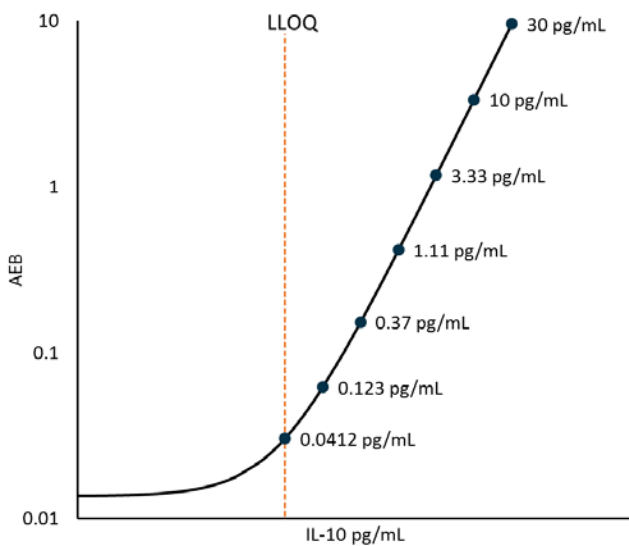


Description

Interleukin 10 (IL-10) is an alpha-helical, homodimeric cytokine, each subunit composed of 178 amino acids (18 kDa). The major role of IL-10 is to act as an anti-inflammatory cytokine. It is produced primarily by monocytes, type 2 T helper cells and B cells. IL-10 is also released by cytotoxic T cells to inhibit the action of natural killer cells during the immune response to viral infection. It has multiple effects in immunoregulation and inflammation, including down regulation of Th1 cytokine expression, MHC class II antigens, and stimulatory molecules on macrophages. IL-10 can also inhibit synthesis of pro-inflammatory cytokines such as IFN-g, IL-2, TNFα and GM-CSF made by macrophages and regulatory T cells. IL-10 is among cytokines secreted by muscle cells, whose elevation during physical activity suggests that exercise promotes an environment of anti-inflammatory cytokines. IL-10 has garnered interest as a potential anti-inflammatory therapeutic, but initial studies with rheumatoid arthritis have shown limited efficacy.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



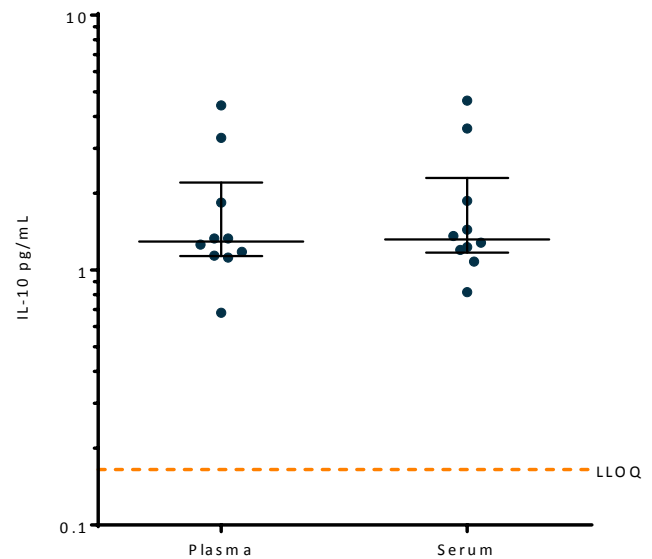
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	0.0412 pg/mL pooled CV 14% mean recovery 98%
LOD	0.0054 pg/mL range 0.0026-0.0097 pg/mL
Dynamic range	0–120 pg/mL
Diluted Sample volume (1:4 Dilution) *	100 µL per measurement
Tests per kit	96

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) samples were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean IL-10 pg/mL	Median IL-10 pg/mL	% Above LOD
EDTA plasma	1.76	1.29	100%
Serum	1.85	1.32	100%

Precision: Measurements of 3 serum or plasma based panels and 2 calibrator based controls. Triplicate measurements were made for 3 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	1.35	4.7%	3.5%	0.5%
Control 2	19.8	7.0%	6.4%	1.6%
Panel 1	1.08	5.9%	4.3%	3.2%
Panel 2	2.78	4.4%	2.2%	0.9%
Panel 3	43.4	5.1%	3.4%	2.5%

Dilution Linearity: 1 spiked EDTA plasma sample and 1 spiked serum sample were diluted 2X serially from 4x (MRD) to 512x with Sample Diluent.

Plasma Dilution Linearity (512x)	Mean = 102% Range: 88-115%
Serum Dilution Linearity (512x)	Mean = 101% Range: 88-110%

Note: Spike and Recovery data were obtained using the HD-1 Analyzer.

Spike and Recovery: 4 serum samples were spiked at high and low concentrations within the range of the assay and analyzed on HD-1.

Spike and Recovery	86% Range 72-103%
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The Simoa IL-10 assay kit is formulated for use on either the SR-X or HD-1 platform. Minor differences in performance claims between the HD-1 and SR-X may be observed when comparing datasheets for the two different platforms, due to experiments run at different time-points with different reagent lots and different samples. Data in this document was obtained from runs on the SR-X platform unless otherwise noted.