This study report demonstrates the Simoa Neurology 4-plex "A" (N4PA) Advantage assay properties on Simoa HD-1/HD-X for the generation of claims data. The N4PA assay measures neurofilament light (NF-L), total tau, glial fibrillary acidic protein (GFAP), and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) in serum, plasma, and CSF. Included are specificity, limit of detection (LOD), sample CV profile, lower limit of quantitation (LLOQ), spike and recovery, dilution linearity, admixture linearity, precision, and normal sample range.

I. N4PA Advantage Kit Summary

NF-L

Test	Claim
LOD	**0.104 ± 0.067** **Range: 0.025 – 0.276 pg/ml**
Analytical LLOQ (Fit for Purpose)	**0.241 pg/mL**
Functional LLOQ	**Serum/Plasma (4x): 0.964 pg/mL** **CSF (40x): 9.64 pg/mL**
Calibrator B/A	**3.8 ± 0.7** **Range: 2.8 – 5.3**
Calibrator A	**0.007 ± 0.001** **Range: 0.004 – 0.01**
Calibrator H	**14.60 ± 1.28** **Range: 12.69 – 17.27**
Reproducibility Precision	**Within Run CV: 5.1%** **Between Run CV: 5.2%** **Between Instrument CV: 0.2%** **Between Lot CV: 2.6%**
Repeatability Precision	**Within Run CV: 5.1%** **Between Run CV: 3.7%** **Between Day CV: 0.50%**
Spike and Recovery	**Serum/Plasma: 67.5%, Range: 54.4 – 85.1%** **CSF: 108%, Range: 88.8 – 125%**
Dilution Linearity	**Spiked Serum (512x): 119%, Range: 101 – 155%** **Endogenous CSF (5120x): 99.9%, Range: 92.6 – 110%**
Admixture Linearity	**Serum: 94.9%**
Normal Samples *	**Mean EDTA Plasma: 20.4 pg/mL, Range: 4.61 – 136 pg/mL** **Mean Serum: 22.2 pg/mL, Range: 4.58 – 145 pg/mL** **Mean CSF: 1400 pg/mL, Range: 410 – 3269 pg/mL**
Kit Stability	**18 months**

* Values below LLOQ are not included in the mean.

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Tau

Test	Claim
LOD	0.024 ± 0.011 Range: 0.007 – 0.059 pg/ml
Analytical LLOQ (Fit for Purpose)	0.053 pg/mL
Functional LLOQ	Serum/Plasma (4x): 0.212 pg/mL CSF (40x): 2.12 pg/mL
Calibrator B/A	4.0 ± 0.9 Range: 2.4 – 5.8
Calibrator A	0.005 ± 0.001 Range: 0.004 – 0.007
Calibrator H	13.24 ± 1.27 Range: 11.75 – 14.99
Reproducibility Precision	Within Run CV: 5.8% Between Run CV: 4.3% Between Instrument CV: 2.8% Between Lot CV: 1.9%
Repeatability Precision	Within Run CV: 5.4% Between Run CV: 7.4% Between Day CV: 0.0%
Spike and Recovery	Serum/Plasma: 113%, Range: 76.7 – 158% CSF: 116%, Range: 96.3 – 138%
Dilution Linearity	Spiked Serum (512x): 115%, Range: 106 – 126% Endogenous CSF (5120x): 91.6%, Range: 78.1 – 121%
Admixture Linearity	Serum: 94.3%
Normal Samples *	Mean EDTA Plasma: 2.43 pg/mL, Range: 0.551 – 7.07 pg/mL Mean Serum: 1.14 pg/mL, Range: 0.109 – 3.12 pg/mL Mean CSF: 142 pg/mL, Range: 41.2 – 492 pg/mL
Kit Stability	18 months

* Values below LLOQ are not included in the mean.

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GFAP

Test	Claim
LOD	0.221 ± 0.108 Range: 0.042 – 0.481 pg/ml
Analytical LLOQ (Fit for Purpose)	0.467 pg/mL
Functional LLOQ	Serum/Plasma (4x): 1.87 pg/mL CSF (40x): 18.7 pg/mL
Calibrator B/A	2.8 ± 0.4 Range: 2.2 – 3.6
Calibrator A	0.007 ± 0.001 Range: 0.006 – 0.011
Calibrator H	10.69 ± 0.941 Range: 9.379 – 12.84
Reproducibility Precision	Within Run CV: 4.8% Between Run CV: 4.8% Between Instrument CV: 0.0% Between Lot CV: 4.8%
Repeatability Precision	Within Run CV: 5.3% Between Run CV: 3.5% Between Day CV: 2.1%
Spike and Recovery	Serum/Plasma: 77.2%, Range: 49.3 – 120% CSF: 119%, Range: 87.5 – 177%
Dilution Linearity	Spiked Serum (512x): 108%, Range: 102 – 121% Endogenous CSF (5120x): 98.1%, Range: 95.5 – 104%
Admixture Linearity	Serum: 101%
Normal Samples *	Mean EDTA Plasma: 121 pg/mL, Range: 37.3 – 706 pg/mL Mean Serum: 129 pg/mL, Range: 30.6 – 873 pg/mL Mean CSF: 17923 pg/mL, Range: 5868 – 37482 pg/mL
Kit Stability	18 months

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UCH-L1

Test	Claim
LOD	1.74 ± 0.917 Range: 0.120 – 3.62 pg/ml
Analytical LLOQ (Fit for Purpose)	5.45 pg/mL
Functional LLOQ	Serum/Plasma (4x): 21.8 pg/mL CSF (40x): 218 pg/mL
Calibrator B/A	4.1 ± 0.7 Range: 3.3 – 5.7
Calibrator A	0.004 ± 0.001 Range: 0.003 – 0.006
Calibrator H	11.61 ± 1.02 Range: 10.15 – 13.65
Reproducibility Precision	Within Run CV: 7.2% Between Run CV: 5.0% Between Instrument CV: 2.3% Between Lot CV: 1.4%
Repeatability Precision	Within Run CV: 6.1% Between Run CV: 6.0% Between Day CV: 1.5%
Spike and Recovery	Serum/Plasma: 106.9%, Range: 87.3 – 124.7% CSF: 118.9%, Range: 96.0 – 167.2%
Dilution Linearity	Spiked Serum (512x): 90.1%, Range: 79.0 – 103% Spiked CSF (5120x): 95.8%, Range: 93.5 – 98.0%
Admixture Linearity	Serum: 95.4%
Normal Samples *	Mean EDTA Plasma: 25.3 pg/mL, Range: 3.36 – 29.9 pg/mL Mean Serum: 28.6 pg/mL, Range: 2.95 – 31.5 pg/mL Mean CSF: 1069 pg/mL, Range: 499 – 2618 pg/mL
Kit Stability	18 months

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II. NF-L Individual Claims Summary

Limit of Detection:

Test Conditions		Claim
Replicates/Run (each test sample)	3	Grand Mean LOD: 0.104 pg/mL Range: 0.025 to 0.276 pg/mL
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

Lower Limit of Quantification:

Test Conditions		Claim
Samples	Calibrator Concentrate diluted to 0.060 pg/mL, 0.120 pg/mL, 0.241 pg/mL, and 0.481 pg/mL	Analytical LLOQ: 0.241 pg/mL Functional LLOQ (serum/plasma): 0.964 pg/mL Functional LLOQ (CSF): 9.64 pg/mL
Replicates/Run (each test sample)	3	
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

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Reproducibility Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 3.3%
Specifications	Replicates/Sample: 3 Instruments: 3 Runs/Instrument: 2 Lots Tested: 2 Total Runs: 12; Total Measurements/Sample: 36	
Within Run CV		5.1%
Between Run CV		5.2%
Between Instrument CV		0.2%
Between Lot CV		2.6%

Repeatability Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 3.1%
Specifications	Replicates/Sample: 3 Instruments: 1 Runs/Instrument: 10 Lots Tested: 1 Total Runs: 10; Total Measurements/Sample: 30	
Within Run CV		5.1%
Between Run CV		3.7%
Between Day CV		0.5%

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Spike Recovery (Serum/Plasma):

Test Conditions		Claim
Test Samples	Normal Human Samples– 2 serum + 2 EDTA plasma	Uncorrected Grand mean: 67.5% Range: 54.4 – 85.1% Buffer Corrected Grand mean: 59.4% Range: 47.5 – 75.3%
Spike Concentrations	Control: Calibrator Diluent Low: 50 pg/mL High: 500 pg/mL	
Replicates/Run (each test sample)	3	

Spike Recovery (CSF):

