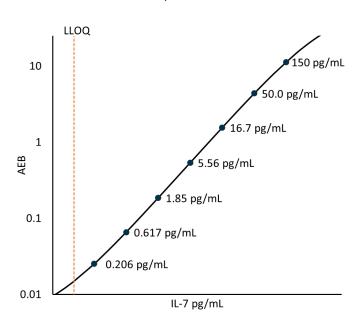
Simoa® IL-7 Advantage Kit HD-1/HD-X Data Sheet Item 103277

Description

Interleukin 7 (IL-7) is a pleiotropic cytokine of 177 amino acids (molecular weight 17.4 kDa) with central roles in modulating T- and B-cell development and T-cell homeostasis. The primary sources of IL-7 are bone marrow-derived stromal and epithelial cells. IL-7 is a hematopoietic growth factor secreted by stromal cells in the bone marrow and thymus. It is also produced by keratinocytes, dendritic cells, and hepatocytes. IL-7 promotes hematologic malignancies and is associated with viral infection. Circulating levels of IL-7 increase in response to T-cell depletion, suggesting a role in T-cell regeneration.

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



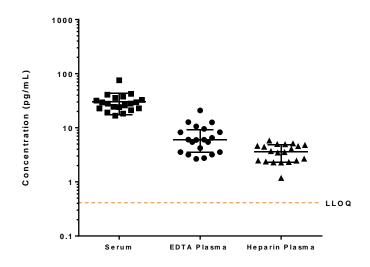
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrators were read back on the calibration curve over 11 runs total over 2 reagent lots across 3 instruments.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 11 runs total over 2 reagent lots across 3 instruments.

LLOQ	0.103 pg/mL pooled CV 7.3% mean recovery 82 %
LOD	0.009 pg/mL range 0.002-0.026 pg/mL
Dynamic range (serum and plasma)	0 - 600 pg/mL
Diluted Sample volume*	100 μL per measurement
Tests per kit	96

^{*}See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched K_2 EDTA plasma (n=20), Na Heparin plasma (n=20), serum (n=20) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean IL-7 pg/mL	Median IL-7 pg/mL	% Above LOD
Serum	30.3	28.0	100%
K ₂ EDTA Plasma	7.07	5.99	100%
Na Heparin Plasma	3.60	3.61	100%

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Precision: Measurements of 3 serum-based panels and 2 calibrator-based controls. Triplicate measurements were made for 14 runs total over 2 reagent lots across 3 instruments.

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV	Between Lot CV
Control 1	6.3	3.6%	11.3%	8.3%	11.2%
Control 2	161	3.5%	9.6%	8.4%	7.7%
Panel 1	2.82	6.5%	10.5%	3.0%	4.3%
Panel 2	34.6	2.9%	10.5%	8.0%	14.6%
Panel 3	113	4.0%	11.0%	3.9%	12.2%

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 HD-1.

Dilution Linearity: 4 EDTA plasma and 4 serum samples were diluted 2x serially from MRD (4x) to 64x with Sample Diluent.

Spike and Recovery	Mean = 82%
(Serum/Plasma)	Range: 48-108%
Endogenous Dilution	Mean = 118%
Linearity (64x)	Range: 65-156%