Quanterix
The Science of Precision Health

Simoa® GFAP* Discovery Kit

HD-1/HD-X Data Sheet

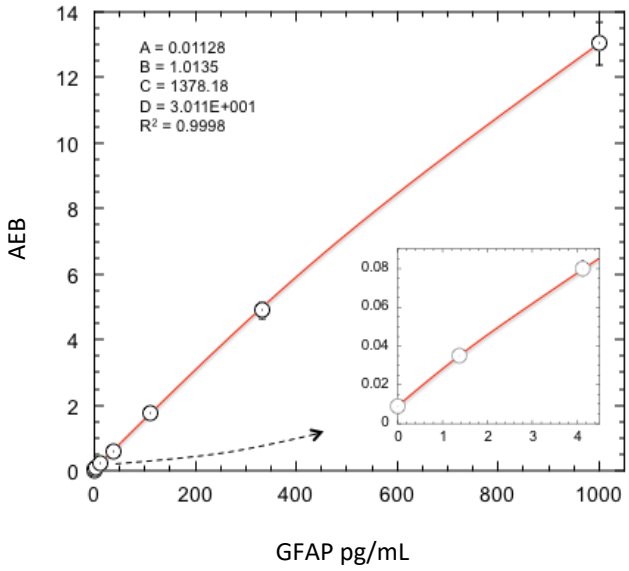
* Banyan GFAP™

Item 102336

Description

Glial Fibrillary Acidic Protein (GFAP) is a class-III intermediate filament majorly expressed in astrocytic glial cells in the central nervous system. Astrocytes play a variety of key roles in supporting, guiding, nurturing, and signaling neuronal architecture and activity. Monomeric GFAP is about 55kD. It can form both homodimers and heterodimers; GFAP can polymerize with other type III proteins or with neurofilament protein (such as NF-L). GFAP is involved in many important CNS processes, including cell communication and the functioning of the blood brain barrier. As a potential biomarker, GFAP has been shown to associate with multiple diseases such as traumatic brain injury, stroke, brain tumors, etc. Decreases in GFAP expression have been reported in Down's syndrome, schizophrenia, bipolar disorder, and depression.

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



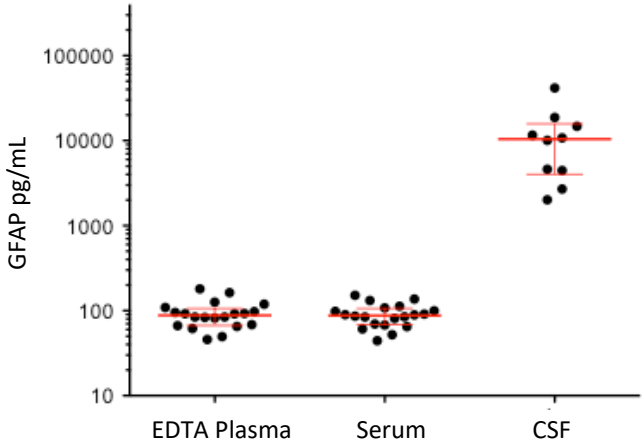
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

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	**0.686 pg/mL** pooled CV 13.6% mean recovery 108%
LOD	**0.211 pg/mL** range 0.108–0.284 pg/mL
Dynamic range (serum and plasma)	0–4,000 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 CSF samples were measured. Error bars depict median with interquartile ranges.



Sample Type	Median GFAP pg/mL	% Above LOD
Serum	90.6	100%
Plasma	88.0	100%
CSF	10,427	100%

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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	31.75	6.3%	5.7%
Panel 2	317.6	10.9%	13.0%
Panel 3	2,282	8.2%	13.6%

Spike and Recovery (Serum/Plasma): GFAP spiked into 4 serum and 4 plasma samples at 2 levels.

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

Dilution Linearity (CSF): CSF sample diluted 2x serially from MRD (40x) to 5,120x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean = 71.6%** Range: 43.1–110.8%
Dilution Linearity (Serum/Plasma 512x)	**Mean = 110%** Range: 94.3–120%
Dilution Linearity (CSF 5,120x)	**Mean = 90.1%** Range: 85.1–90.4%

The Simoa GFAP Discovery assay kit is formulated for use on the SR-X®, HD-1, or HD-X® platform. Data in this document was obtained from runs on the HD-1 platform unless otherwise noted. Some differences in performance claims between SR-X and HD-1/HD-X may be observed when comparing datasheets for these platforms. This may be due to experiments run at different time-points with different reagent lots and different samples, or it may be due to minor differences in antibody and analyte behavior in the different assay formats.

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