Test Conditions		Claim
Test Samples	Normal Human Samples– 4 CSF	Uncorrected Grand mean: 108% Range: 88.8 – 125% Buffer Corrected Grand mean: 99.0% Range: 83.4 – 112%
Spike Concentrations	Control: Calibrator Diluent Low: 500 pg/mL High: 5000 pg/mL	
Replicates/Run (each test sample)	3	

Dilution Linearity:

Test Conditions		Claim
Test Samples	1 spiked human serum 1 human CSF	Spiked Serum Dilution Linearity (512x total dilution): 119% Range: 101 - 155% Endogenous CSF Dilution Linearity (5120x total dilution): 99.9% Range: 92.6 - 110%
Dilutions	Human Serum: 2X serial from MRD (4x) to 512x Human CSF: 2X serial from MRD (40x) to 5120x	
Replicates/Run (each test sample)	3	

Admixture Linearity:

Test Conditions		Claim
Test Samples	Low Human Serum, [NF-L] = 3.17 pg/mL High Human Serum, [NF-L] = 1350 pg/mL	Mean Deviation from Linearity: -5.1% Range: -12.4 to +1.3% Admixture Linearity: 94.9% Slope = 1.0175 R^2: 0.993
Admixtures	12 combinations of Low + High serum including 100% Low and 100% High serum.	
Replicates/Run (each test sample)	3	

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Normal Sample Reading:

Test Conditions		Claim
Test Samples	20 Normal Human matched serum, EDTA plasma, and CSF	Mean Serum: 22.2 pg/mL Serum Range: 4.58 – 145 pg/mL Mean Plasma: 20.4 pg/mL Plasma Range: 4.61 – 136 pg/mL Mean CSF: 1400 pg/mL CSF Range: 410 – 3269 pg/mL
Replicates (each test sample)	3	

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III. Tau Individual Claims Summary

Limit of Detection:

Test Conditions		Claim
Replicates/Run (each test sample)	3	Grand Mean LOD: 0.024 pg/mL Range: 0.007 to 0.059 pg/mL
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

Lower Limit of Quantification:

Test Conditions		Claim
Samples	Calibrator Concentrate diluted to 0.013 pg/mL, 0.026 pg/mL, 0.053 pg/mL, and 0.105 pg/mL	Analytical LLOQ: 0.053 pg/mL Functional LLOQ (serum/plasma): 0.212 pg/mL Functional LLOQ (CSF): 2.12 pg/mL
Replicates/Run (each test sample)	3	
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

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Reproducibility Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 3.7%
Specifications	Replicates/Sample: 3 Instruments: 3 Runs/Instrument: 2 Lots Tested: 2 Total Runs: 12; Total Measurements/Sample: 36	
Within Run CV		5.8%
Between Run CV		4.3%
Between Instrument CV		2.8%
Between Lot CV		1.9%

Repeatability Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 4.3%
Specifications	Replicates/Sample: 3 Instruments: 1 Runs/Instrument: 10 Lots Tested: 1 Total Runs: 10; Total Measurements/Sample: 30	
Within Run CV		5.4%
Between Run CV		7.4%
Between Day CV		0.0%

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Spike Recovery (Serum/Plasma):

Test Conditions		Claim
Test Samples	Normal Human Samples– 2 serum + 2 EDTA plasma	Uncorrected Grand mean: 113% Range: 76.7 – 158% Buffer Corrected Grand mean: 73.8% Range: 48.5 – 105%
Spike Concentrations	Control: Calibrator Diluent Low: 15 pg/mL High: 150 pg/mL	
Replicates/Run (each test sample)	3	

Spike Recovery (CSF):

Test Conditions		Claim
Test Samples	Normal Human Samples– 4 CSF	Uncorrected Grand mean: 217% Range: 179 – 259% Buffer Corrected Grand mean: 116% Range: 96.3 – 138%
Spike Concentrations	Control: Calibrator Diluent Low: 100 pg/mL High: 1000 pg/mL	
Replicates/Run (each test sample)	3	

Dilution Linearity:

Test Conditions		Claim
Test Samples	1 spiked human serum 1 human CSF	Spiked Serum Dilution Linearity (512x total dilution): 115% Range: 106 - 126% Endogenous CSF Dilution Linearity (5120x total dilution): 91.6% Range: 78.1 - 121%
Dilutions	Human Serum: 2X serial from MRD (4x) to 512x Human CSF: 2X serial from MRD (40x) to 5120x	
Replicates/Run (each test sample)	3	

Admixture Linearity:

Test Conditions		Claim
Test Samples	Low Human Serum, [Tau] = 0.836 pg/mL High Human Serum, [Tau] = 243 pg/mL	Mean Deviation from Linearity: -5.7% Range: -16.6 to +5.6% Admixture Linearity: 94.3% Slope = 1.034 R^2: 0.9911
Admixtures	12 combinations of Low + High serum including 100% Low and 100% High serum.	
Replicates/Run (each test sample)	3	

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Normal Sample Reading:

Test Conditions		Claim
Test Samples	20 Normal Human matched serum, EDTA plasma, and CSF	Mean Serum: 1.09 pg/mL Serum Range: 0.109 – 3.12 pg/mL Mean Plasma: 2.43 pg/mL Plasma Range: 0.551 – 7.07 pg/mL Mean CSF: 142 pg/mL CSF Range: 41.2 – 492 pg/mL
Replicates (each test sample)	3	

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IV. GFAP Individual Claims Summary

Limit of Detection:

Test Conditions		Claim
Replicates/Run (each test sample)	3	Grand Mean LOD: 0.221 pg/mL Range: 0.042 to 0.481 pg/mL
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

Lower Limit of Quantification:

Test Conditions		Claim
Samples	Calibrator Concentrate diluted to 0.117 pg/mL, 0.234 pg/mL, 0.467 pg/mL, and 0.934 pg/mL	Analytical LLOQ: 0.467 pg/mL Functional LLOQ (serum/plasma): 1.87 pg/mL Functional LLOQ (CSF): 18.7 pg/mL
Replicates/Run (each test sample)	3	
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

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Reproducibility Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 3.6%
Specifications	Replicates/Sample: 3 Instruments: 3 Runs/Instrument: 2 Lots Tested: 2 Total Runs: 12; Total Measurements/Sample: 36	
Within Run CV		4.8%
Between Run CV		4.8%
Between Instrument CV		0.0%
Between Lot CV		4.8%

Repeatability Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 3.6%
Specifications	Replicates/Sample: 3 Instruments: 1 Runs/Instrument: 10 Lots Tested: 1 Total Runs: 10; Total Measurements/Sample: 30	
Within Run CV		5.3%
Between Run CV		3.5%
Between Day CV		2.1%

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Spike Recovery (Serum/Plasma):

Test Conditions		Claim
Test Samples	Normal Human Samples– 2 serum + 2 EDTA plasma	Uncorrected Grand mean: 77.2% Range: 49.3 – 120% Buffer Corrected Grand mean: 77.9% Range: 46.7 – 123%
Spike Concentrations	Control: Calibrator Diluent Low: 80 pg/mL High: 800 pg/mL	
Replicates/Run (each test sample)	3	

Spike Recovery (CSF):

Test Conditions		Claim
Test Samples	Normal Human Samples– 4 CSF	Uncorrected Grand mean: 119% Range: 87.5 – 177% Buffer Corrected Grand mean: 108% Range: 78.7 – 159%
Spike Concentrations	Control: Calibrator Diluent Low: 1500 pg/mL High: 15000 pg/mL	
Replicates/Run (each test sample)	3	

Dilution Linearity:

Test Conditions		Claim
Test Samples	1 spiked human serum 1 human CSF	Spiked Serum Dilution Linearity (512x total dilution): 108% Range: 102 - 121% Endogenous CSF Dilution Linearity (5120x total dilution): 98.1% Range: 95.5 - 104%
Dilutions	Human Serum: 2X serial from MRD (4x) to 512x Human CSF: 2X serial from MRD (40x) to 5120x	
Replicates/Run (each test sample)	3	

Admixture Linearity:

Test Conditions		Claim
Test Samples	Low Human Serum, [GFAP] = 30.5 pg/mL High Human Serum, [GFAP] = 1738 pg/mL	Mean Deviation from Linearity: +0.6% Range: -11 to +12% Admixture Linearity: 101% Slope = 1.0093 R^2: 0.9957
Admixtures	12 combinations of Low + High serum including 100% Low and 100% High serum.	
Replicates/Run (each test sample)	3	

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Normal Sample Reading:

