Quanterix®
The Science of Precision Health

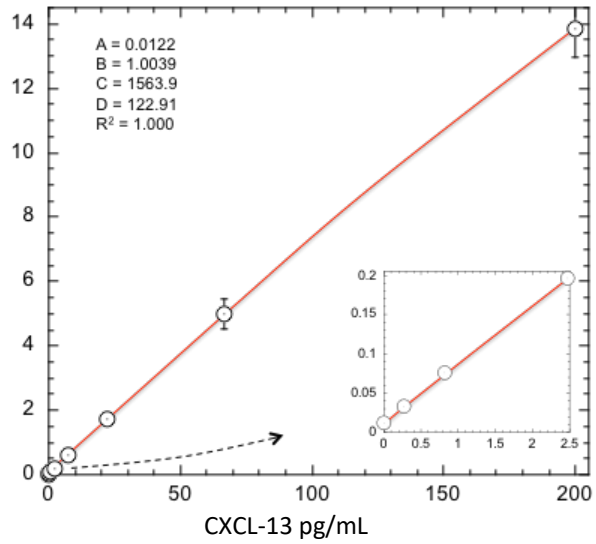
Simoa® CXCL-13 Discovery Kit
HD-1/HD-X Data Sheet

Item 102635

Description

The CXCL-13 (CXC Ligand 13) protein, also known as B cell attracting chemokine 1 (BCA-1) or B lymphocyte chemo-attractant (BLC) is a chemokine ligand. It is expressed in secondary lymphoid tissue by stromal cells within B-cell follicles and by follicular dendritic cells, macrophages, and germinal center T cells. The CXCL-13 receptor CXCR5 is expressed on follicular B cells. CXCL-13 interaction with its receptor causes germinal center formation as part of a normal immune response to infection. The main role of CXCL-13 is homeostatic immune cell trafficking and levels may become up-regulated under pathological conditions. CXCL-13 and CXCR5 are expressed in prostrate, breast, neuronal and oral carcinomas. Elevated serum CXCL-13 levels have been observed in lung cancer and breast cancer patients. CSF data shown is for information only.

Calibration Curve: Four-parameter curve fit parameters are depicted.



Minimum Required Dilution (MRD)

Diluted Sample Volume	100 µL per measurement
Serum and Plasma Dilution	1:4
CSF Dilution	Neat
Tests per kit	192

See Kit Instruction for details.

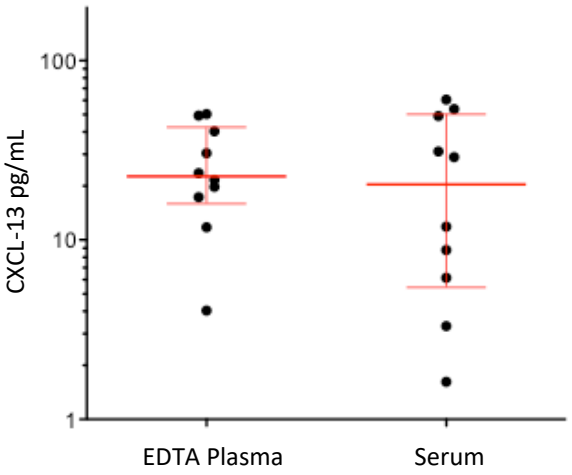
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total). The functional LLOQ (fLLOQ) value below is for serum and plasma.

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 1 reagent lot across 1 instrument (5 runs total).

Assay Range: The upper end of the dynamic range is equal to the top calibrator concentration multiplied by MRD. The range below is for serum and plasma. The range for CSF is equivalent to the calibrator range.

Analytical LLOQ	**0.070 pg/mL** pooled CV 16% mean recovery 105%
Functional LLOQ (serum and plasma)	**0.28 pg/mL**
LOD	**0.048 pg/mL** range 0.045–0.057 pg/mL
Dynamic Range (serum and plasma)	0 – 800 pg/mL

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



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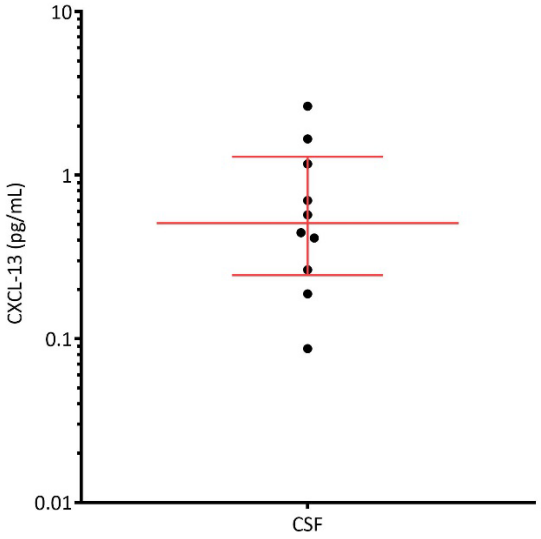
Endogenous CSF Reading: Healthy donor CSF (n=10), was measured. Bars depict median with interquartile range.



Sample Type	Median CXCL-13 pg/mL	% Above LOD
Serum	20.4	100%
Plasma	22.6	100%
CSF	0.510	100%

Precision: Measurements of 3 serum-based panels and 2 plasma-based panels. Triplicate measurements were made for 5 runs each for 1 reagent lot across 3 instruments (5 runs total, 15 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV
Serum Panel 1	3.32	6.7%	7.4%
Serum Panel 2	5.68	4.2%	10.6%
Serum Panel 3	0.866	15.1%	9.0%
Plasma Panel 4	23.8	7.8%	9.1%
Plasma Panel 5	18.7	4.4%	8.7%

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

Dilution Linearity: 1 spiked EDTA plasma and 1 spiked serum sample were diluted 2x serially from MRD (4x) to 128x with Sample Diluent. 2 endogenous CSF samples were diluted 2x serially to 16x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean 87.1%** range 65.4–107.9%
Spike and Recovery (CSF)	**Mean 93.6%** range 87.6-99.7%
Dilution Linearity (Serum/Plasma, 128x)	**Mean 92.8%** range 82.6–103.9%
Dilution Linearity (CSF, 16x)	**Mean 112.3%** range 95.6–125.5%

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