Quanterix™
The Science of Precision Health

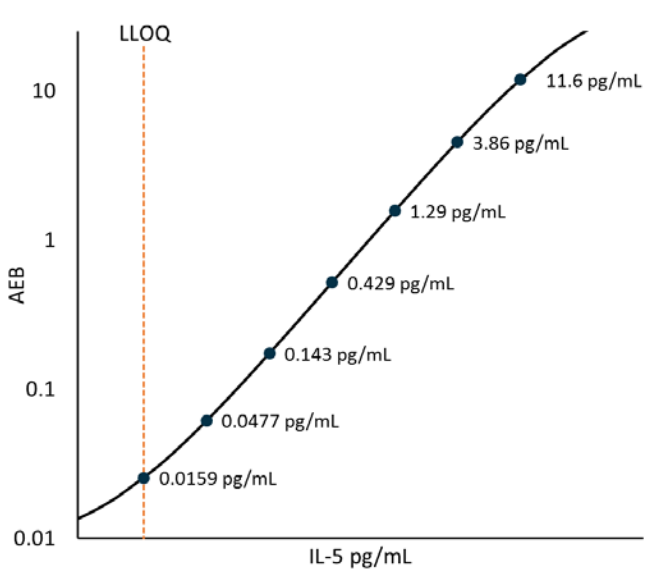
Simoa™ IL-5 Advantage Kit
SR-X™ Data Sheet

Item 102860

Description

Interleukin 5 (IL-5) is a cytokine with a length of 115 amino acids and a molecular weight of 15.2 kDa that is derived from T-cells with hematopoietic functions predominantly associated with antigen-induced eosinophilia. IL-5 induces differentiation of B-cells to immunoglobulin secreting cells and is an important factor in growth, differentiation and activation of eosinophils. IL-5, GM-CSF and IL-3 comprise the β-common (βc) cytokine family, so named because the receptors share a common β chain complexed with cytokine-specific α chains. IL-5 and IL-5R are the targets of therapeutic antibodies for treatment of eosinophilic asthma and are involved in type 2 inflammation in the mucosal allergic reaction to grass pollen. Activation of the IL-3/IL-5/GM-CSF receptors results in rapid activation of the JAK/STAT pathway.

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



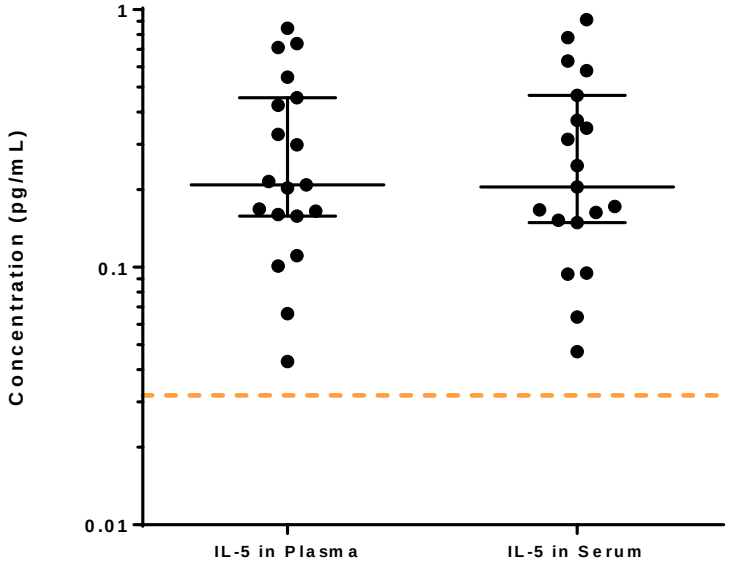
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 13 runs total over 2 reagent lots across 4 instruments.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 13 runs total over 2 reagent lots across 4 instruments.

LLOQ	**0.0165 pg/mL** pooled CV 18% mean recovery 102%
LOD	**0.0034 pg/mL** range 0.0007-0.0075 pg/mL
Dynamic range (serum and plasma)	0 - ~12 pg/mL
Diluted Sample volume*	152 µL per measurement
Tests per kit	96

***See Kit Instruction for details**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=19), and serum (n=19) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean IL-5 pg/mL	Median IL-5 pg/mL	% Above LOD
Serum	0.31	0.21	100%
Plasma	0.31	0.21	100%

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Assay designed by Joe Johnson

Precision: Measurements of 3 serum-based panels and 2 calibrator-based controls. Triplicate measurements were made for 15 runs total over 2 reagent lots across 4 instruments.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	0.31	8.1%	16.2%	9.9%	17.9%
Control 2	5.68	14.2%	11.7%	8.3%	10.2%
Panel 1	0.53	7.6%	9.6%	8.6%	0.3%
Panel 2	1.47	6.4%	11.9%	7.6%	7.0%
Panel 3	4.97	8.5%	12.3%	8.2%	3.1%

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: 2 EDTA plasma (1 endogenous and 1 spiked) and 2 serum samples (1 endogenous and 1 spiked) were diluted 2X serially starting from MRD (2x).

Spike and Recovery (Serum/Plasma)	**Mean = 82%** Range: 64-92%
Endogenous Dilution Linearity (16x)	**Mean = 96%** Range: 86–110%
Spiked Dilution Linearity (256x)	**Mean = 104%** Range: 85–130%

The Simoa IL-5 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.

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