Test Conditions		Claim
Test Samples	20 Normal Human matched serum, EDTA plasma, and CSF	Mean Serum: 129 pg/mL Serum Range: 30.6 – 873 pg/mL Mean Plasma: 121 pg/mL Plasma Range: 37.3 – 706 pg/mL Mean CSF: 17923 pg/mL CSF Range: 5868 – 37482 pg/mL
Replicates (each test sample)	3	

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V. UCH-L1 Individual Claims Summary

Limit of Detection:

Test Conditions		Claim
Replicates/Run (each test sample)	3	Grand Mean LOD: 1.74 pg/mL Range: 0.120 to 3.62 pg/mL
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

Lower Limit of Quantification:

Test Conditions		Claim
Samples	Calibrator Concentrate diluted to 1.36 pg/mL, 2.73 pg/mL, 5.45 pg/mL, and 10.9 pg/mL	Analytical LLOQ: 5.45 pg/mL Functional LLOQ (serum/plasma): 21.8 pg/mL Functional LLOQ (CSF): 218 pg/mL
Replicates/Run (each test sample)	3	
# Instruments	3	
Runs/Instrument	2	
# Lots Tested	2	
Total Runs	12	

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Reproducibility Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 4.0%
Specifications	Replicates/Sample: 3 Instruments: 3 Runs/Instrument: 2 Lots Tested: 2 Total Runs: 12; Total Measurements/Sample: 36	
Within Run CV		7.2%
Between Run CV		5.0%
Between Instrument CV		2.3%
Between Lot CV		1.4%

Repeatability Precision Profile:

Test Conditions		Claim
Test Samples	Control 1: Low Concentration Calibrator spiked into calibrator diluent Control 2: High Concentration Calibrator spiked into calibrator diluent Panel 1: Normal Human Serum Sample Panel 2: Normal Human EDTA Plasma Sample spiked with kit calibrator Panel 3: Normal Human Serum Sample spiked with kit calibrator	Mean Total CV: 4.5%
Specifications	Replicates/Sample: 3 Instruments: 1 Runs/Instrument: 10 Lots Tested: 1 Total Runs: 10; Total Measurements/Sample: 30	
Within Run CV		6.1%
Between Run CV		6.0%
Between Day CV		1.5%

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Spike Recovery (Serum/Plasma):

Test Conditions		Claim
Test Samples	Normal Human Samples– 2 serum + 2 EDTA plasma	Uncorrected Grand mean: 107% Range: 87.3 – 125% Buffer Corrected Grand mean: 89.8% Range: 70.6 – 108%
Spike Concentrations	Control: Calibrator Diluent Low: 300 pg/mL High: 3000 pg/mL	
Replicates/Run (each test sample)	3	

Spike Recovery (CSF):

Test Conditions		Claim
Test Samples	Normal Human Samples– 4 CSF	Uncorrected Grand mean: 119% Range: 96.0 – 167% Buffer Corrected Grand mean: 119% Range: 113 – 147%
Spike Concentrations	Control: Calibrator Diluent Low: 15000 pg/mL High: 150000 pg/mL	
Replicates/Run (each test sample)	3	

Dilution Linearity:

Test Conditions		Claim
Test Samples	1 spiked human serum 1 spiked human CSF	Spiked Serum Dilution Linearity (512x total dilution): 90.1% Range: 79.0 - 103% Spiked CSF Dilution Linearity (5120x total dilution): 95.8% Range: 93.5 - 98.0%
Dilutions	Human Serum: 2X serial from MRD (4x) to 512x Human CSF: 2X serial from MRD (40x) to 5120x	
Replicates/Run (each test sample)	3	

Admixture Linearity:

Test Conditions		Claim
Test Samples	Low Human Serum, [UCH-L1] = 46.5 pg/mL High Human Serum, [UCH-L1] = 15951 pg/mL	Mean Deviation from Linearity: -4.6% Range: -15 to +4.0% Admixture Linearity: 95.4% Slope = 0.9927 R^2: 0.9942
Admixtures	12 combinations of Low + High serum including 100% Low and 100% High serum	
Replicates/Run (each test sample)	3	

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Normal Sample Reading:

Test Conditions		Claim
Test Samples	20 Normal Human matched serum, EDTA plasma, and CSF	Mean Serum: 13.3 pg/mL Serum Range: 2.95 – 31.5 pg/mL Mean Plasma: 13.4 pg/mL Plasma Range: 3.36 – 29.9 pg/mL Mean CSF: 1069 pg/mL CSF Range: 499 – 2618 pg/mL
Replicates (each test sample)	3	

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VI. NF-L Claims Details

LOD Lot 1

Reagent Lot	PD Lot 1							
Instrument	CU20		CU24		VU16		AVE	SD
Primary Cal LOD (pg/mL)	0.103	0.123	0.159	0.025	0.074	0.133	**0.103**	**0.048**
Primary Cal B/A	3.3	2.9	3.0	3.1	2.9	2.6	**3.0**	**0.2**
Primary Cal A	0.008	0.007	0.007	0.007	0.008	0.009	**0.008**	**0.001**
Primary Cal A CV	17.2%	18.0%	23.8%	4.3%	11.0%	17.2%	**15.2%**	**6.7%**
Reference Cal LOD (pg/mL)	0.073	0.034	0.240	0.276	0.058	0.110	**0.132**	**0.102**
Reference Cal B/A	4.3	5.3	3.2	2.8	3.9	4.0	**3.9**	**0.9**
Reference Cal A	0.005	0.004	0.007	0.008	0.006	0.006	**0.006**	**0.001**
Reference Cal A CV	19.3%	11.8%	42.2%	41.9%	14.5%	26.6%	**26.1%**	**13.4%**
Reference Cal H	13.278	14.939	12.885	12.685	14.167	14.969	**13.820**	**1.015**

CV>20%

LOD Lot 2

Reagent Lot	PD Lot 2							
Instrument	CU20		CU24		VU16		AVE	SD
Primary Cal LOD (pg/mL)	0.035	0.088	0.040	0.108	0.043	0.134	**0.074**	**0.041**
Primary Cal B/A	3.3	3.1	2.9	3.0	3.3	2.9	**3.1**	**0.2**
Primary Cal A	0.006	0.008	0.011	0.008	0.008	0.008	**0.008**	**0.001**
Primary Cal A CV	6.1%	14.4%	5.9%	18.0%	7.7%	20.4%	**12.1%**	**6.4%**
Reference Cal LOD (pg/mL)	0.135	0.035	0.106	0.215	0.112	0.031	**0.106**	**0.068**
Reference Cal B/A	3.9	3.9	3.0	3.3	4.2	3.7	**3.7**	**0.4**
Reference Cal A	0.006	0.006	0.010	0.008	0.006	0.006	**0.007**	**0.002**
Reference Cal A CV	29.7%	7.9%	17.4%	38.7%	28.0%	7.1%	**21.5%**	**12.8%**
Reference Cal H	15.180	14.473	17.265	14.326	15.558	15.457	**15.377**	**1.055**

CV>20%

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LLOQ Lot 1

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.481 pg/mL	25.9%	22.9%	5.8%	8.5%	2.5%	1.2%
0.241 pg/mL	2.5%	13.8%	7.5%	23.0%	12.4%	13.7%
0.120 pg/mL	12.4%	13.6%	6.0%	24.2%	45.8%	14.9%
0.060 pg/mL	79.8%	44.3%	53.0%	32.8%	42.6%	18.6%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
0.481 pg/mL	105%	106%	105%	108%	92.1%	106%
0.241 pg/mL	113%	113%	101%	94.1%	125%	117%
0.120 pg/mL	112%	153%	117%	106%	112%	161%
0.060 pg/mL	105%	129%	88.3%	109%	155%	185%

LLOQ Lot 2

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.481 pg/mL	11.9%	3.8%	3.2%	3.6%	16.3%	4.5%
0.241 pg/mL	8.8%	4.5%	16.4%	8.3%	9.1%	10.7%
0.120 pg/mL	45.4%	47.8%	14.7%	28.5%	6.8%	40.2%
0.060 pg/mL	39.5%	47.8%	55.3%	16.3%	38.3%	40.4%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
0.481 pg/mL	121%	101%	105%	107%	99.6%	107%
0.241 pg/mL	112%	102%	94.3%	118%	120%	110%
0.120 pg/mL	158%	138%	99.1%	117%	122%	62.5%
0.060 pg/mL	95.6%	138%	131%	136%	151%	72.2%

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LLOQ Summary

LOQ Point	LOQ Point (pg/mL)	Mean Pooled CV	Mean Recovery	LLOQ Claim (pg/mL)
Low	**0.060**	42.4%	125%	**0.241**
Mid 1	**0.120**	25.0%	121%	
Mid 2	**0.241**	10.9%	110%	
High	**0.481**	9.2%	105%	

