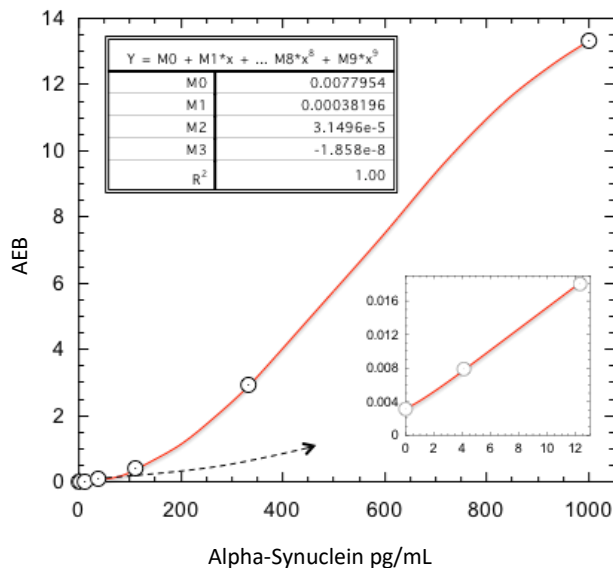


**Description**

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

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



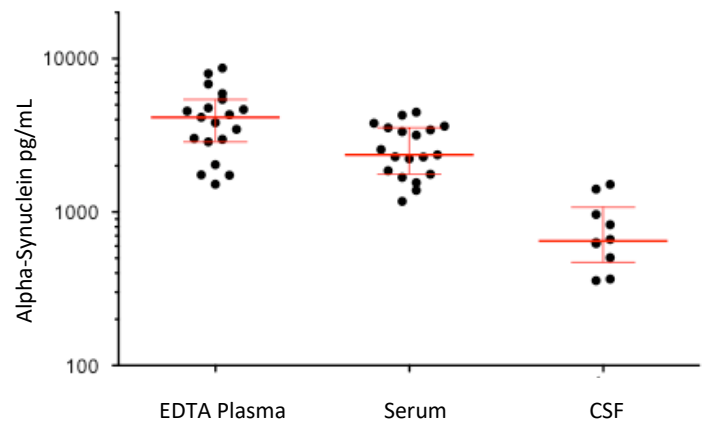
**Lower Limit of Quantification (LLOQ):** Triplicate measurements of serially diluted calibrator were read back on the calibration curve for 1 reagent lot on 1 instrument (5 runs total).

**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).

<b>LLOQ</b>	<b>4.12 pg/mL</b> pooled CV 14.0% mean recovery 101%
<b>LOD</b>	<b>0.955 pg/mL</b> range 0.202–1.760 pg/mL
<b>Dynamic range (serum and plasma)</b>	0–10,000 pg/mL
<b>Diluted Sample volume*</b>	152 $\mu$ L per measurement
<b>Tests per kit</b>	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:**  $\alpha$ -Synuclein spiked into 2 serum and 2 plasma samples at 2 levels.  $\alpha$ -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.

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