Quanterix

Discovery 102233 simoa Alpha-Synuclein

SUMMARY AND EXPLANATION OF THE TEST

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.

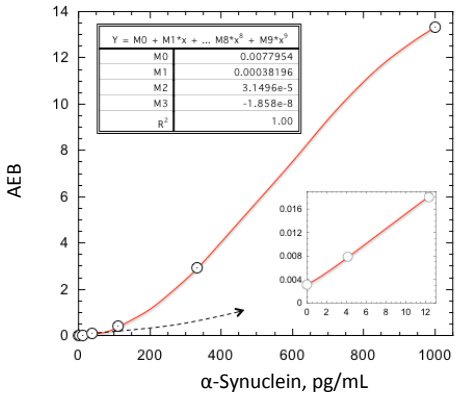

Figure 1: Simoa™ α-Synuclein immunoassay calibration curve. Cubic curve fit parameters are depicted.

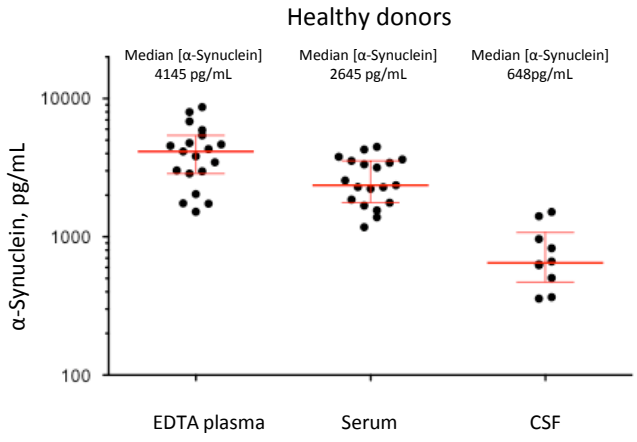

Figure 2: [α-Synuclein] in EDTA plasma (n = 20), matched serum (n = 20), and cerebral spinal fluid (CSF, n = 10). Error bars depict median and interquartile ranges.

Table 1: General characteristics of Simoa Human α-Synuclein immunoassay

Calibration range	0-1,000 pg/mL
Dynamic range[1]	0-10,000 pg/mL
Lower limit of detection (2.5SD; 3 reps x 5 runs, 1 instrument, 1 reagent lot; mean LoD[2]	0.955 pg/mL
Lower limit of quantification (5 runs, 1 instrument, 1 reagent lot)[3]	4.12 pg/mL
Spike-recovery (serum/plasma) (α-Synuclein spiked into 2 serum and 2 plasma samples at 2 levels, mean[4])	86.0%
Spike-recovery (CSF) (α-Synuclein spiked into 4 CSF samples at 2 levels, mean[5])	105.7%
Dilution Linearity (serum) (Spiked serum diluted 2x serially from MRD to 32xMRD with Sample Diluent, mean recovery[6])	94.7%
Dilution Linearity (CSF) (CSF sample diluted 2x serially from MRD to 64xMRD with Sample Diluent, mean recovery[7])	88.0%
Typical sample volume (Includes dead volume; see Package Insert for details)	19 µL
Minimum sample volume (Includes dead volume; see Package Insert for details)	2.1 µL

The Simoa Human α-Synuclein immunoassay quantifies α-synuclein in serum, plasma and CSF with median α-synuclein values well above the sensitivity limit.

[1]Samples auto-diluted 10X. [2]SD 0.691 pg/mL; range 0.202-1.760 pg/mL. [3]≤20%CV, 80-120% recovery; pooled CV 14.0%, mean recovery 101.1%; not corrected for pre-dilutions; 10X LoQ 41.2 pg/mL. [4]Range 79.7-93.6%. [5]Range 102.4-108.4%. [6]Range 82.2-105.7%; minimum recommended dilution (MRD) 1:10 . [7]Range 74.9-100.1%; MRD 1:10.

Table 2: Precision characteristics of Simoa Human α-Synuclein immunoassay. 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 α-Synuclein (pg/mL)	Within Run %CV (n=5)	Between Run %CV (n=5)
Serum panel 1	1933.4	3.1	3.2
Serum panel 2	3325.0	5.2	2.2
Serum panel 3	563	3.1	2.3

Simoa HD-1 Analyzer

Representative data. Individual results may vary depending upon samples tested and protocols followed.

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