Reproducibility Precision Sample Results

Sample	Mean (pg/mL)	Between Instrument CV	Between Lot CV	Between Run CV	Within Run CV
Control 1	9.31	0.9%	3.4%	5.8%	6.2%
Control 2	925	0.0%	6.1%	4.6%	4.4%
Panel 1	16.8	0.0%	0.0%	5.1%	5.4%
Panel 2	60.1	0.0%	0.0%	5.6%	4.7%
Panel 3	332	0.0%	3.7%	5.0%	4.7%

Repeatability Precision Sample Results

Sample	Mean (pg/mL)	Between Day CV	Between Run CV	Within Run CV
Control 1	8.74	0.0%	6.5%	6.1%
Control 2	852	2.5%	0.0%	4.3%
Panel 1	16.1	0.0%	4.4%	6.0%
Panel 2	61.5	0.0%	0.0%	4.6%
Panel 3	325	0.0%	7.8%	4.5%

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Spike Recovery

NF-L Serum/Plasma (w/ Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**50 pg/mL**	**500 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
Serum 1	47.5%	49.8%	48.7%	59.4%
Serum 2	73.1%	75.3%	74.2%	
Plasma 1	58.1%	61.0%	59.5%	
Plasma 2	50.6%	59.6%	55.1%	

NF-L Serum/Plasma (w/o Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**50 pg/mL**	**500 pg/mL**	**Mean**	**Grand Mean**
Diluent	115%	113%		
Serum 1	54.4%	56.2%	55.3%	67.5%
Serum 2	83.7%	85.1%	84.4%	
Plasma 1	66.5%	68.8%	67.7%	
Plasma 2	58.0%	67.3%	62.6%	

NF-L CSF (w/Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + spiked buffer conc)] x 100				
Sample ID	**500 pg/mL**	**5000 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
BRH1299850	88.7%	83.4%	86.1%	99.0%
BRH1299858	98.2%	104%	101%	
BRH1299860	112%	104%	108%	
BRH1299865	98.6%	103%	101%	

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NF-L CSF (w/o Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + target spike conc)] x 100				
Sample ID	**500 pg/mL**	**5000 pg/mL**	**Mean**	**Grand Mean**
Diluent	111%	106%		
BRH1299850	98.5%	88.8%	93.6%	108%
BRH1299858	109%	110%	110%	
BRH1299860	125%	111%	118%	
BRH1299865	110%	110%	110%	

Dilution Linearity

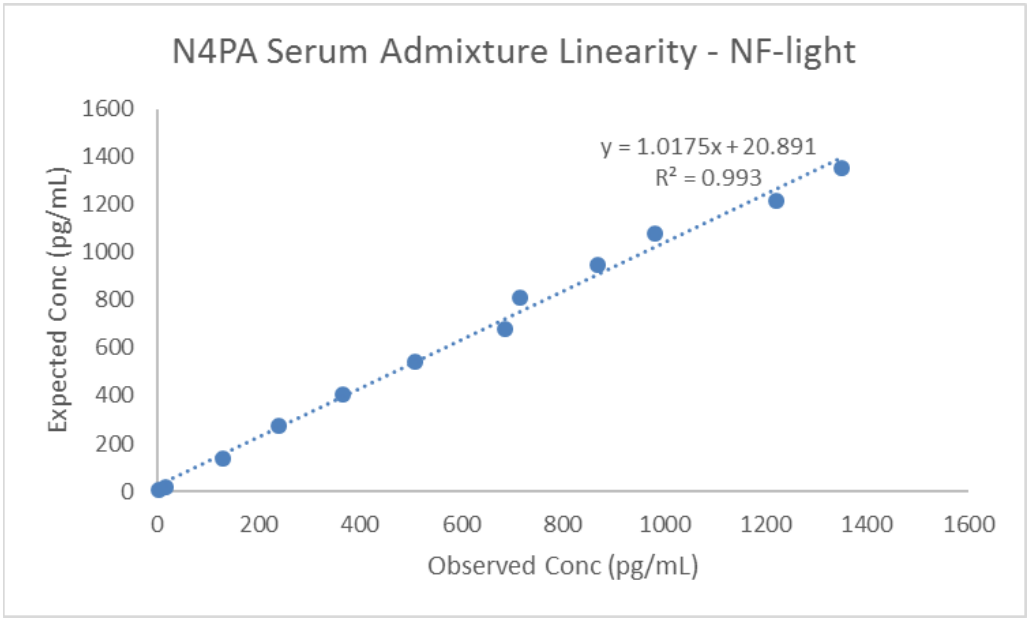
Dilution	Spiked Serum	Dilution	Endogenous CSF
8X	143%	80X	92.6%
16X	155%	160X	97.6%
32X	123%	320X	99.2%
64X	115%	640X	95.8%
128X	113%	1280X	95.3%
256X	101%	2560X	110%
512X	102%	5120X	109%

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Admixture Linearity - Serum

Linearity Sample	% High Pool	% Low Pool	Observed NF-L (pg/mL)	% Bias
1	100%	0%	1350	-
2	90%	10%	1222	0.5%
3	80%	20%	981	-9.3%
4	70%	30%	869	-8.2%
5	60%	40%	716	-12%
6	50%	50%	685	1.3%
7	40%	60%	509	-6.1%
8	30%	70%	365	-10%
9	20%	80%	239	-12%
10	10%	90%	130	-5.7%
11	1%	99%	16.7	0.5%
12	0%	100%	3.17	-
			Average	-5.1%



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Normal Sample Reading

Donor	Lot 1					
	Plasma Conc. (pg/mL)	CV	Serum Conc. (pg/mL)	CV	CSF Conc. (pg/mL)	CV
1	19.7	10%	23.1	4.2%	1178	0.5%
2	6.77	2.5%	7.63	4.2%	599	1.7%
3	20.0	3.6%	22.0	2.6%	2059	5.6%
4	12.4	5.1%	15.4	4.3%	700	7.3%
5	7.78	5.3%	9.15	1.9%	1518	5.3%
6	63.5	1.4%	70.5	7.6%	1489	2.3%
7	136	4.5%	145	4.7%	784	8.2%
8	15.4	3.1%	16.1	3.6%	1352	2.0%
9	13.8	2.4%	15.1	5.0%	1035	11%
10	16.5	8.9%	20.0	5.2%	1249	3.7%
11	6.26	2.6%	6.56	5.2%	799	4.3%
12	9.18	5.4%	10.1	6.7%	856	2.2%
13	30.4	6.6%	33.7	6.7%	2177	4.0%
14	6.38	2.4%	6.52	11%	410	3.4%
15	6.05	3.2%	6.06	9.6%	565	1.5%
16	6.79	8.7%	7.76	4.9%	1233	2.8%
17	8.37	2.7%	7.04	4.0%	1341	3.3%
18	4.61	4.8%	4.58	14%	3024	3.4%
19	12.0	3.2%	11.6	9.1%	2369	5.0%
20	6.32	7.9%	6.95	11%	3268	5.1%
Mean *	**20.4 pg/mL**		**22.2 pg/mL**		**1400 pg/mL**	
Median *	**10.6 pg/mL**		**10.8 pg/mL**		**1241 pg/mL**	
Range	**4.61 – 136 pg/mL**		**4.58 – 145 pg/mL**		**410 – 3269 pg/mL**	

* Values below LLOQ are not included in the mean and median.

