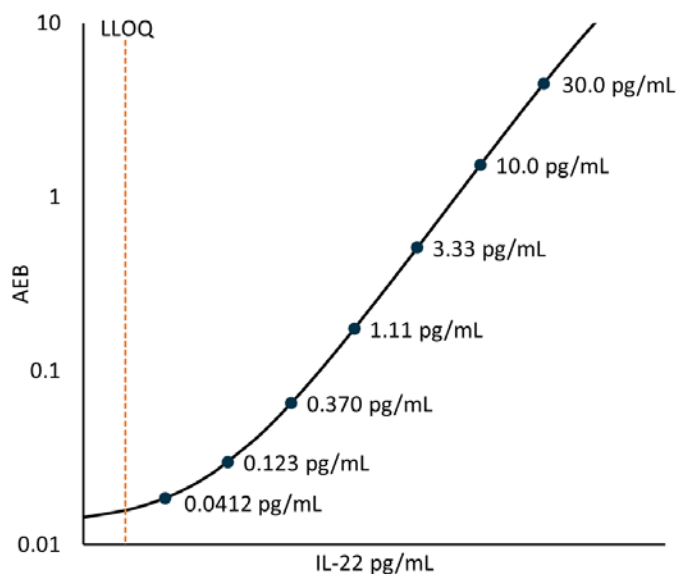


Description

IL-22 is a member of the IL-10 superfamily of cytokines. These cytokines are pleiotropic, affecting a wide range of immune functions. IL-22 is produced by Dendritic, T, and Innate Lymphoid cells and can be found in a wide range of tissues. Biological activity of IL-22 is initiated through interactions with IL-22R1 and IL-10R2, as well as IL-22BP1 and is regulated by IL-17A. IL-22 activation plays a role in the initiation and regulation of nonspecific immune response. IL-22 is associated with psoriasis; serum levels of the cytokine correlate with the severity of the disease. Emerging evidence suggests that IL-22 can play a role in other autoimmune disorders such as Inflammatory Bowel Disease, Rheumatoid Arthritis, and Multiple Sclerosis. IL-22 has also been implicated as a Reg gene regulator promoting β -cell production in Type 1 diabetes. The Total IL-22 Discovery assay detects free IL-22 and IL-22 bound to IL-22BP.

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



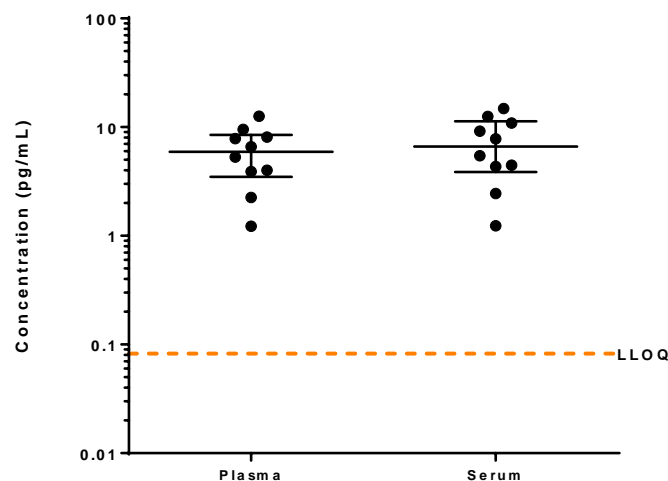
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

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	0.0206 pg/mL pooled CV 17% mean recovery 107%
LOD	0.0045 pg/mL range 0.0030-0.0063 pg/mL
Dynamic range (serum and plasma)	0-120 pg/mL
Diluted Sample volume*	100 μ L per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10), and serum (n=10) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean IL-22 pg/mL	Median IL-22 pg/mL	% Above LOD
Serum	7.31	6.62	100%
EDTA Plasma	6.13	5.94	100%

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	0.889	4.8%	3.4%	0.1%
Control 2	25.7	3.1%	2.4%	0.5%
Panel 1	0.928	3.3%	4.5%	2.2%
Panel 2	6.88	4.0%	4.4%	1.3%
Panel 3	20.9	2.4%	5.6%	2.0%

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 spiked EDTA plasma and 1 spiked serum sample were diluted 2X serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 93% Range: 78-112%
Dilution Linearity (256x)	Mean = 106% Range: 102–117%

The Simoa Total IL-22 Discovery 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.