Quanterix™
The Science of Precision Health

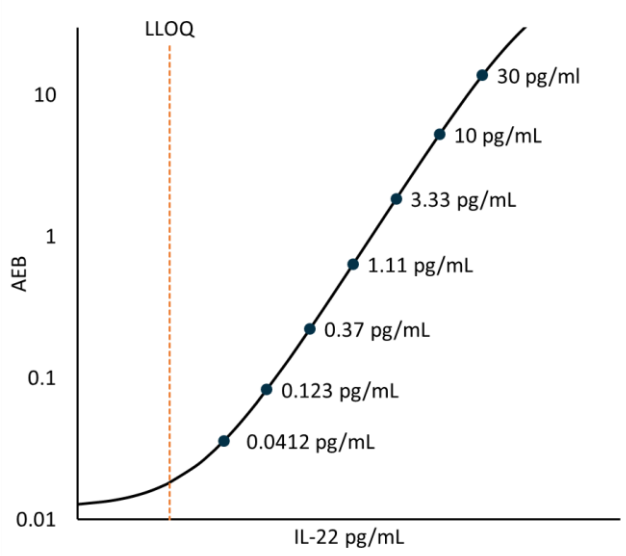
Simoa® Total IL-22 Discovery Kit
HD-1/HD-X Data Sheet

Item 103071

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, perhaps due to its role in inflammatory responses, which are regulated by IL-17A. 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.

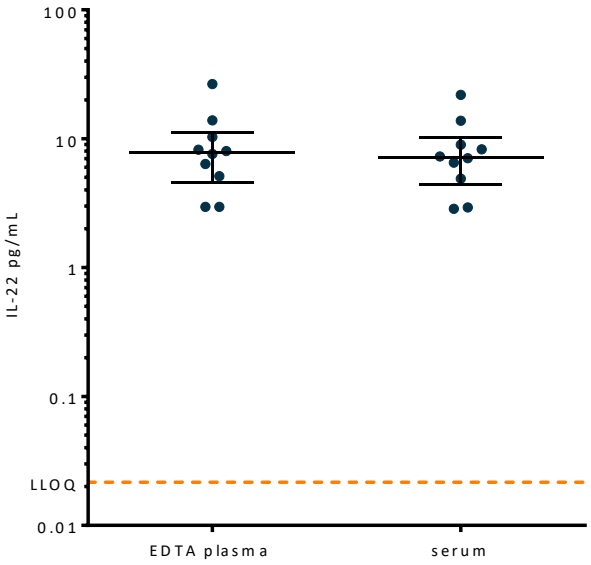


Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve for 5 runs each for 1 reagent lot on a single instrument (5 runs total). The LLOQ is determined as the lowest dilution with a pooled CV ≤ 20% and sample concentration recovery 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 each calibration over 5 runs for 1 reagent lot on a single instrument (5 runs total).

LLOQ	**0.0103 pg/mL** pooled CV 9% mean recovery 120%
LOD	**0.0054 pg/mL** range 0.0026-0.0090 pg/mL
Dynamic range	0–120 pg/mL
Sample volume	80 µL Minimum for 2 reps
Tests per kit	192

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=10) and serum (n=10) samples were measured. Bars depict median with interquartile range.



Matched human samples (n=10)	Mean IL-22 pg/mL	Median IL-22 pg/mL	% Above LOD
EDTA plasma	9.19	7.82	100%
Serum	8.44	7.16	100%

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Precision: Measurements of 3 serum or plasma-based panels. Triplicate measurements were made for 5 runs using 1 reagent lot and a single instrument (5 runs total, 15 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV
Panel 1	0.834	8.2%	4.7%
Panel 2	6.10	6.1%	7.4%
Panel 3	20.3	5.4%	7.0%

Spike and Recovery: 2 EDTA plasma and 4 serum samples were spiked at high and low concentrations within the range of the assay.

Dilution Linearity: 1 endogenous EDTA plasma and 1 endogenous serum sample were serially diluted 2x serially from MRD (4x) to 256x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**97%** Range 86-119%
Plasma Dilution Linearity (256x)	**Mean = 117%** Range: 107-128%
Serum Dilution Linearity (256x)	**Mean = 115%** Range: 104-124%

Specificity: Two normal serum samples and one normal plasma sample were pre-incubated with 100X capture antibody. Antibody was removed and samples were run at MRD in the assay. Average knock-down relative to control without pre-incubation was **100%**.

The Simoa Total IL-22 Discovery 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.