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VII. Tau Claims Details

LOD Lot 1

Reagent Lot	PD Lot 1							
Instrument	CU20		CU24		VU16		AVE	SD
Primary Cal LOD (pg/mL)	0.013	0.021	0.038	0.028	0.020	0.022	**0.024**	**0.009**
Primary Cal B/A	3.5	3.5	3.4	3.0	5.1	4.6	**3.8**	**0.8**
Primary Cal A	0.005	0.004	0.005	0.004	0.004	0.005	**0.004**	**0.000**
Primary Cal A CV	12.8%	20.1%	34.2%	23.0%	32.6%	27.7%	**25.1%**	**8.1%**
Reference Cal LOD (pg/mL)	0.007	0.024	0.059	0.035	0.025	0.016	**0.028**	**0.018**
Reference Cal B/A	3.9	5.8	3.3	3.2	3.8	4.2	**4.0**	**1.0**
Reference Cal A	0.005	0.004	0.006	0.006	0.006	0.005	**0.005**	**0.001**
Reference Cal A CV	7.6%	42.8%	50.9%	28.2%	27.1%	18.8%	**29.2%**	**15.7%**
Reference Cal H	11.931	14.593	12.229	12.026	14.633	14.822	**13.372**	**1.441**

CV>20%

LOD Lot 2

Reagent Lot	PD Lot 2							
Instrument	CU20		CU24		VU16		AVE	SD
Primary Cal LOD (pg/mL)	0.011	0.020	0.025	0.033	0.020	0.019	**0.021**	**0.008**
Primary Cal B/A	4.5	4.4	2.8	2.7	3.6	3.6	**3.6**	**0.8**
Primary Cal A	0.004	0.004	0.006	0.006	0.005	0.005	**0.005**	**0.001**
Primary Cal A CV	13.8%	26.0%	16.4%	23.7%	18.7%	20.2%	**19.8%**	**4.5%**
Reference Cal LOD (pg/mL)	0.014	0.015	0.022	0.040	0.019	0.025	**0.022**	**0.009**
Reference Cal B/A	4.4	4.3	2.4	3.0	5.1	4.5	**3.9**	**1.0**
Reference Cal A	0.004	0.004	0.007	0.006	0.004	0.005	**0.005**	**0.001**
Reference Cal A CV	16.7%	17.5%	10.9%	28.9%	28.2%	29.8%	**22.0%**	**8.0%**
Reference Cal H	13.437	12.855	11.958	11.745	13.653	14.993	**13.107**	**1.200**

CV>20%

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LLOQ Lot 1

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.105 pg/mL	11.4%	6.6%	10.7%	11.4%	3.7%	0.9%
0.053 pg/mL	18.4%	8.3%	2.5%	11.8%	15.4%	11.4%
0.026 pg/mL	55.8%	12.9%	7.3%	46.1%	47.6%	23.5%
0.013 pg/mL	35.0%	47.3%	44.9%	27.7%	31.5%	10.5%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
0.105 pg/mL	110%	107%	92.9%	95.7%	98.8%	94.3%
0.053 pg/mL	105%	110%	104%	104%	109%	124%
0.026 pg/mL	74.5%	147%	125%	69.5%	92.7%	168%
0.013 pg/mL	158%	251%	106%	134%	129%	198%

LLOQ Lot 2

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.105 pg/mL	13.6%	16.7%	15.9%	14.9%	12.7%	11.4%
0.053 pg/mL	3.8%	7.0%	14.5%	13.4%	13.8%	14.6%
0.026 pg/mL	8.3%	21.4%	4.2%	7.0%	50.4%	37.3%
0.013 pg/mL	39.5%	47.8%	68.2%	30.2%	34.5%	58.8%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
0.105 pg/mL	91.6%	105%	93.8%	106%	87.3%	101%
0.053 pg/mL	115%	118%	100%	117%	114%	88.0%

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0.026 pg/mL	136%	90.0%	121%	120%	110%	74.3%
0.013 pg/mL	95.6%	138%	160%	194%	147%	66.6%

LLOQ Summary

LOQ Point	LOQ Point (pg/mL)	Mean Pooled CV	Mean Recovery	LLOQ Claim (pg/mL)
Low	**0.013**	39.7%	148%	**0.053**
Mid 1	**0.026**	26.8%	111%	
Mid 2	**0.053**	11.2%	109%	
High	**0.105**	10.8%	99%	

Reproducibility Precision Sample Results

Sample	Mean (pg/mL)	Between Instrument CV	Between Lot CV	Between Run CV	Within Run CV
Control 1	3.71	7.1%	2.6%	1.6%	7.6%
Control 2	200	0.0%	6.7%	4.5%	4.5%
Panel 1	2.66	0.0%	0.0%	5.7%	6.7%
Panel 2	20.2	1.5%	0.0%	6.6%	4.9%
Panel 3	148	5.2%	0.0%	3.0%	5.2%

Repeatability Precision Sample Results

Sample	Mean (pg/mL)	Between Day CV	Between Run CV	Within Run CV
Control 1	3.55	0.0%	6.0%	6.3%
Control 2	183	0.0%	4.6%	4.8%
Panel 1	2.66	0.0%	12.4%	7.4%
Panel 2	20.6	0.0%	7.6%	4.3%
Panel 3	142	0.0%	6.2%	4.3%

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Spike Recovery

Tau Serum/Plasma (w/ Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**15 pg/mL**	**150 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
Serum 1	83.5%	78.9%	81.2%	73.8%
Serum 2	99.8%	105%	103%	
Plasma 1	58.3%	62.1%	60.2%	
Plasma 2	48.5%	54.2%	51.4%	

Tau Serum/Plasma (w/o Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**15 pg/mL**	**150 pg/mL**	**Mean**	**Grand Mean**
Diluent	158%	147%		
Serum 1	132%	116%	124%	113%
Serum 2	158%	155%	156%	
Plasma 1	92.3%	91.2%	91.7%	
Plasma 2	76.7%	79.7%	78.2%	

Tau CSF (w/Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + spiked buffer conc)] x 100				
Sample ID	**100 pg/mL**	**1000 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
BRH1299850	96.3%	97.0%	96.7%	116%
BRH1299858	98.0%	109%	104%	
BRH1299860	134%	138%	136%	
BRH1299865	122%	137%	129%	

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Tau CSF (w/o Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + target spike conc)] x 100				
Sample ID	**100 pg/mL**	**1000 pg/mL**	**Mean**	**Grand Mean**
Diluent	186%	188%		
BRH1299850	179%	182%	181%	217%
BRH1299858	182%	204%	193%	
BRH1299860	248%	259%	253%	
BRH1299865	226%	257%	241%	

Dilution Linearity

Dilution	Spiked Serum	Dilution	Endogenous CSF
8X	119%	80X	80.8%
16X	126%	160X	78.1%
32X	114%	320X	79.4%
64X	106%	640X	84.4%
128X	117%	1280X	92.3%
256X	120%	2560X	96.5%
512X	119%	5120X	121%

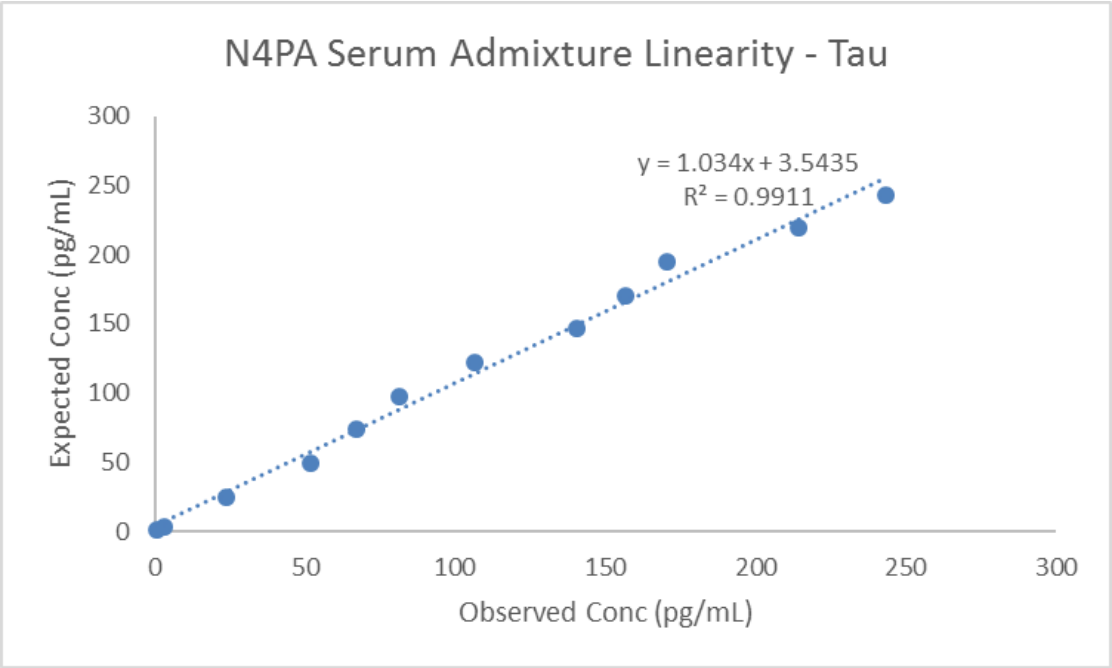
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Admixture Linearity - Serum

