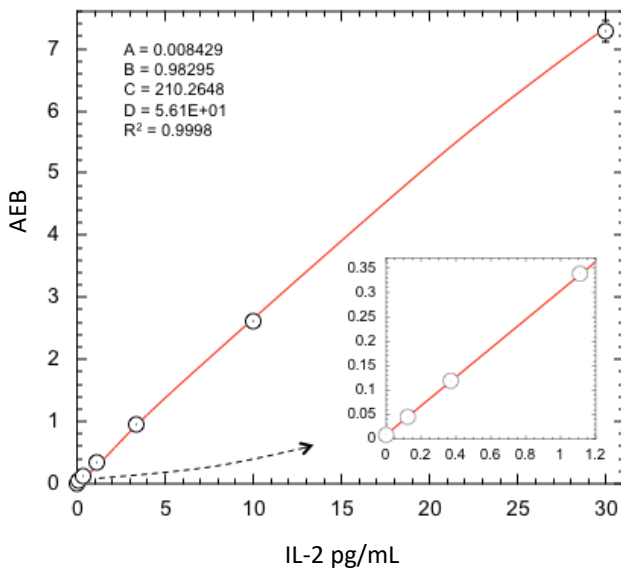


**Description**

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.



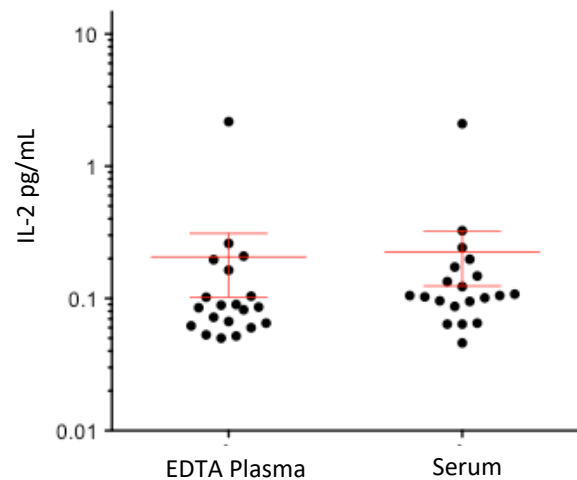
**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (10 runs total).

**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).

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

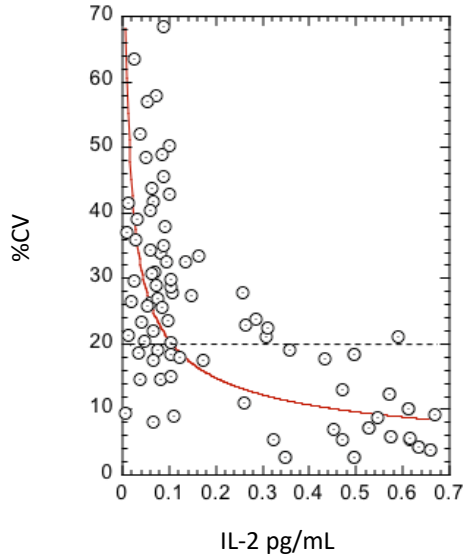
\*See Kit Instruction for details

**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).



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