Quanterix™
The Science of Precision Health

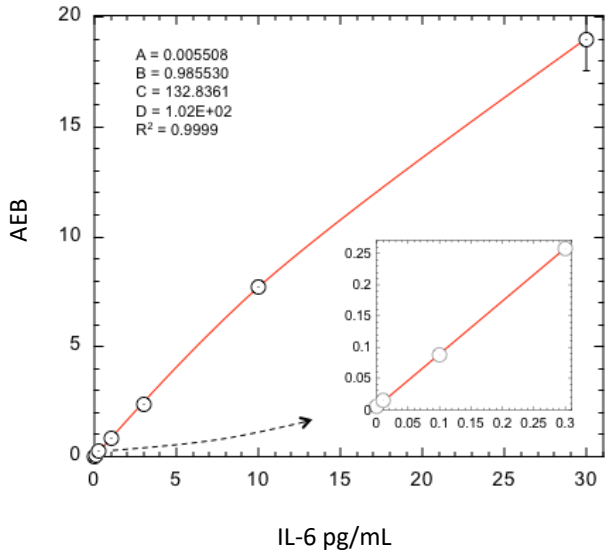
Simoa® IL-6 Advantage Kit
HD-1/HD-X Data Sheet

Item 101622

Description

Interleukin 6 (IL-6) is an alpha-helical cytokine with a wide variety of biological functions, including inducement of acute phase reactions, inflammation, hematopoiesis, bone metabolism, and cancer progression. It is secreted by multiple cell types as a 22k-28k dalton phosphorylated and variably glycosylated molecule. Mature human IL-6 is 183 amino acids (aa) in length and shares 41% aa sequence identity with mouse and rat IL-6. IL-6 is secreted by T cells and macrophages to induce immune responses following tissue trauma leading to inflammation. IL-6 also acts as an anti-inflammatory myokine, secreted by muscles during contraction after which it acts to increase breakdown of fats and improve insulin resistance. Because of its role in inducing inflammation and auto-immune response, there is interest in developing anti-IL-6 agents as potential therapies against various diseases, including rheumatoid arthritis and cancer.

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



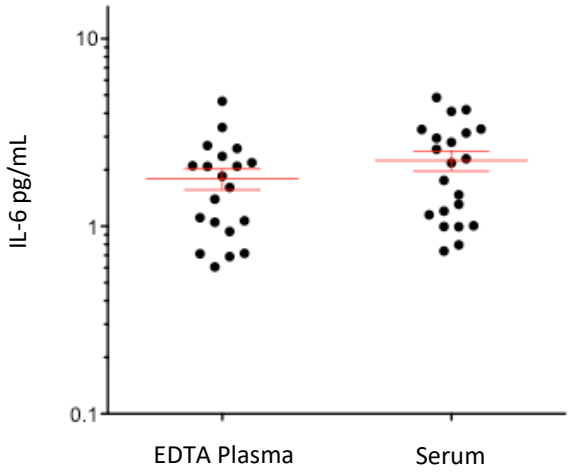
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (12 runs total).

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	**0.010 pg/mL**
LOD	**0.0055 pg/mL** SD 0.0045 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=21) were measured. Error bars depict mean and SEM.



Sample Type	Median IL-6 pg/mL	% Above LOD
EDTA Plasma	1.73	100%
Serum	2.18	100%

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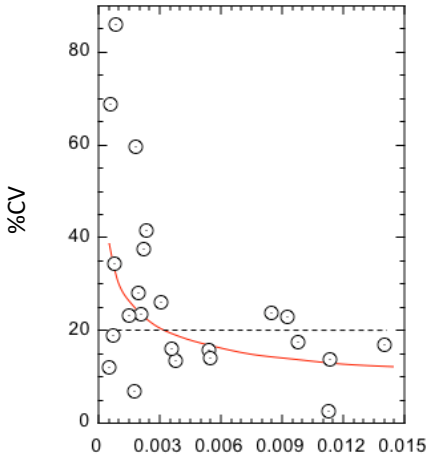
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (28 measurements).



Precision: Five samples consisting of serum and plasma-based panels and two IL-6 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	1.54	5.8%	0.0%	2.7%
Control 2	24.0	6.1%	6.0%	0.0%
Panel 1	1.05	11.9%	5.1%	0.0%
Panel 2	9.00	6.5%	0.0%	7.1%
Panel 3	47.1	5.0%	0.0%	2.7%

Inter Lot CV: Pool of CVs from 5 samples (range: 1.23–54.8 pg/mL) tested with 2 reagent lots across 2 runs x 3 instruments.

Spike and Recovery: IL-6 spiked into 4 serum samples at 2 levels.

Admixture Linearity: High IL-6 serum sample admixed with low IL-6 sample, mean of 10 levels.

Dilution Linearity: Serum and plasma samples were diluted 2x serially from MRD (4x) to 128x with Sample Diluent, mean of 3 experiments.

Inter Lot CV	**7.3%**
Spike and Recovery (Serum)	**Mean = 82.8%** Range: 69.0–97.9%
Admixture Linearity	**Mean = 97.1%**
Dilution Linearity (128x)	**Mean = 114%** Range: 98.0–125%

The Simoa IL-6 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.

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