma)	0–24 ng/mL
Diluted Sample volume*	104 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 TGFβ pg/mL	% Above LOD
Serum	1493	100%
EDTA Plasma	3836	100%

Precision: Representative precision was estimated with repeated assay of serum panels using two instruments 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	925	4.8%	8.0%
Serum Panel 2	1439	5.6%	13.0%
Serum Panel 3	1533	5.5%	5.0%

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

Dilution Linearity: Serum samples were diluted 2x serially from MRD (16x) to 1024x with Sample Diluent.

Spike and Recovery (Serum)	Mean = 94.2% Range: 82–105%
Dilution Linearity (1024x)	Mean = 97.4% Range: 92.9–105%