Linearity Sample	% High Pool	% Low Pool	Observed Tau (pg/mL)	% Bias
1	100%	0%	243	-
2	90%	10%	214	-2.2%
3	80%	20%	171	-12%
4	70%	30%	157	-8.0%
5	60%	40%	140	-4.0%
6	50%	50%	107	-13%
7	40%	60%	81.6	-17%
8	30%	70%	67.0	-8.9%
9	20%	80%	52.1	5.6%
10	10%	90%	23.8	-5.3%
11	1%	99%	3.15	-3.4%
12	0%	100%	0.836	-
			Average	-5.7%

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Normal Sample Reading

Donor	Lot 1					
	Plasma Conc. (pg/mL)	CV	Serum Conc. (pg/mL)	CV	CSF Conc. (pg/mL)	CV
1	0.551	14%	0.109*	64%	128	3.5%
2	2.40	20%	1.41	6.2%	134	5.2%
3	3.72	13%	2.81	5.6%	81.6	4.9%
4	2.07	14%	1.48	13%	156	8.8%
5	1.66	6.8%	0.564	18.%	474	7.0%
6	0.981	16%	0.549	12%	56.8	4.6%
7	3.06	4.5%	0.891	8.6%	122	2.4%
8	2.44	12%	0.591	11%	52.4	1.0%
9	1.24	5.8%	0.417	19%	155	7.1%
10	1.15	12%	0.783	9.5%	175	8.2%
11	3.38	4.8%	1.52	5.5%	115	3.1%
12	1.75	6.9%	1.12	14%	142	2.8%
13	1.74	16.%	0.831	4.2%	114	8.0%

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Donor	Lot 1					
	Plasma Conc. (pg/mL)	CV	Serum Conc. (pg/mL)	CV	CSF Conc. (pg/mL)	CV
14	4.40	2.4%	1.69	4.3%	83.7	4.6%
15	2.34	10%	1.13	5.7%	67.5	3.8%
16	1.97	4.9%	0.821	13%	41.2	5.2%
17	2.62	13%	0.936	7.5%	121	7.6%
18	7.07	6.0%	3.12	7.6%	60.1	8.8%
19	1.42	2.9%	0.365	23%	492	7.4%
20	2.71	8.8%	0.676	7.4%	62.5	6.5%
Mean **	**2.43 pg/mL**		**1.14 pg/mL**		**142 pg/mL**	
Median **	**2.21 pg/mL**		**0.891 upg/mL**		**118 pg/mL**	
Range	**0.551 – 7.07 pg/mL**		**0.109 – 3.12 pg/mL**		**41.2 – 492 pg/mL**	

* Sample concentration below LLOQ

** Values below LLOQ are not included in the mean and median.

VIII. GFAP Claims Details

LOD Lot 1

Reagent Lot	PD Lot 1							
Instrument	**CU20**		**CU24**		**VU16**		**AVE**	**SD**
Primary Cal LOD (pg/mL)	0.152	0.109	0.169	0.434	0.209	0.118	**0.199**	**0.121**
Primary Cal B/A	2.4	2.5	3.2	2.7	2.6	2.5	**2.7**	**0.3**
Primary Cal A	0.008	0.008	0.003	0.006	0.008	0.009	**0.007**	**0.002**
Primary Cal A CV	8.5%	6.4%	13.7%	29.4%	13.2%	6.6%	**13.0%**	**8.7%**
Reference Cal LOD (pg/mL)	0.295	0.042	0.329	0.481	0.122	0.247	**0.253**	**0.156**

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Reference Cal B/A	2.6	3.6	2.4	2.7	2.6	3.6	**2.9**	**0.5**
Reference Cal A	0.007	0.006	0.008	0.007	0.007	0.006	**0.007**	**0.001**
Reference Cal A CV	20.1%	4.9%	20.4%	34.4%	8.9%	25.2%	**19.0%**	**10.8%**
Reference Cal H	9.700	11.202	9.560	9.379	10.341	11.104	**10.214**	**0.797**

CV>20%

LOD Lot 2

Reagent Lot	**PD Lot 2**							
Instrument	**CU20**		**CU24**		**VU16**		**AVE**	**SD**
Primary Cal LOD (pg/mL)	**0.151**	**0.263**	**0.199**	**0.249**	**0.191**	**0.130**	**0.197**	**0.052**
Primary Cal B/A	**2.9**	**3.0**	**3.0**	**3.1**	**2.4**	**2.8**	**2.9**	**0.3**
Primary Cal A	**0.007**	**0.007**	**0.010**	**0.007**	**0.010**	**0.008**	**0.008**	**0.001**
Primary Cal A CV	**11.2%**	**20.3%**	**16.1%**	**20.5%**	**10.8%**	**9.8%**	**14.8%**	**4.9%**
Reference Cal LOD (pg/mL)	**0.086**	**0.191**	**0.327**	**0.319**	**0.191**	**0.290**	**0.234**	**0.094**
Reference Cal B/A	**3.1**	**2.8**	**2.2**	**2.9**	**2.7**	**2.8**	**2.8**	**0.3**
Reference Cal A	**0.006**	**0.007**	**0.011**	**0.007**	**0.007**	**0.007**	**0.008**	**0.002**
Reference Cal A CV	**7.8%**	**14.4%**	**17.6%**	**30.5%**	**14.1%**	**20.3%**	**17.5%**	**7.7%**
Reference Cal H	**11.016**	**10.288**	**12.835**	**10.720**	**11.153**	**11.031**	**11.174**	**0.871**

CV>20%

LLOQ Lot 1

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.934 pg/mL	3.0%	8.4%	7.4%	14.6%	12.4%	18.3%
0.467 pg/mL	14.2%	6.7%	7.5%	7.1%	10.6%	25.6%
0.234 pg/mL	79.8%	17.0%	21.0%	23.2%	6.9%	41.2%
0.117 pg/mL	N/A	25.2%	11.3%	46.4%	56.5%	14.3%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	

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Experiment	RUN01	RUN02	RUN01	Experiment	RUN01	RUN02
0.934 pg/mL	91.1%	104%	89.9%	94.9%	91.7%	87.7%
0.467 pg/mL	96.9%	109%	96.7%	87.6%	109%	105%
0.234 pg/mL	56.6%	166%	118%	114%	106%	121%
0.117 pg/mL	68.6%	189%	158%	128%	64.4%	223%

N/A: Not able to be calculated due to loss of replicate(s)

LLOQ Lot 2

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
0.934 pg/mL	11.2%	4.5%	8.0%	13.6%	12.5%	23.3%
0.467 pg/mL	3.8%	12.3%	7.4%	23.5%	4.5%	9.5%
0.234 pg/mL	28.5%	10.7%	21.1%	10.4%	31.9%	51.1%
0.117 pg/mL	39.5%	47.8%	35.6%	59.2%	35.8%	134%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
0.934 pg/mL	107%	95.8%	88.1%	104%	90.0%	97.9%
0.467 pg/mL	101%	105%	113%	99.3%	108%	104%
0.234 pg/mL	110%	127%	104%	127%	118%	105%
0.117 pg/mL	95.6%	138%	204%	194%	137%	52.9%

LLOQ Summary

LOQ Point	LOQ Point (pg/mL)	Mean Pooled CV	Mean Recovery	LLOQ Claim (pg/mL)
Low	**0.117**	44.7%	113%	**0.467**
Mid 1	**0.234**	28.6%	114%	
Mid 2	**0.467**	11.1%	103%	
High	**0.934**	11.4%	95%	

Reproducibility Precision Sample Results

Sample	Mean (pg/mL)	Between Instrument CV	Between Lot CV	Between Run CV	Within Run CV

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Control 1	27.6	0.0%	3.9%	3.0%	7.7%
Control 2	1492	0.0%	2.2%	7.1%	4.2%
Panel 1	59.4	0.0%	8.5%	3.8%	3.9%
Panel 2	226	0.0%	3.0%	6.2%	3.6%
Panel 3	2095	0.0%	6.5%	3.8%	4.5%

Repeatability Precision Sample Results

Sample	Mean (pg/mL)	Between Day CV	Between Run CV	Within Run CV
Control 1	26.2	2.7%	0.0%	7.2%
Control 2	1372	5.4%	3.1%	4.5%
Panel 1	60.5	2.6%	2.0%	5.6%
Panel 2	221	0.0%	4.0%	4.2%
Panel 3	1910	0.0%	8.5%	5.0%

Spike Recovery

GFAP Serum/Plasma (w/ Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**80 pg/mL**	**800 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
Serum 1	62.0%	83.5%	72.7%	77.9%
Serum 2	113%	123%	118%	
Plasma 1	61.4%	64.6%	63.0%	

