Quanterix™
The Science of Precision Health

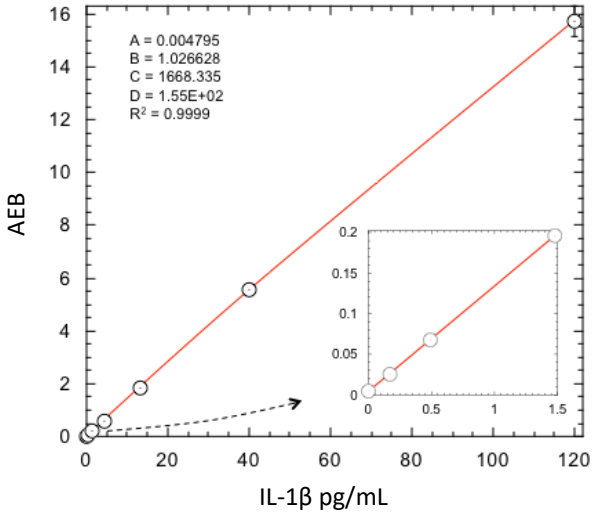
Simoa® IL-1β Advantage Kit
HD-1/HD-X Data Sheet

Item 101605

Description

Interleukin-1 beta (IL-1β), also known as catabolin, is a cytokine of 269 amino acids (molecular weight 31 kDa). This cytokine is produced by activated macrophages as a proprotein, which is proteolytically processed to its active form by caspase-1. IL-1β is an important mediator of the inflammatory response and is involved in a variety of cellular activities, including cell proliferation, differentiation, and apoptosis. IL-1β is the most studied member of the IL-1 family of cytokines due to its role in mediating autoinflammatory diseases. Blood monocytes from patients with autoinflammatory syndromes release more processed IL-1β than cells from healthy subjects and thus likely account for the inflammation in these diseases. Neutralization of IL-1β results in rapid and sustained reduction in disease severity. Although some autoinflammatory diseases are due to gain-of-function mutations for caspase-1 activity, common diseases such as gout, type 2 diabetes, heart failure, recurrent pericarditis, rheumatoid arthritis, and smouldering myeloma are also responsive to IL-1β neutralization.

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



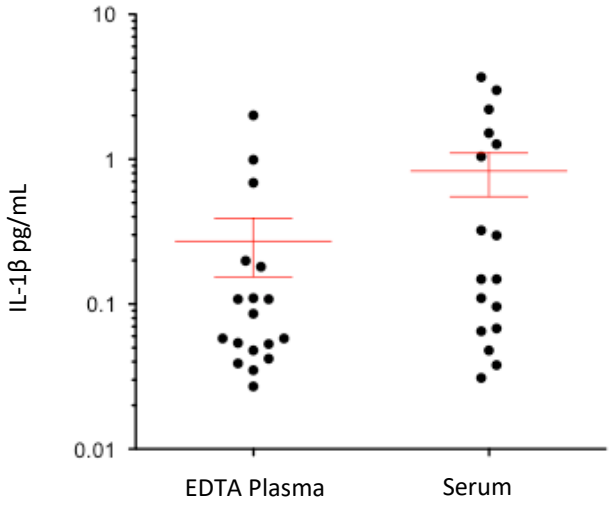
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 2 reagent lots across 3 instruments (12 runs total).

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	**0.083 pg/mL**
LOD	**0.016 pg/mL** SD 0.013 pg/mL
Dynamic range (serum and plasma)	0–240 pg/mL
Diluted Sample volume*	170 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=18) and serum (n=17) were measured. Error bars depict mean and SEM. IL-1β was undetectable in 2 plasma and 3 serum samples (not shown).



Sample Type	Median IL-1β pg/mL	% Above LOD
EDTA Plasma	0.058	100%
Serum	0.149	100%

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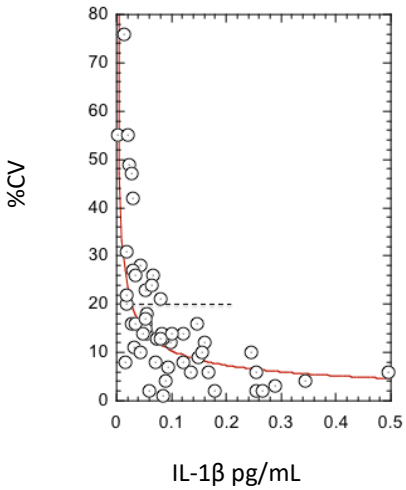
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (62 measurements)



Precision: Five samples consisting of three serum-based panels, and two IL-1β 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	6.19	7.0%	5.2%	3.4%
Control 2	197	6.6%	7.0%	3.8%
Panel 1	9.84	5.9%	2.8%	3.4%
Panel 2	22.3	8.1%	2.3%	0.0%
Panel 3	53.4	5.8%	0.0%	9.8%

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

Spike and Recovery: IL-1β spiked into 4 serum samples at 2 levels.

Admixture Linearity: High IL-1β serum sample admixed with low IL-1β sample, mean of 10 levels.

Dilution Linearity: 1 spiked serum sample was diluted 2x serially from MRD (2x) to 512x with Sample Diluent.

Inter Lot CV	**6.6%** Sample Range: 6.29–53.8 pg/mL
Spike and Recovery (Serum)	**Mean = 94.9%** Range: 71.5–109%
Admixture Linearity	**Mean = 107%**
Dilution Linearity (512x)	**Mean = 124%** Range: 116–134%

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