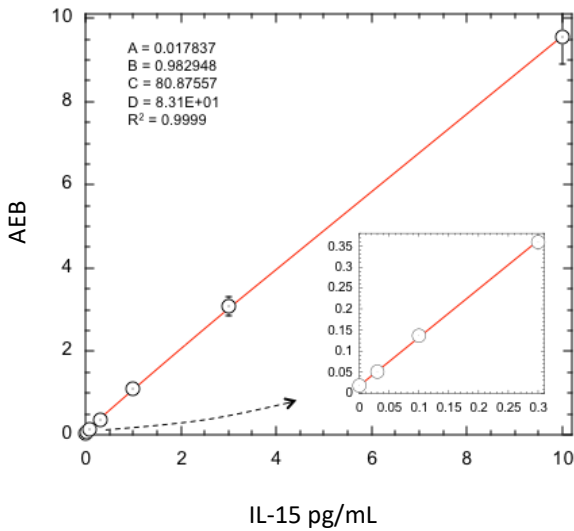


Description

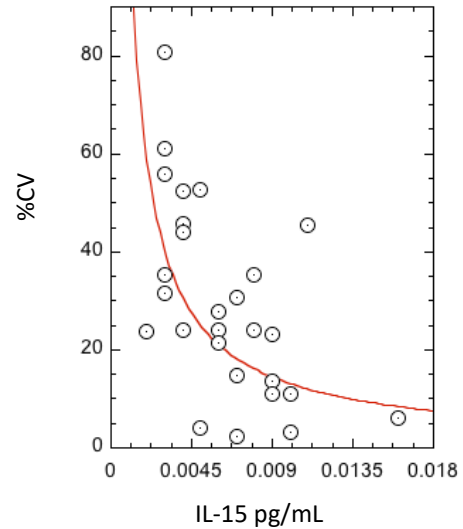
Interleukin 15 (IL-15) is a glycosylated 14-15 kDa cytokine with structural similarity to IL-2. Like IL-2, IL-15 binds to and signals through the IL-2/IL-15 beta chain (CD122) and the common gamma chain (gamma-C, CD132). IL-15 is constitutively expressed by a large number of cell types and tissues, including monocytes, macrophages, dendritic cells, keratinocytes, fibroblasts, and nerve cells. IL-15 up-regulation plays a central role in the development of several autoimmune or chronic inflammatory disorders. This cytokine induces cell proliferation of natural killer cells; cells of the innate immune system whose principal role is to kill virally infected cells. IL-15 has been shown to enhance the anti-tumor immunity of CD8+ T cells in pre-clinical models.

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



Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 10 runs.

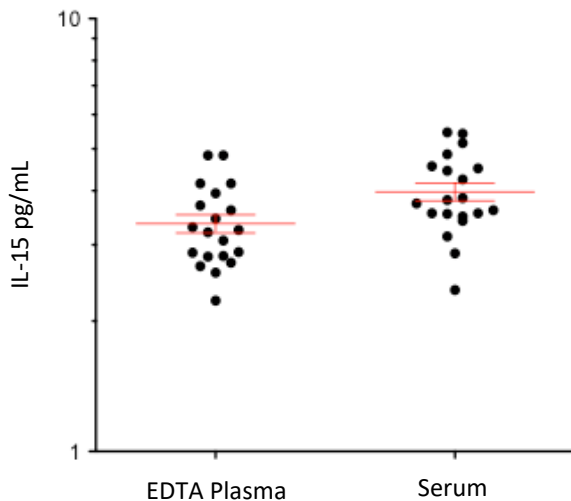
Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (28 measurements). LLOQ determined as the concentration at which %CV exceeds 20% according to the power equation fit to the data.



LLOQ	0.0062 pg/mL
LOD	0.0030 pg/mL SD 0.00217 pg/mL
Dynamic range (serum and plasma)	0–40 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-15 pg/mL	% Above LOD
Serum	3.78	100%
Plasma	3.23	100%

Precision: Five samples consisting of three serum-based panels and two IL-15 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	0.346	4.6%	4.0%	0.0%
Control 2	5.79	4.9%	7.1%	2.0%
Panel 1	3.16	11.9%	3.8%	4.5%
Panel 2	4.23	11.7%	6.0%	0.0%
Panel 3	26.2	4.9%	6.5%	1.7%

Spike and Recovery: IL-15 spiked into 4 serum samples at 2 levels.

Admixture Linearity: High IL-15 serum sample admixed with low IL-15 sample, mean of 10 levels.

Dilution Linearity: 1 spiked serum sample and 1 endogenous plasma sample were diluted from MRD (4x) to 128x with Sample Diluent.

Spike and Recovery (Serum)	Mean = 104.2% Range: 95.8–116.2%
Admixture Linearity	Mean = 104.9%
Dilution Linearity (128x)	Mean = 99.1% Range: 87.5–110.0%

The Simoa IL-15 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.