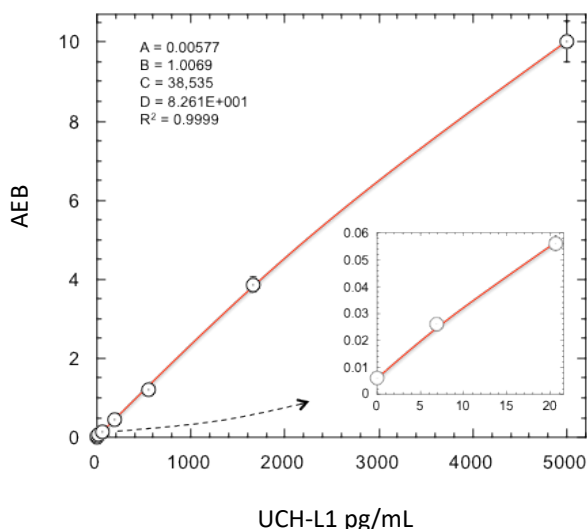


Description

Ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) hydrolyzes small C-terminal adducts of ubiquitin to generate the ubiquitin monomer. It is also called PARK5 or neuronal-specific protein gene product 9.5. Expressed predominantly in neurons, UCH-L1 is one of the most abundant brain protein, representing 1 to 2% of total soluble brain protein. In vivo, UCH-L1 has been shown to be involved in the regulation of the ubiquitin pool, apoptosis, learning and memory, and its absence in mice because of spontaneous intragenic deletions yields phenotypes with neurological defects.³ A point mutation (I93M) and a polymorphism (S18Y) in this gene have been shown to associate with Parkinson’s disease. Recently, UCH-L1 has been proposed as a candidate biomarker for brain injury. UCH-L1 can be released from injured neurons and flow into the cerebrospinal fluid and circulating blood.

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



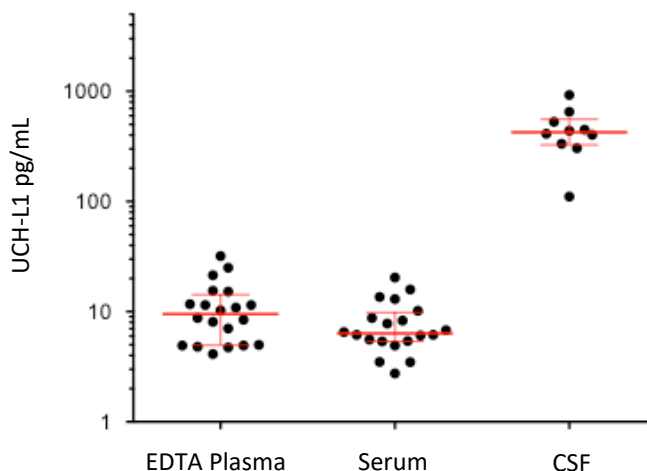
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

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

LLOQ	3.43 pg/mL pooled CV 10.6% mean recovery 107%
LOD	1.05 pg/mL range 0.481–1.78 pg/mL
Dynamic range (serum and plasma)	0–20,000 pg/mL
Diluted Sample volume*	152 µL per measurement
Tests per kit	192

*See Kit Instruction for details

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



Sample Type	Median UCH-L1 pg/mL	% Above LOD
Serum	7.62	100%
EDTA Plasma	9.51	100%
CSF	425	100%

Precision: Representative precision was estimated with repeated assay of serum panels using one instrument 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
Serum Panel 1	27.49	9.9%	3.9%
Serum Panel 2	1483	7.4%	4.3%
Plasma Panel 3	231	6.3%	4.6%

Spike and Recovery (Serum/Plasma): UCH-L1 spiked into 2 serum and 2 plasma samples at 2 levels.

Spike and Recovery (CSF): UCH-L1 spiked into 4 CSF samples at 2 levels.

Dilution Linearity (Serum): Spiked serum diluted 2x serially from MRD (4x) to 512x with Sample Diluent.

Dilution Linearity (CSF): CSF sample diluted 2x serially from MRD (10x) to 1280x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	Mean = 103% Range: 74.8–127%
Spike and Recovery (CSF)	Mean = 112% Range: 106–124%
Dilution Linearity (Serum, 512x)	Mean = 106% Range: 96.1–114%
Dilution Linearity (CSF, 1280x)	Mean = 90.5% Range: 83.0–94.7%