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Plasma 2	46.7%	69.5%	58.1%	

GFAP Serum/Plasma (w/o Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**80 pg/mL**	**800 pg/mL**	**Mean**	**Grand Mean**
Diluent	106%	93.6%		
Serum 1	65.5%	78.1%	71.8%	77.2%
Serum 2	120%	115%	117%	
Plasma 1	64.9%	60.4%	62.6%	
Plasma 2	49.3%	65.0%	57.2%	

GFAP CSF (w/Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + spiked buffer conc)] x 100				
Sample ID	**1500 pg/mL**	**15000 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
BRH1299850	86.9%	98.4%	92.7%	108%
BRH1299858	78.7%	106%	92.1%	
BRH1299860	159%	123%	141%	
BRH1299865	88.8%	120%	104%	

GFAP CSF (w/o Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + target spike conc)] x 100				
Sample ID	**1500 pg/mL**	**15000 pg/mL**	**Mean**	**Grand Mean**
Diluent	111%	110%		
BRH1299850	96.7%	108%	102%	119%
BRH1299858	87.5%	116%	102%	
BRH1299860	177%	135%	156%	
BRH1299865	98.9%	132%	115%	

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Dilution Linearity

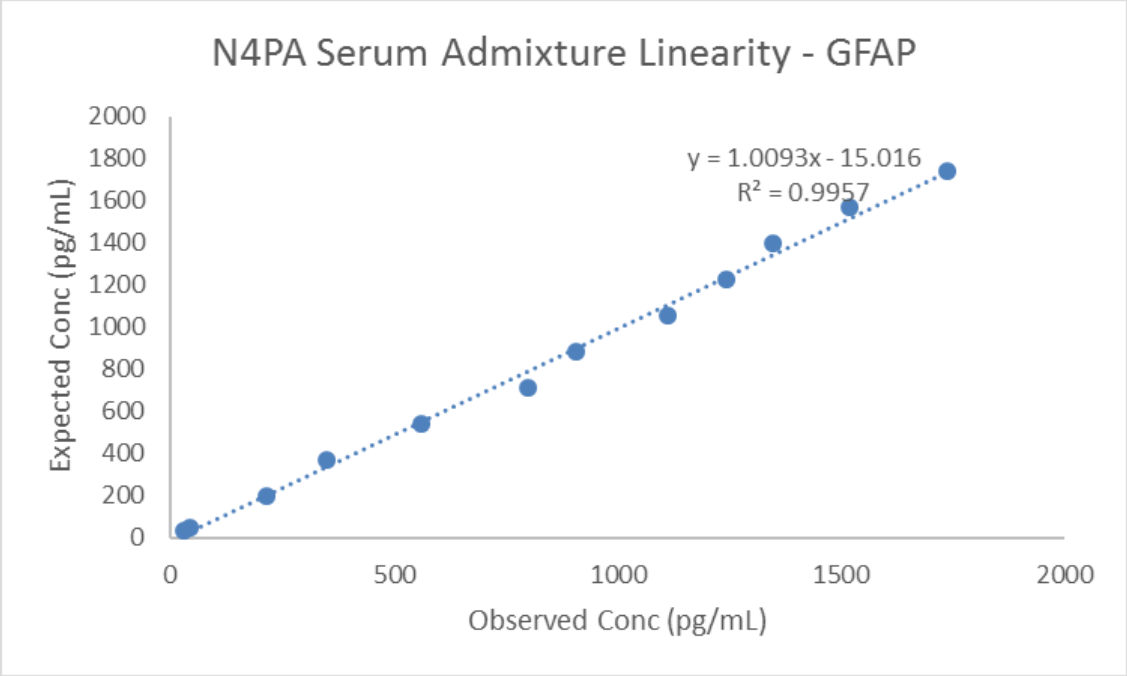
Dilution	Spiked Serum	Dilution	Endogenous CSF
8X	118%	80X	95.5%
16X	121%	160X	96.5%
32X	102%	320X	96.6%
64X	106%	640X	96.8%
128X	105%	1280X	98.9%
256X	103%	2560X	96.8%
512X	111%	5120X	104%

Admixture Linearity - Serum

Linearity Sample	% High Pool	% Low Pool	Observed GFAP (pg/mL)	% Bias
1	100%	0%	1738	-
2	90%	10%	1518	-3.2%
3	80%	20%	1347	-3.6%
4	70%	30%	1242	1.4%

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5	60%	40%	1111	5.3%
6	50%	50%	909	2.8%
7	40%	60%	800	12%
8	30%	70%	562	3.5%
9	20%	80%	350	-6.0%
10	10%	90%	214	6.1%
11	1%	99%	42.3	-11%
12	0%	100%	30.5	-
			Average	0.6%



Normal Sample Reading

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Donor	Lot 1					
	Plasma Conc. (pg/mL)	CV	Serum Conc. (pg/mL)	CV	CSF Conc. (pg/mL)	CV
1	706	6.9%	873	5.0%	15042	6.4%
2	133	1.1%	128	1.7%	5868	10%
3	95.9	3.0%	105	3.9%	11194	8.3%
4	58.7	4.6%	67.4	0.6%	17690	4.0%
5	111	3.9%	114	2.7%	24467	6.2%
6	139	3.1%	144	5.4%	29411	6.7%
7	191	1.9%	195	2.8%	14110	14%
8	127	2.4%	132	2.0%	15100	8.8%
9	52.3	1.7%	54.6	5.1%	14206	2.3%
10	77.5	5.5%	86.1	1.6%	7206	4.5%
11	66.6	4.5%	61.2	3.1%	24303	3.0%
12	101	5.0%	94.3	5.3%	8945	3.2%
13	83.5	8.2%	82.5	2.8%	13532	11%
14	38.2	4.7%	30.6	1.0%	6619	17%
15	61.9	4.2%	61.2	5.4%	11000	6.0%
16	105	0.5%	104	4.7%	10201	4.2%
17	72.1	2.7%	59.0	4.2%	37482	6.4%
18	37.3	3.2%	37.7	8.2%	33236	7.5%
19	52.6	9.9%	45.9	0.7%	23549	5.2%
20	108	3.4%	100	5.5%	35295	8.5%
Mean *	**121 pg/mL**		**129 pg/mL**		**17923 pg/mL**	
Median *	**89.7 pg/mL**		**90.2 pg/mL**		**14624 pg/mL**	
Range	**37.3 – 706 pg/mL**		**30.6 – 873 pg/mL**		**5868 – 37482 pg/mL**	

* Values below LLOQ are not included in the mean and median.

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IX. UCH-L1 Claims Details

LOD Lot 1

Reagent Lot	PD Lot 1							
Instrument	**CU20**		**CU24**		**VU16**		**AVE**	**SD**
Primary Cal LOD (pg/mL)	0.776	1.420	1.335	3.618	1.157	3.046	**1.892**	**1.152**
Primary Cal B/A	4.3	3.9	4.7	3.1	4.4	4.4	**4.1**	**0.6**
Primary Cal A	0.004	0.004	0.003	0.004	0.004	0.004	**0.004**	**0.000**
Primary Cal A CV	9.8%	16.1%	18.7%	31.1%	16.4%	38.7%	**21.8%**	**10.8%**
Reference Cal LOD (pg/mL)	1.376	2.385	1.667	2.408	0.624	1.427	**1.648**	**0.677**
Reference Cal B/A	4.0	4.4	3.3	3.6	5.7	4.7	**4.3**	**0.9**
Reference Cal A	0.004	0.004	0.005	0.005	0.003	0.004	**0.004**	**0.001**
Reference Cal A CV	14.9%	30.0%	14.1%	23.6%	10.6%	19.3%	**18.7%**	**7.1%**
Reference Cal H	10.778	11.976	10.602	10.151	11.051	11.972	**11.088**	**0.746**

CV>20%

LOD Lot 2

Reagent Lot	PD Lot 2							
Instrument	**CU20**		**CU24**		**VU16**		**AVE**	**SD**
Primary Cal LOD (pg/mL)	1.652	0.931	2.255	1.975	1.226	1.417	**1.576**	**0.488**
Primary Cal B/A	4.6	4.9	3.7	3.8	4.7	3.9	**4.3**	**0.5**
Primary Cal A	0.003	0.003	0.005	0.005	0.004	0.004	**0.004**	**0.001**
Primary Cal A CV	22.0%	14.0%	25.8%	21.3%	17.7%	16.4%	**19.5%**	**4.3%**
Reference Cal LOD (pg/mL)	1.604	0.688	3.477	3.163	2.013	0.120	**1.844**	**1.326**
Reference Cal B/A	3.7	3.9	3.5	3.6	5.1	3.9	**3.9**	**0.6**
Reference Cal A	0.004	0.004	0.006	0.005	0.004	0.004	**0.005**	**0.001**
Reference Cal A CV	15.5%	7.5%	32.6%	31.1%	28.2%	2.6%	**19.6%**	**12.9%**
Reference Cal H	11.417	11.242	13.102	11.196	13.653	12.143	**12.125**	**1.043**

