Quanterix™
The Science of Precision Health

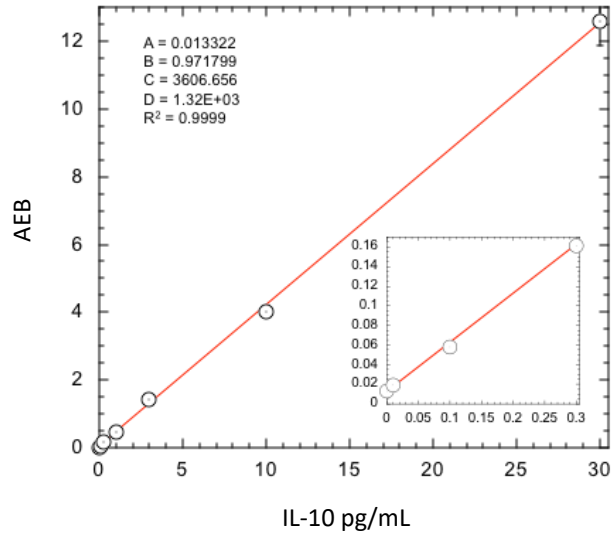
Simoa® IL-10 Advantage Kit
HD-1/HD-X Data Sheet

Item 101643

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-γ, 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: Four-parameter curve fit parameters are depicted.



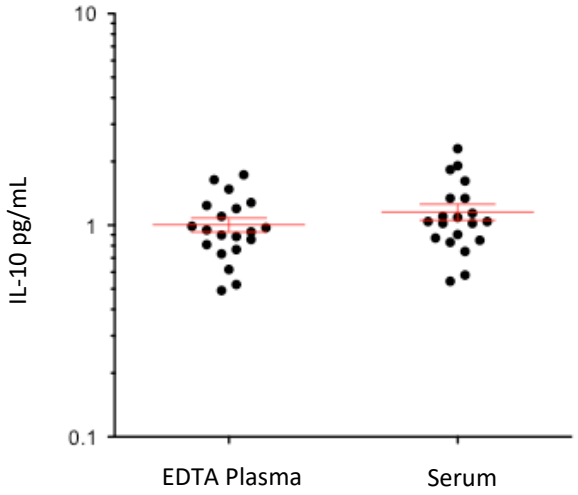
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (12 runs total).

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	**0.021 pg/mL** pooled CV 20% mean recovery 109.5%
LOD	**0.0038 pg/mL** range 0.0002–0.0177 pg/mL
Dynamic range (serum and plasma)	0–120 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

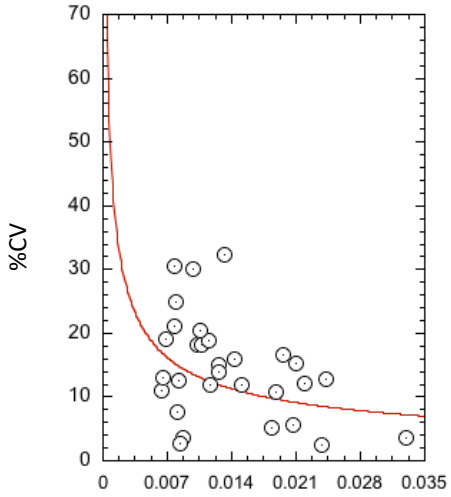
***See Kit Instruction for details**

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-10 pg/mL	% Above LOD
Serum	1.04	100%
Plasma	0.940	100%

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (30 measurements).



Precision: Five samples consisting of two serum-based panels, one plasma-based panel* and two IL-10 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	1.16	4.3	7.3	0.0
Control 2	18.7	3.6	4.5	4.6
Panel 1	0.675	5.6	7.8	1.2
Panel 2	2.57	4.7	4.5	2.8
Panel 3*	59.3	4.7	7.0	0.0

Inter Lot CV: Pool of CVs from 5 samples tested with 2 reagent lots across 2 runs x 3 instruments.

Spike and Recovery: IL-10 spiked into 4 serum samples at 2 levels.

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

Dilution Linearity: IL-10 spiked into three EDTA plasma samples and diluted 2x serially from MRD (4x) to 64x with Sample Diluent.

Inter Lot CV	**6.5%** Range: 0.57–68.4%
Spike and Recovery (Serum)	**Mean = 86.2%** Range: 72.2–102.8%
Admixture Linearity	**Mean = 95.7%** Range: 84–106%
Dilution Linearity (64x)	**Mean = 108%** Range: 96-117%

The Simoa IL-10 Advantage assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.