Quanterix™
The Science of Precision Health

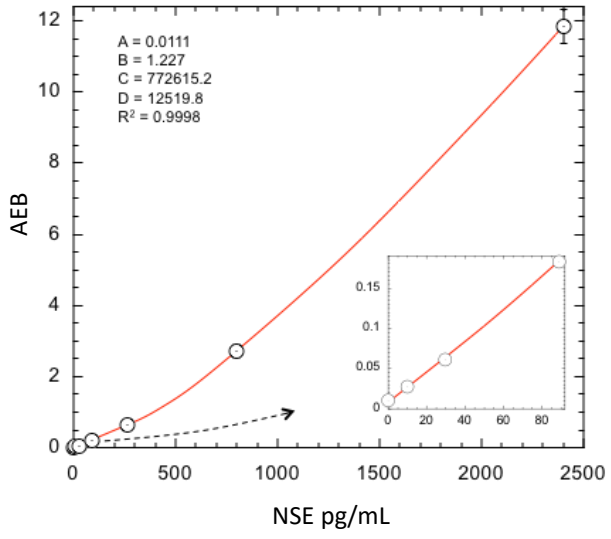
Simoa® NSE Discovery Kit
HD-1/HD-X Data Sheet

Item 102475

Description

Neuron-Specific Enolase (NSE), also known as Gamma-enolase, is a 78kDa enzyme of the glycolytic pathway expressed predominantly in neurons and cells of the neuroendocrine system. The C-terminal part of the molecule has been shown to promote survival of neuronal cells by regulating neuronal growth factor receptor dependent signaling pathways, resulting also in extensive actin cytoskeleton remodeling. NSE is a tumor marker used in diagnosis and prognosis of cancer; however its mechanism in malignant progression remains elusive. Studies in Traumatic Brain Injury (TBI) have shown NSE levels increase during the first 12 hours after trauma and decrease within hours. NSE is not secreted, but when there is axonal damage to neurons NSE levels are up regulated to maintain homeostasis, therefore it can be used to directly assess damage to neurons. Mortality and unfavorable outcome were significantly associated with greater NSE concentrations. NSE is also present in Erythrocytes, and even mild hemolysis can significantly increase serum NSE levels.

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



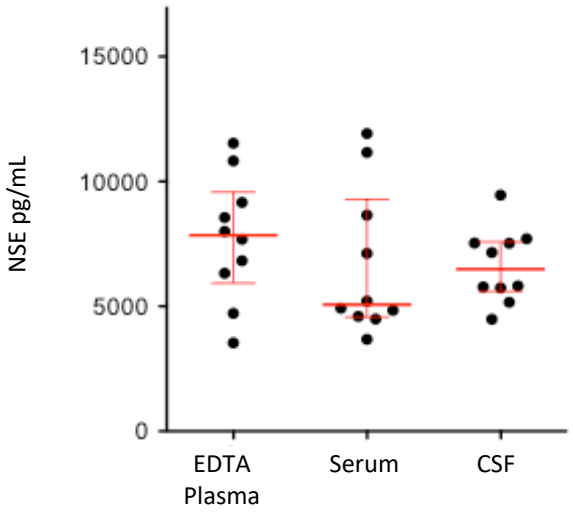
Lower Limit of Quantification (LLOQ): Triplicate measurements of serially diluted calibrator were read back on the calibration curve over 1 reagent lot on 1 instrument (5 runs total).

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	**9.88 pg/mL** pooled CV 8% mean recovery 124%
LOD	**1.296 pg/mL** range 0.3–2.0 pg/mL
Dynamic range (serum and plasma)	0–120 ng/mL
Diluted Sample volume*	100 µL per measurement
Tests per kit	192

***See Kit Instruction for details**

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



Sample Type	Median NSE pg/mL	% Above LOD
EDTA Plasma	7845	100%
Serum	5068	100%
CSF	6488	100%

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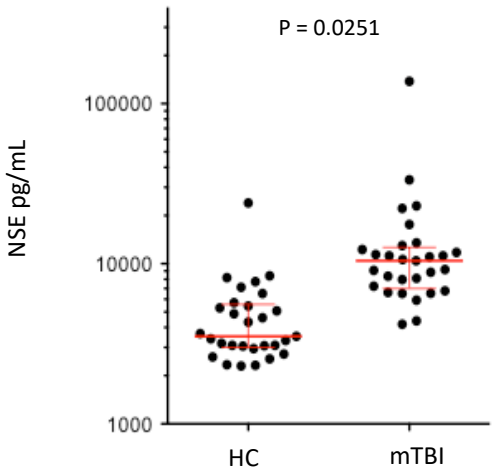
Endogenous Sample Reading (Mild Traumatic Brain Injury): Healthy serum controls (n=29) and mild traumatic brain injury serum (n=29) were measured. Depicted P value from two-tailed t-test at 95% confidence. Error bars depict median and interquartile ranges.



Sample Type	Median NSE pg/mL	% Above LOD
HC	3522	100%
mTBI	10451	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
Serum Panel 1	4221	5.0%	5.0%
Serum Panel 2	2881	4.1%	6.1%
Serum Panel 3	4885	3.5%	4.6%
Plasma Panel 4	2096	5.1%	3.8%
Plasma Panel 5	1533	5.6%	4.7%

Spike and Recovery: NSE spiked into 4 serum samples at 2 levels.

Dilution Linearity: Serum diluted 2x serially from MRD (50x) to 400x with Sample Diluent.

Spike and Recovery (Serum)	**Mean = 96.0%** Range: 88.8–108%
Dilution Linearity (400x)	**Mean = 113%** Range: 101–132%

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