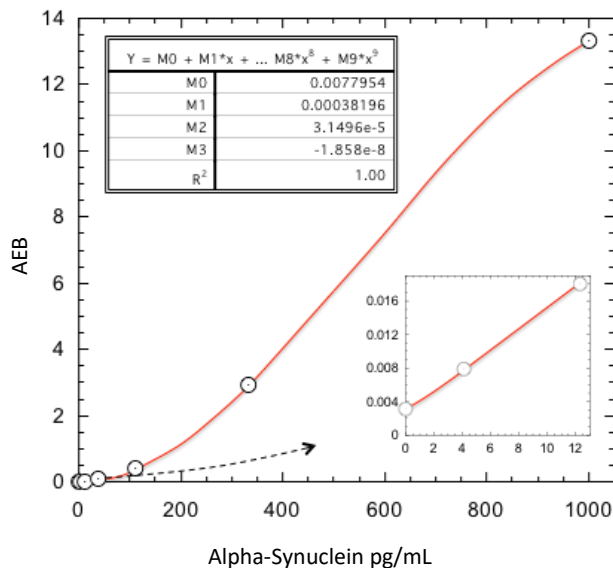


Description

Alpha-Synuclein (α -Synuclein) is a member of the synuclein family of proteins including β -synuclein and γ -synuclein. 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: Four-parameter curve fit parameters are depicted.



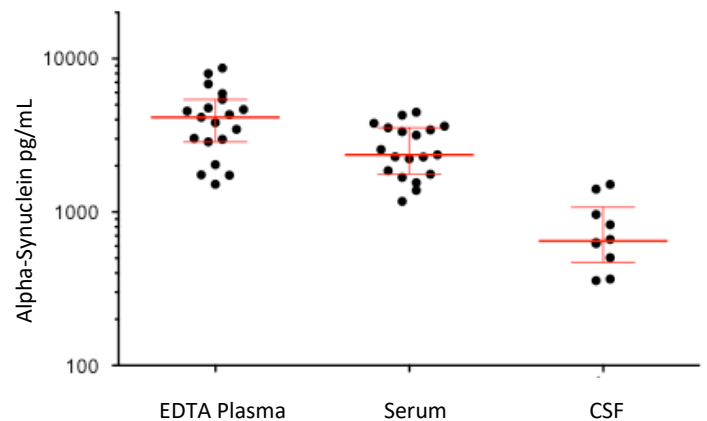
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve for 1 reagent lot on 1 instrument (5 runs total).

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

LLOQ	4.12 pg/mL pooled CV 14.0% mean recovery 101%
LOD	0.955 pg/mL range 0.202–1.760 pg/mL
Dynamic range (serum and plasma)	0–10,000 pg/mL
Diluted Sample volume*	152 μ L per measurement
Tests per kit	192

*See Kit Instruction for details

Endogenous Sample Reading: Healthy donor EDTA plasma (n=20) and serum (n=20) were measured. 10 CSF samples were measured. Error bars depict median with interquartile range.



Sample Type	Median Alpha-Synuclein pg/mL	% Above LOD
Serum	2645	100%
Plasma	4145	100%
CSF	648	100%

Precision: Representative precision was estimated with repeated assay of serum panels using three instruments and one reagent lot. Within-run and between-run CVs are depicted in the following table. Within-run CVs reflect average CVs across 5 experiments of 3 replicates each.

Sample	Mean (pg/mL)	Within run CV	Between run CV
Panel 1	1933.4	3.1%	3.2%
Panel 2	3325.0	5.2%	2.2%
Panel 3	562.9	3.1%	2.3%

Spike and Recovery: α -Synuclein spiked into 2 serum and 2 plasma samples at 2 levels. α -Synuclein spiked into 4 CSF samples at 2 levels.

Dilution Linearity: Spiked serum diluted 2x serially from MRD (10x) to 320x with Sample Diluent. CSF sample diluted 2x serially from MRD (10x) to 640x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 86.0% Range: 79.7-93.6%
Spike and Recovery (CSF)	Mean = 105.7% Range: 102.4-108.4%
Dilution Linearity (Serum, 320x)	Mean = 94.7% Range: 82.2-105.7%
Dilution Linearity (CSF, 640x)	Mean = 88.0% Range: 74.9-100.1%