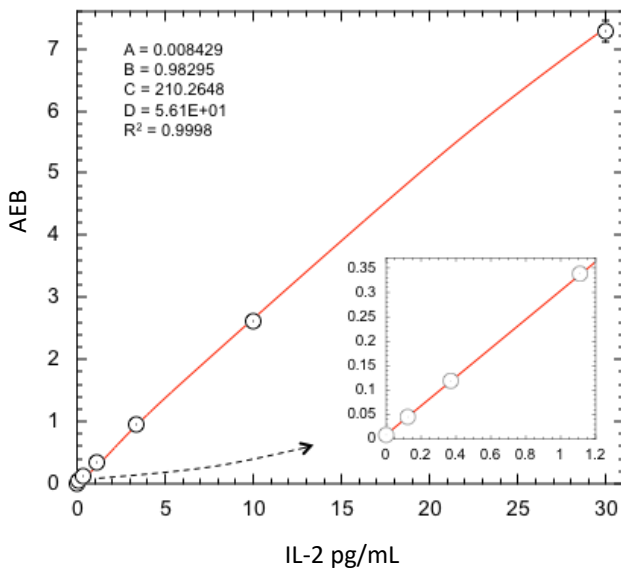


Description

Interleukin 2 (IL-2) is an alpha-helical cytokine of 153 amino acids (molecular weight 17.6kDa) whose primary role is regulation of activities of lymphocytes that are responsible for immunity. During infection, the binding of antigens to T cell receptors trigger secretion of IL-2 and expression of IL-2 receptors (IL-2R), promoting the growth, proliferation, and differentiation of T cells to become effector T cells. IL2/IL2R interaction stimulates growth and differentiation of antigen-specific CD4+ and CD8+ T cells, resulting in immunologic memory of the antigens. IL-2 is also responsible for discrimination between foreign ("non-self") and "self", and as such is a target of immunosuppressive regimens which inhibit the production of IL-2 by antigen-activated T cells and block IL-2R signaling, preventing the clonal expansion and function of antigen-selected T cells.

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



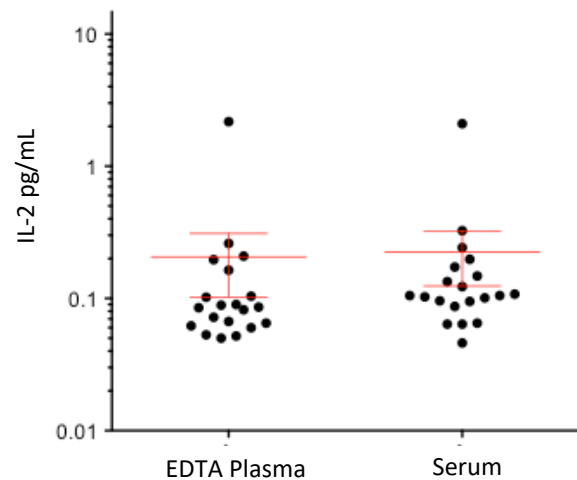
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (10 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 2 reagent lots across 3 instruments (12 runs total).

LLOQ	0.0410 pg/mL pooled CV 13.7% mean recovery 92.1%
LOD	0.0110 pg/mL range 0.0022–0.0669 pg/mL
Dynamic range (serum and plasma)	0–120 pg/mL
Diluted Sample volume*	168 µL per measurement
Tests per kit	96

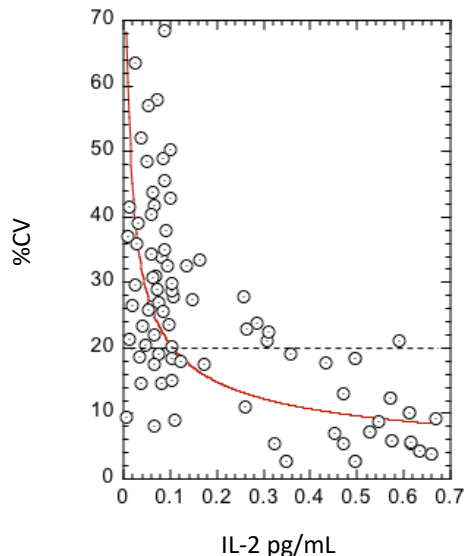
*See Kit Instruction for details

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 IL-2 pg/mL	% Above LOD
EDTA Plasma	0.086	100%
Serum	0.105	100%

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (90 measurements).



Spike and Recovery (Serum/Plasma)	Mean = 138% Range: 101–163%
Admixture Linearity	Mean = 98.5%
Dilution Linearity (Serum 128x, Plasma 32x)	Mean = 88.7% Range: 75.1–96.2%

Precision: Four samples consisting of two serum-based panels and two IL-2 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	0.589	9.3%	7.8%	2.2%
Control 1	53.7	8.8%	9.2%	5.6%
Panel 1	3.45	7.7%	8.1%	5.3%
Panel 2	34.6	8.6%	7.0%	1.0%

Spike and Recovery: IL-2 spiked into 4 serum and 4 plasma samples at different concentrations.

Admixture Linearity: High IL-2 plasma sample admixed with low IL-2 sample, mean of 10 levels.

Dilution Linearity: 1 spiked serum sample was diluted 2x serially from MRD (4x) to 128x and 1 endogenous plasma sample was diluted 2x serially from MRD (4x) to 32x with Sample Diluent.