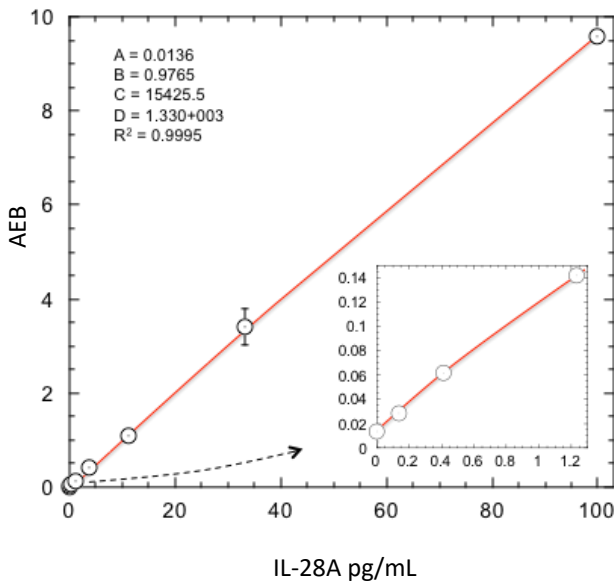


Description

Interleukin-28 (IL-28) is a cytokine that comes in 2 isoforms: IL-28A and IL-28B. The two isoforms are 96% homologous. It plays a role in immune defense against viruses, including the induction of the “Antiviral State.” IL-28A has a molecular weight of 22.3 KDa. It exerts its immunomodulatory effect by up-regulating MHC class I antigen expression. IL-28A acts as a ligand for the heterodimeric class II cytokine receptor (IL-10RB and IFNLR1) and leads to the activation of the JACK/STAT signaling pathway, resulting in the expression of Interferon stimulated genes, which mediate the Antiviral State. IL-28A also has antitumor activity. Addition of IL-28 to influenza vaccine results in 100% protection from a lethal H1N1 Influenza challenge in a small animal model when it was paired with an Influenza vaccine that protected only 50% of the time without IL-28.

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



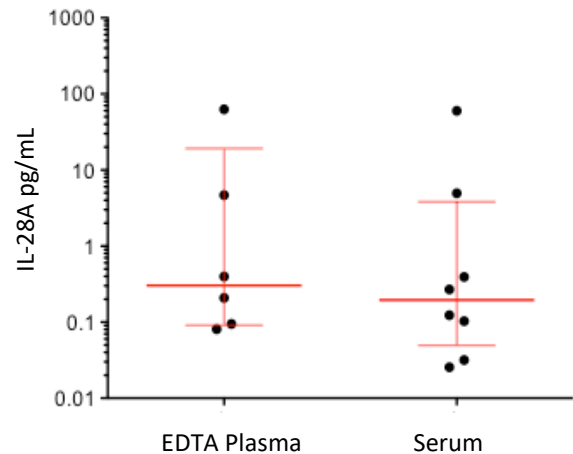
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot across 3 instruments (10 runs total).

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 across 3 instruments (10 runs total).

LLOQ	0.069 pg/mL pooled CV 7.9% mean recovery 100%
LOD	0.022 pg/mL range 0.0064–0.069 pg/mL
Dynamic range (serum and plasma)	0–200 pg/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=6) and serum (n=8) were measured. Error bars depict median and interquartile ranges. 4 plasma samples and 2 serum samples were below the LOD of the assay.



Sample Type	Median IL-28A pg/mL	% Above LOD
EDTA Plasma	0.303	60%
Serum	0.196	80%

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
Plasma Panel 1	2.23	9.4%	12.4%
Serum Panel 2	10.1	4.4%	15.4%
Plasma Panel 3	60.0	6.9%	7.1%

Spike and Recovery: IL-28A spiked into 4 serum samples at 2 levels.

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

Spike and Recovery (Serum)	Mean = 99.2% Range: 82.5–121%
Dilution Linearity (128x)	Mean = 113.8% Range: 108.3–122.5%