Simoa® NF-light™ Advantage (SR-X) Kit
SR-X Data Sheet

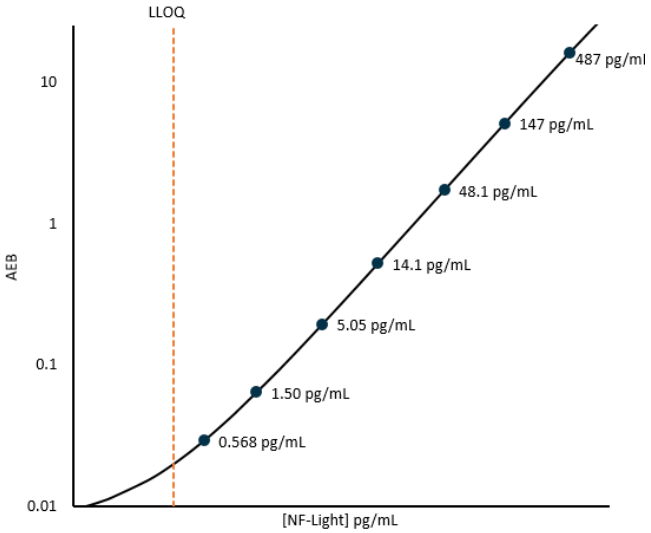
Item 103400

Description

The Simoa NF-light (SR-X) assay kit is formulated for use on the Quanterix SR-X™ platform only.

Neurofilament light (NF-L) is a 68 kDa cytoskeletal intermediate filament protein that is expressed in neurons. It associates with the 125 kDa Neurofilament medium (NF-M) and the 200 kDa Neurofilament heavy (NF-H) to form neurofilaments. They are major components of the neuronal cytoskeleton and are believed to function primarily to provide structural support for the axon and to regulate axon diameter. Neurofilaments can be released in significant quantity following axonal damage or neuronal degeneration. NF-light has been shown to associate with traumatic brain injury, multiple sclerosis, frontotemporal dementia, and other neurodegenerative diseases. The Simoa NF-light assay is a digital immunoassay for the quantitative determination of NF-light in serum, plasma, and CSF. The antibodies (Uman Diagnostics, Umeå Sweden) also cross react with murine, bovine, and macaque NF-light epitopes, and the assay can be used for research with these species.

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



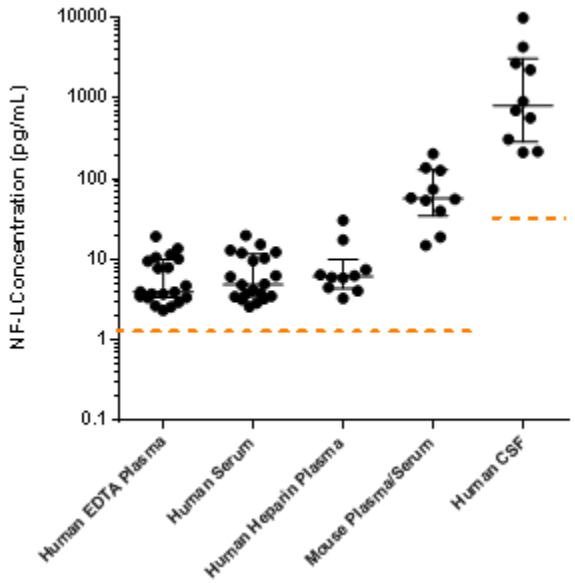
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 3 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**0.316 pg/mL** pooled CV 19% mean recovery 102%
LOD	**0.0552 pg/mL** range 0.0152-0.108 pg/mL
Dynamic range (serum/plasma)	0– ~2000 pg/mL
Dynamic range (CSF)	0- ~50 ng/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	96

***Serum and Plasma diluted 1:4, CSF diluted 1:100. Refer to Kit Instruction for details.**

Endogenous Sample Reading: Healthy donor matched EDTA plasma (n=20), serum (n=20), and unmatched Heparin Plasma (n=10), CSF samples (n=10) and Mouse serum and plasma (n=5 each) were measured. Bars depict median with interquartile range. Orange lines represent functional LLOQ.



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Sample Type	Mean NF-light pg/mL	Median NF-light pg/mL	% Above LOD
EDTA plasma	6.59	3.97	100%
Serum	7.29	4.91	100%
CSF	2214	808	100%
Heparin Plasma	9.23	6.20	100%
Mouse Serum and Plasma	78.6	57.0	100%

Precision: Measurements of 3 serum or plasma based panels and 2 calibrator based controls. Triplicate measurements were made for 3 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	5.08	10.7%	6.9%	0%
Control 2	169	9.3%	5.3%	2.4%
Panel 1	5.16	6.5%	8.5%	1.3%
Panel 2	7.22	7.9%	6.2%	4.7%
Panel 3	88.7	3.3%	7.1%	5.1%
Panel 4	358	5.4%	11.7%	6.4%

Spike and Recovery: 2 EDTA plasma samples and 2 serum samples were spiked with CSF* containing two different concentrations of endogenous NF-light within the range of the assay and analyzed on the SR-X.

Dilution Linearity: Endogenous or CSF spiked EDTA plasma and serum samples were diluted 2X serially with sample diluent from MRD (4X) to 32X for endogenous samples and from MRD (4X) to 128X for CSF spiked samples.

2 CSF samples were diluted 2x serially with sample diluent from MRD (100X) to 6400X.

Spike and Recovery (Serum/Plasma)	**Mean = 78%** Range: 74%-82%
Serum/Plasma Endogenous Linearity (32X)	**Mean = 109%** Range: 96%-127%
Serum/Plasma with CSF Spike Linearity (128X)	**Mean = 120%** Range: 103%-138%
CSF Dilution Linearity	**Mean = 83%** Range: 68%-102%

*CSF as a source of native NF-light for serum/plasma spike-recovery experiments is recommended over commercially available antigen, as the latter is typically recombinant or animal-sourced NF-light. Non-native and animal forms of NF-light have been found to interact differently with sample matrix than native NF-light, which can lead to poor recovery or linearity results.

The Simoa NF-light (SR-X) assay kit is formulated for use on the SR-X platform only. Data in this document was obtained from runs on the SR-X platform.

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