Quanterix™
The Science of Precision Health

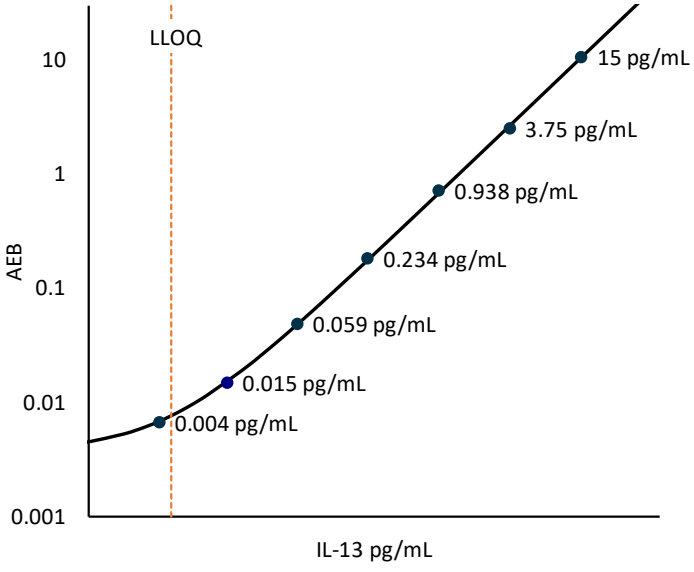
Simoa® IL-13 Advantage Kit
HD-1/HD-X Data Sheet

Item 102732

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)[1] and mediation of allergic responses.[2] 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.[3] 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.[4] IL-13 has therefore become a therapeutic target for allergic diseases with several anti-IL-13 antibodies under evaluation as treatment for bronchial asthma.[5] 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.[6]

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



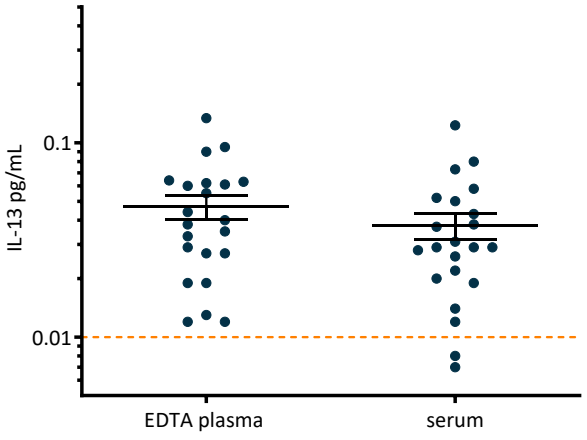
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve for 9 runs each for 2 reagent lots across 3 instruments (18 runs total). The LLOQ is determined as the lowest dilution with a pooled CV ≤ 20% and recovery between 80-120% of the expected.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on 2 calibration curves for 9 runs each for 2 reagent lots across 3 instruments (18 runs total).

LLOQ	**0.005 pg/mL** pooled CV 15%, mean recovery 108%
LOD	**0.002 pg/mL** range 0.0001-0.004 pg/mL
Sample range	0–30 pg/mL
Diluted sample volume*	100 µL per measurement
Tests per kit	96

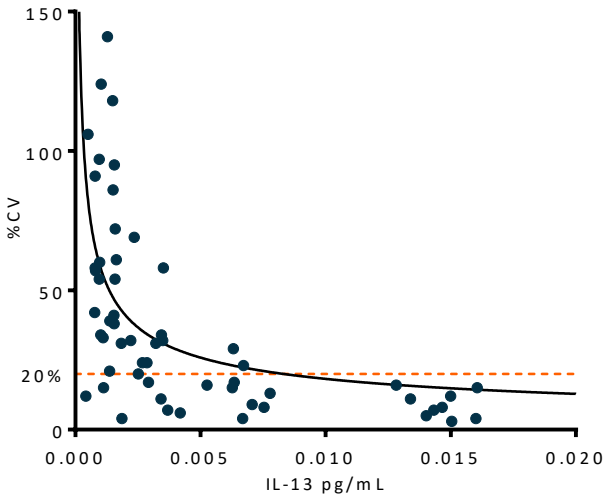
***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=22) and serum (n=22) samples were measured. Bars depict mean with SEM.



Matched human samples (n=22)	Mean IL-13 pg/mL	Median IL-13 pg/mL	% Above LOD
EDTA plasma	0.047	0.039	100%
Serum	0.038	0.029	100%

Sample Dose CV Profile: Triplicate measurements of diluted serum samples assayed over multiple runs (57 measurements).



Precision: Measurements of 3 serum or plasma-based panels and 2 calibrator-based controls. Triplicate measurements were made for 9 runs each for 2 reagent lots across 3 instruments (18 runs total, 54 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between lot CV
Control 1	0.227	5.9%	7.6%	0.5%	6.8%
Control 2	4.749	4.3%	5.6%	2.1%	1.3%
Panel 1	0.062	7.2%	6.9%	2.4%	2.6%
Panel 2	0.349	4.5%	7.8%	0.7%	8.0%
Panel 3	6.291	4.7%	9.4%	1.9%	6.7%

Spike and Recovery: 4 EDTA plasma samples and 4 serum samples were spiked at high and low concentrations within the range of the assay.

Endogenous Dilution Linearity: 2 endogenous EDTA plasma samples and 2 endogenous serum samples were diluted 2x serially from MRD (2x) to 32x with Sample Diluent.

Spiked Dilution Linearity: 1 spiked EDTA plasma sample was diluted 2x serially from MRD (2x) to 256x with Sample Diluent.

Spike and Recovery	**112%** Range 85-133%
Endogenous Dilution Linearity (32x)	**Mean = 87%** Range: 72-109%
Spiked Dilution Linearity (256x)	**Mean = 89%** Range: 78-102%

Specificity: Normal serum (n=5) and EDTA plasma (n=3) were directly incubated with capture antibody and run at MRD. Average knock-down was **98.1%** with a range of **94.5% -100%**.

The Simoa IL-13 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.

References:

1 Zurawski G and de Vries JE. Interleukin 13, an interleukin 4-like cytokine that acts on monocytes and B cells, but not on T cells. Immunol Today 1994; 15(1):19–26.

2 Ingram J and Kraft M. IL-13 in asthma and allergic disease: asthma phenotypes and targeted therapies. J Allergy Clin Immunol 2012 Oct; 130(4):829–42.

3 Minton K. Allergy and asthma: what "drives" IL-4 versus IL-13 signaling? Nature Reviews Immunol 2008; 8:166–167.

4 Wynn TA. IL-13 effector functions. Ann Rev Immunol 2003; 21:425–56.

5 Grunig G, Corry D, Reibman J, Wills-Karp M. Interleukin 13 and the evolution of asthma therapy. Am J Clin Exp Immunol 2013; 1(1):20–27.

6 Natoli A, Lüpertz R, Merz C, Müller W, Köhler R, Krammer P, Li-Weber M. Targeting the IL-4/IL-13 signaling pathway sensitizes Hodgkin lymphoma cells to chemotherapeutic drugs. Int J Cancer 2013; 133(8):1945–54.