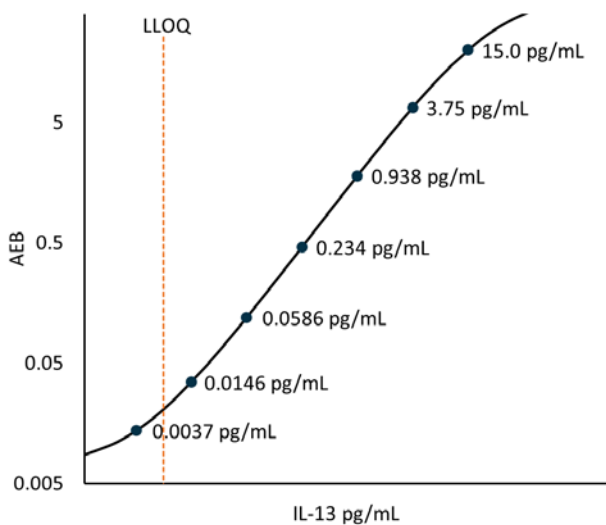


Description

Interleukin 13 (IL-13) is a cytokine of 111 amino acids (molecular weight 15.8 kDa) whose major roles include down-modulation of macrophage activity (lowering the production of pro-inflammatory cytokines) and mediation of allergic responses. It is secreted by many cell types, but primarily by activated T-cells, in particular T-helper type 2 cells. IL-13 affects immune cells in a manner similar to IL-4 but is more associated with physiological changes induced by allergic inflammation. The effects of IL-13 are induced through a receptor that includes the alpha chain of the IL-4 receptor and at least one or two known IL-13 specific binding chains. IL-13 is the central mediator of allergic asthma, where it regulates eosinophilic inflammation, mucus secretion, and airway hyperresponsiveness. IL-13 has therefore become a therapeutic target for allergic diseases with several anti-IL-13 antibodies under evaluation as treatment for bronchial asthma. Manipulation of IL-13 effector function may also prove useful in the treatment of some cancers like B-cell chronic lymphocytic leukemia and Hodgkin's disease, where IL-13 modulates apoptosis or tumor cell growth.

Calibration Curve: Calibrator concentrations and Lower Limit of Quantification depicted.



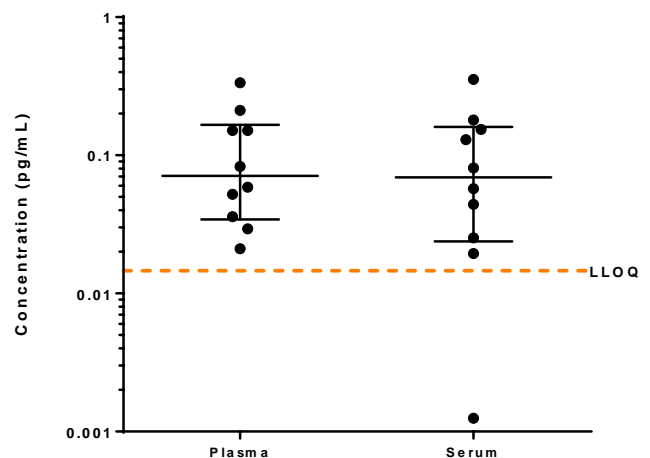
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on 6 calibration curves over 4 runs each for 1 reagent lot across 2 instruments (4 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	0.0073 pg/mL pooled CV 15% mean recovery 102%
LOD	0.0014 pg/mL range 0.0003-0.0029 pg/mL
Dynamic range (serum and plasma)	0-30 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=10), and serum (n=10) were measured. One serum sample read below the LLOQ and was excluded from the mean concentration. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean IL-13 pg/mL	Median IL-13 pg/mL	% Above LOD
Serum	0.116*	0.0692	100%
Plasma	0.113	0.0708	100%

*Values below LLOQ are not included in the mean

Precision: Measurements of 3 serum and EDTA plasma-based panels and 2 calibrator based controls. Triplicate measurements were made for 6 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	0.172	8.4%	6.2%	6.9%
Control 2	3.88	9.5%	6.7%	1.8%
Panel 1	0.111	7.9%	5.8%	4.9%
Panel 2	0.320	6.3%	6.9%	2.1%
Panel 3	4.32	5.6%	9.9%	10.4%

Spike and Recovery: 2 serum and 2 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SR-X.

Dilution Linearity: 1 endogenous plasma and 1 spiked serum sample were diluted 2X serially from MRD (2x) to 128x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 100% Range: 82-121%
Dilution Linearity (128x)	Mean = 108% Range: 96–117%

The Simoa IL-13 assay kit is formulated for use on either the SR-X or HD-1 platform. Data in this document was obtained from runs on the SR-X platform unless otherwise noted. Some differences in performance claims between the HD-1 and SR-X may be observed when comparing datasheets for the two platforms. This may be due to experiments run at different time-points with different reagent lots and different samples or may be due to minor differences in antibody and analyte behavior in the different assay formats.