Quanterix™
The Science of Precision Health

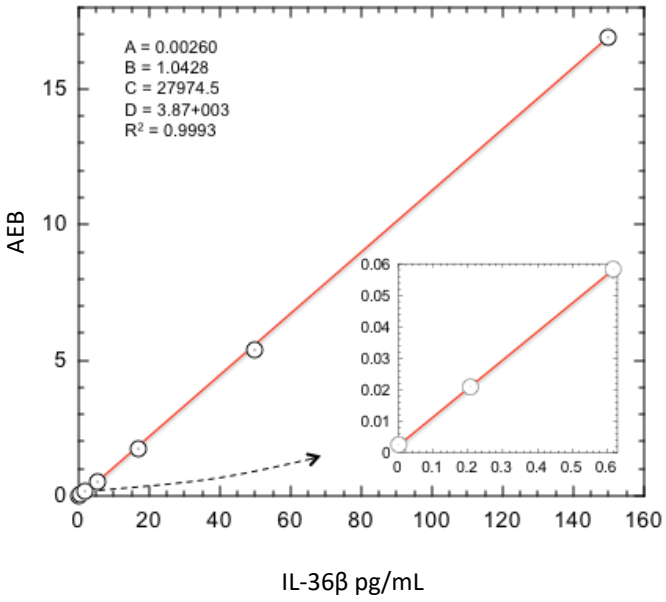
Simoa® IL-36β Discovery Kit
HD-1/HD-X Data Sheet

Item 101808

Description

Interleukin 36 beta (IL-36β, IL-1F8) is a member of the IL-1 family of cytokines. The inflammatory activity of IL-36β occurs through indirect activation of the NF-kappaB and MAPK pathways. This activation occurs via the intermediary Interleukin-1 receptor and accessory proteins (IL-1Rrp2 and IL-1RAcP, respectively). IL-36α, IL-36β, and IL-36γ are associated with the immune system in the skin. These cytokines directly activate keratinocytes and antigen-presenting cells and indirectly activate T cells to cause psoriasis. In primary human joint cells (synovial fibroblasts and articular chondrocytes) IL-36β exerts proinflammatory effects, but serum levels of IL-36β do not correlate with joint inflammation.

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



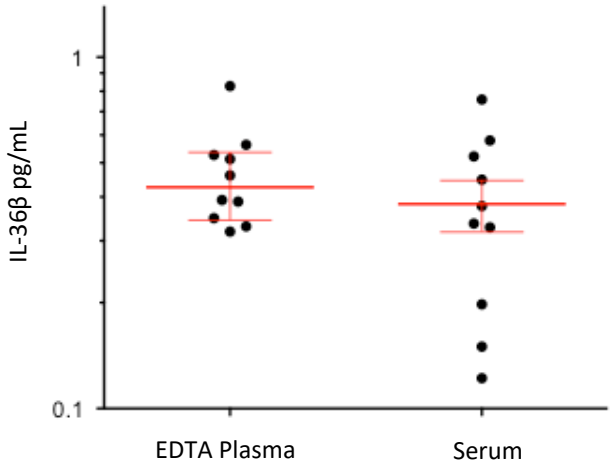
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 2 instruments (5 runs total).

LLOQ	**0.206 pg/mL** pooled CV 8.2% mean recovery 117%
LOD	**0.010 pg/mL** range 0.0058–0.0356 pg/mL
Dynamic range (serum and plasma)	0–600 pg/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) were measured. Error bars depict median and interquartile ranges.



Sample Type	Median IL-36β pg/mL	% Above LOD
EDTA Plasma	0.426	100%
Serum	0.357	100%

Precision: Representative precision was estimated with repeated assay of serum panels using one instrument and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Serum Panel 1	0.414	10.2%	14.4%
Serum Panel 2	7.11	6.0%	2.9%
Serum Panel 3	28.9	5.5%	3.5%

Spike and Recovery: IL-36β spiked into 4 serum samples at 2 levels.

Dilution Linearity: Serum samples pre-diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery (Serum)	**Mean = 93.4%** Range: 88–98%
Dilution Linearity (256x)	**Mean = 103.8%** Range: 95.8–114.9%