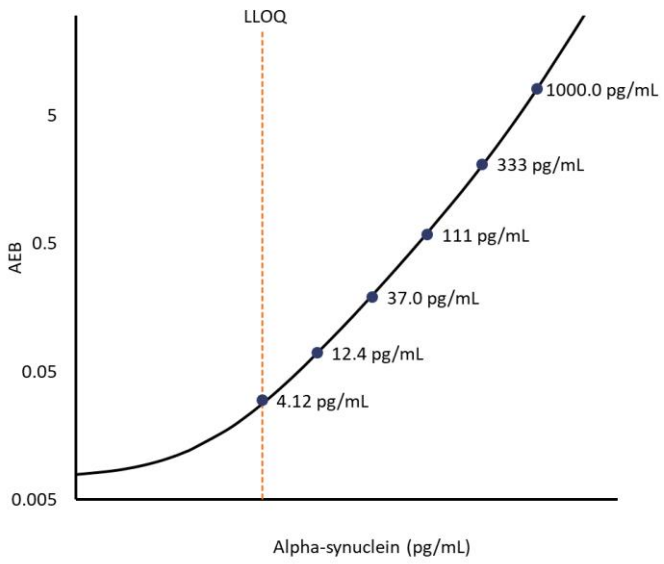
Simoa® Alpha-Synuclein Discovery Kit

SR-X® Data Sheet Item 102233

Description

Alpha-Synuclein (α-Synuclein) is a member of the synuclein family of proteins including β-synuclein and γ-synuclein. This assay measures total α-synuclein, including monomeric and oligomeric conformations, regardless of phosphorylation. α-Synuclein has been found concentrated in the presynaptic nerve terminals of neurons and in the nucleus of neurons. The human α-synuclein protein is made of 140 amino acids, encoded by the SNCA gene. The physiological function of α-synuclein may associate with regulating synaptic transmission, dopamine metabolism, vesicle trafficking etc. While native α-synuclein is unfolded, it has a propensity to form toxic soluble oligomers (i.e., protofibrils) that ultimately aggregate into insoluble fibrils. The fibrils and amyloidal forms of α-synuclein are major components of Lewy bodies. α-Synuclein has been linked to the pathogenesis of Parkinson's disease, Parkinson's disease dementia, and dementia with Lewy bodies. α-Synuclein is also shown to be linked with Alzheimer's disease.

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



Minimum Required Dilution (MRD)

Diluted Sample Volume	152 µL per measurement
Serum, Plasma, and CSF Dilution	1:10
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 6 runs each for 1 reagent lot across 2 instruments (6 runs total). The functional LLOQ (fLLOQ) values below are for serum, plasma, and CSF.

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).

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

Analytical LLOQ	**4.12 pg/mL** pooled CV 13% mean recovery 93%
Functional LLOQ	**41.2 pg/mL**
LOD	**0.440 pg/mL** range 0.008–0.953 pg/mL
Dynamic Range	0 – 10,000 pg/mL

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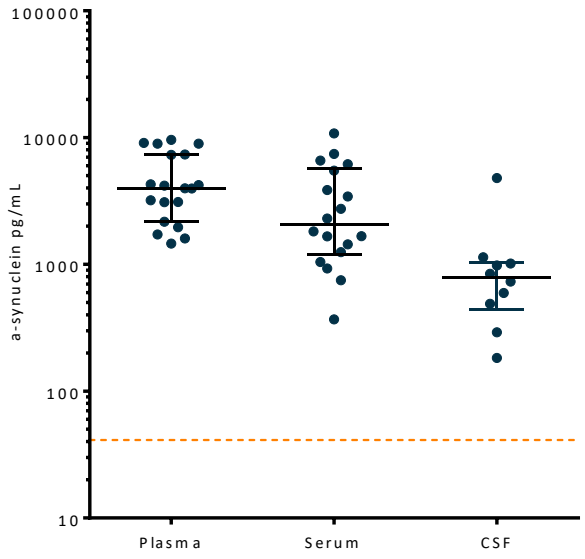
SR-X® Data Sheet Item 1022332233

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



Sample Type	Mean Alpha-synuclein pg/mL	Median Alpha-synuclein pg/mL	% Above LOD	% Above LLOQ
Serum*	3,317	2,059	100%	100%
Plasma*	4,747	3,976	100%	100%
CSF	1,106	787	100%	100%

*Does not include one plasma and two serum samples above the assay range

Precision: Measurements of 2 endogenous serum samples, 2 endogenous plasma samples, 2 endogenous CSF samples, 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	265	2.7%	16%	17%
Control 2	2,742	2.6%	11%	12%
Serum 1	1,695	4.3%	10%	22%
Serum 2	2,059	4.2%	12%	17%
Plasma 1	869	3.1%	16%	13%
Plasma 2	2,453	6.3%	14%	11%
CSF 1	1,249	4.6%	28%	4%
CSF 2	648	4.4%	16%	10%

Spike and Recovery: 2 serum, 2 EDTA plasma, and 2 CSF samples were spiked at a concentration within the range of the assay and analyzed on SR-X.

Dilution Linearity: 2 endogenous EDTA plasma, 2 endogenous serum, and 2 endogenous CSF samples were diluted 2x serially from MRD (10x) to 640x with Sample Diluent.

Spike Recovery (Serum/Plasma)	**Mean 124%** Range: 72–164%
Spike Recovery (CSF)	**Mean 135%** Range: 106-165%
Dilution Linearity (serum) (640x)	**Mean 83%** Range: 65-106%
Dilution Linearity (plasma) (640x)	**Mean 84%** Range: 66-94%
Dilution Linearity (CSF) (640x)	**Mean 80%** Range: 60-88%

The Simoa Alpha-synuclein Discovery assay kit is formulated for use on the SR-X, HD-1, or HD-X platform. Some differences in performance claims between the HD and SR-X platforms may be observed when comparing data sheets for these 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.

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