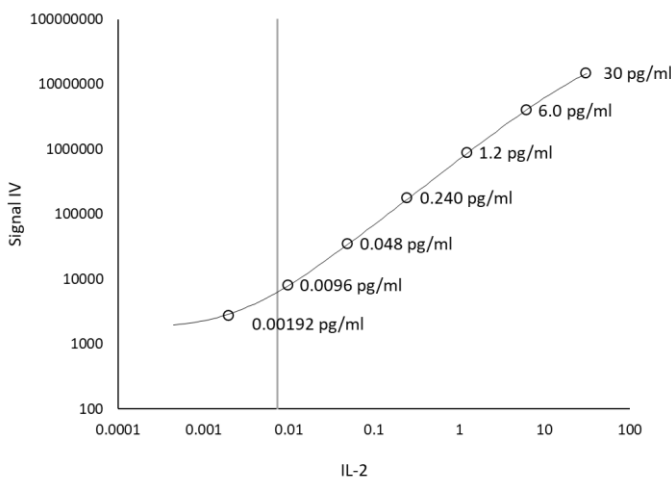


**Description**

Interleukin 2 (IL-2) is an alpha-helical cytokine of 153 amino acids (molecular weight 17.6 kDa) 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:** Calibrator concentrations and Lower Limit of Quantification depicted.



**Minimum Required Dilution (MRD)**

<b>Diluted Sample Volume</b>	12.5 µL per measurement
<b>Serum and Plasma Dilution</b>	1:4
<b>Tests per kit</b>	96

See Kit Instruction for details.

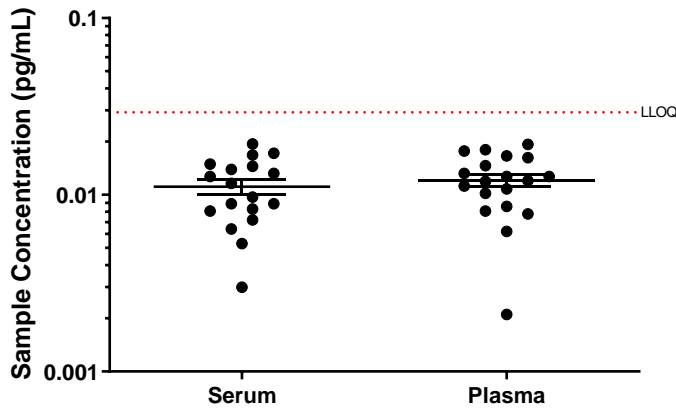
**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 2 reagent lot across 2 instruments (12 runs total). The functional LLOQ (fLLOQ) values below are for serum and plasma.

**Limit of Detection (LOD):** Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 2 reagent lot across 2 instruments (12 runs total).

**Assay Range:** The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The ranges below are for serum and plasma.

<b>Analytical LLOQ</b>	<b>0.00732 pg/mL</b> pooled CV 14% mean recovery 97%
<b>Functional LLOQ</b>	<b>0.0293 pg/mL</b>
<b>LOD</b>	<b>0.000893 pg/mL</b> range 0.00000930 – 0.00355 pg/mL
<b>Dynamic Range</b>	0 – 120 pg/mL

**Endogenous Sample Reading:** Healthy donor matched EDTA plasma (n=20), and serum (n=20) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



**Precision:** Measurements of 4 serum-based panels. Triplicate measurements were made for 6 runs each for 2 reagent lot across 2 instruments (12 runs total, 48 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between Lot CV
Panel 1	4.09	2.03%	8.34%	4.32%
Panel 2	1.08	2.97%	8.49%	6.23%
Panel 3	0.200	4.68%	10.8%	2.61%
Panel 4	0.0446	7.83%	17.3%	5.53%

**Spike and Recovery:** 6 serum and 6 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SP-X.

**Dilution Linearity:** 5 spiked EDTA plasma and 5 spiked serum samples were diluted 2x serially from MRD (4x) to 128x with Sample Diluent.

Sample Type	Mean IL-2 pg/mL	Median IL-2 pg/mL	% Above LOD	% Above LLOQ
Serum	*0.0121	*0.0120	90%	0%
Plasma	*0.0111	*0.0106	85%	0%

\*Values below LLOQ are included in the mean / median

<b>Spike and Recovery (Serum/Plasma)</b>	<b>Mean 87%</b> range 62–100%
<b>Dilution Linearity (128x)</b>	<b>Mean 118%</b> range 100–142%

The Simoa<sup>®</sup>Corplex<sup>™</sup> Human IL-2 assay kit is formulated for use on the SP-X platform.