Quanterix™
The Science of Precision Health

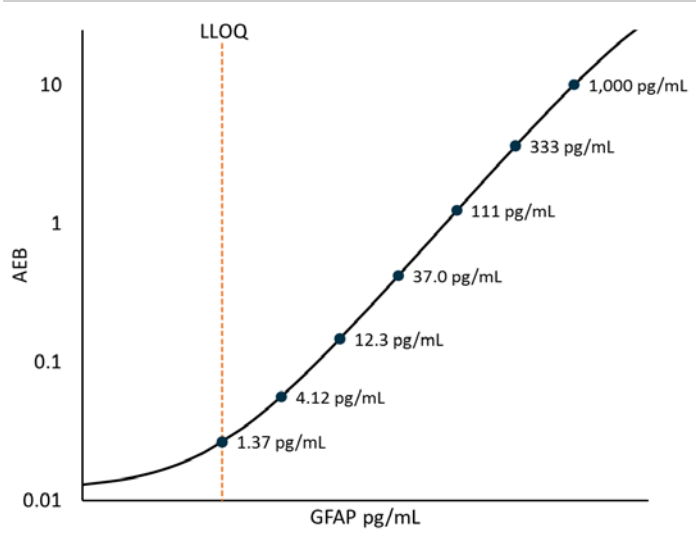
Simoa™ GFAP Discovery Kit
SR-X™ Data Sheet

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 is capable of forming 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. GFAP, as a potential biomarker, 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: Calibrator concentrations and Lower Limit of Quantification depicted.



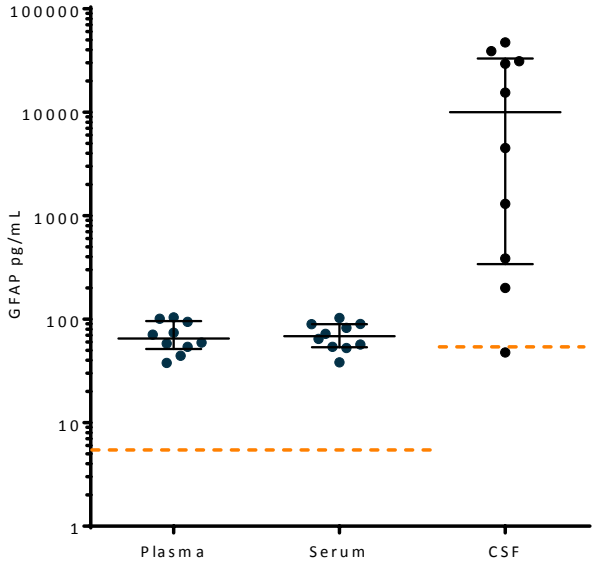
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

Limit of Detection (LOD): Calculated as 2.5 standard deviations from the mean of background signal read back on each calibration curve over 6 runs each for 1 reagent lot across 2 instruments (6 runs total).

LLOQ	**1.37 pg/mL** pooled CV 15% mean recovery 109%
LOD	**0.26 pg/mL** range 0.049-0.511 pg/mL
Dynamic range (serum,plasma and CSF)	Serum and plasma: 0 - 4 ng/mL CSF: 0 - 40 ng/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=10) and serum (n=10), and cerebral spinal fluid (n=10) were measured. Bars depict median with interquartile range. Orange line represents functional LLOQ.



Sample Type	Mean GFAP pg/mL	Median GFAP pg/mL	% Above LOD
Serum	70.4	68.4	100%
Plasma	69.8	65.2	100%
CSF	18761*	10010	100%

*Values below LLOQ are not included in the mean

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Assay designed by Marcella

Precision: Measurements of 2 serum-based and 1 plasma-based panels and 2 calibrator-based controls. Triplicate measurements were made for 6 runs each for 1 reagent lot across 2 instruments (6 runs total, 18 measurements).

Sample	Mean (pg/mL)	Within run CV	Between run CV	Between inst CV
Control 1	48.0	7.1%	6.7%	0.1%
Control 2	1063	5.2%	6.2%	3.9%
Panel 1	35.0	9.6%	5.7%	5.1%
Panel 2	399	13.7%	9.5%	1.6%
Panel 3	2040	5.4%	3.7%	0.8%

Spike and Recovery: 2 serum and 2 EDTA plasma samples were spiked at high and low concentrations within the range of the assay and analyzed on SR-X.

Dilution Linearity: 1 spiked EDTA plasma and 1 spiked serum sample were diluted 2X serially from MRD (4x) to 128x with Sample Diluent. 1 endogenous CSF sample was diluted 2X serially from MRD (40x) to 128x with Sample Diluent.

Spike and Recovery (Serum/Plasma)	**Mean = 57%** Range: 37-81%
Dilution Linearity Serum and Plasma (128x)	**Mean = 104** Range: 83–122%
Dilution Linearity CSF (128x)	**Mean = 86%** Range: 69–118%

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

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