CV>20%

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LLOQ Lot 1

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
10.9 pg/mL	7.9%	8.8%	3.2%	4.9%	6.2%	15.6%
5.45 pg/mL	22.2%	7.3%	19.8%	12.7%	12.6%	8.8%
2.73 pg/mL	19.0%	24.5%	15.5%	11.0%	51.4%	15.3%
1.36 pg/mL	19.5%	34.2%	22.6%	60.2%	50.4%	33.2%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
10.9 pg/mL	108%	104%	107%	103%	105%	107%
5.45 pg/mL	112%	115%	103%	107%	111%	124%
2.73 pg/mL	80.0%	167%	93.7%	124%	87.7%	120%
1.36 pg/mL	106%	217%	107%	53.9%	56.2%	257%

LLOQ Lot 2

Pooled CV						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**RUN02**	**RUN01**	**RUN02**
10.9 pg/mL	11.2%	4.5%	15.7%	10.8%	7.9%	17.1%
5.45 pg/mL	3.8%	12.3%	15.7%	15.9%	22.6%	14.5%
2.73 pg/mL	28.5%	10.7%	10.8%	21.2%	15.0%	66.2%
1.36 pg/mL	39.5%	47.8%	29.2%	34.0%	55.5%	43.7%
% Recovery						
Instrument	**CU20**		**CU61**		**CU58**	
Experiment	**RUN01**	**RUN02**	**RUN01**	**Experiment**	**RUN01**	**RUN02**
10.9 pg/mL	107%	95.8%	99.3%	98.4%	112%	113%
5.45 pg/mL	101%	105%	96.6%	100%	108%	124%
2.73 pg/mL	110%	127%	152%	113%	118%	79.3%
1.36 pg/mL	95.6%	138%	115%	107%	123%	76.6%

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LLOQ Summary

LOQ Point	LOQ Point (pg/mL)	Mean Pooled CV	Mean Recovery	LLOQ Claim (pg/mL)
Low	**1.36**	39.2%	121%	**5.45**
Mid 1	**2.73**	24.1%	114%	
Mid 2	**5.45**	14.0%	109%	
High	**10.9**	9.5%	105%	

Reproducibility Precision Sample Results

Sample	Mean (pg/mL)	Between Instrument CV	Between Lot CV	Between Run CV	Within Run CV
Control 1	129	1.8%	0.0%	2.9%	9.3%
Control 2	13145	0.0%	2.8%	4.9%	5.4%
Panel 1	71.9	5.0%	0.0%	6.4%	11%
Panel 2	381	4.8%	0.0%	4.9%	5.6%
Panel 3	6663	0.0%	4.2%	5.9%	4.2%

Repeatability Precision Sample Results

Sample	Mean (pg/mL)	Between Day CV	Between Run CV	Within Run CV
Control 1	125	0.0%	2.8%	6.9%
Control 2	11681	3.6%	3.1%	4.0%
Panel 1	73.0	0.0%	11%	9.6%
Panel 2	356	4.0%	6.7%	5.6%
Panel 3	6082	0.0%	7.0%	4.2%

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Spike Recovery

UCH-L1 Serum/Plasma (w/ Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**300 pg/mL**	**3000 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
Serum 1	85.7%	70.6%	78.1%	89.8%
Serum 2	102%	79.5%	90.5%	
Plasma 1	108%	85.3%	96.8%	
Plasma 2	94.5%	93.1%	93.8%	

UCH-L1 Serum/Plasma (w/o Buffer Correction) % Recovery [Spiked serum/(Unspiked serum + spiked buffer conc)] x 100				
Sample ID	**300 pg/mL**	**3000 pg/mL**	**Mean**	**Grand Mean**
Diluent	115%	124%		
Serum 1	98.6%	87.3%	93.0%	107%
Serum 2	117%	98.3%	108%	
Plasma 1	125%	106%	115%	
Plasma 2	109%	115%	112%	

UCH-L1 CSF (w/Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + spiked buffer conc)] x 100				
Sample ID	**15000 pg/mL**	**150000 pg/mL**	**Mean**	**Grand Mean**
Diluent	100%	100%		
BRH1299850	117%	113%	115%	119%
BRH1299858	113%	116%	114%	
BRH1299860	116%	147%	131%	
BRH1299865	118%	115%	117%	

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UCH-L1 CSF (w/o Buffer Correction) % Recovery [Spiked CSF/(Unspiked CSF + target spike conc)] x 100				
Sample ID	**15000 pg/mL**	**150000 pg/mL**	**Mean**	**Grand Mean**
Diluent	85.0%	114%		
BRH1299850	99.6%	128%	114%	119%
BRH1299858	96.0%	132%	114%	
BRH1299860	98.2%	167%	133%	
BRH1299865	101%	130%	115%	

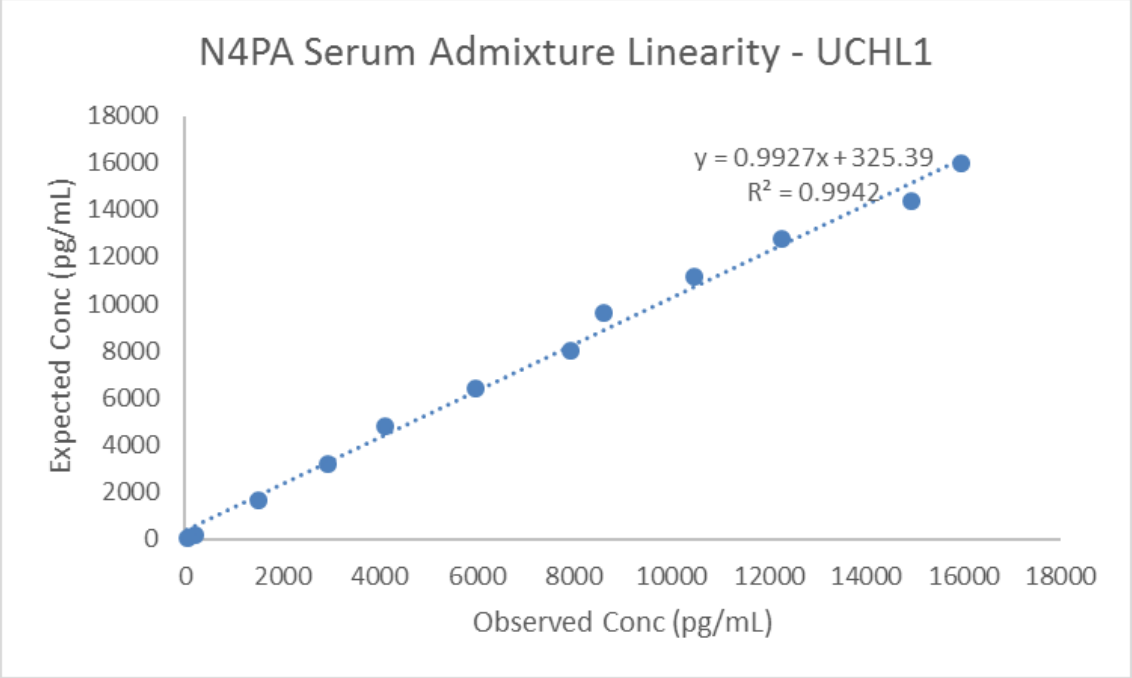
Dilution Linearity

Dilution	Spiked Serum	Dilution	Spiked CSF
8X	103%	80X	94.8%
16X	99.6%	160X	93.5%
32X	84.6%	320X	94.2%
64X	85.5%	640X	95.8%
128X	87.3%	1280X	95.6%
256X	79.0%	2560X	94.2%
512X	82.3%	5120X	98.0%

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Admixture Linearity - Serum

Linearity Sample	% High Pool	% Low Pool	Observed UCH-L1 (pg/mL)	% Bias
1	100%	0%	15951	-
2	90%	10%	14930	4.0%
3	80%	20%	12265	-4.0%
4	70%	30%	10469	-6.4%
5	60%	40%	8616	-10%
6	50%	50%	7918	-1.0%
7	40%	60%	5959	-7.0%
8	30%	70%	4102	-15%
9	20%	80%	2930	-9.2%
10	10%	90%	1506	-8.0%
11	1%	99%	209	1.9%
12	0%	100%	46.5	-
			Average	-4.6%



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Normal Sample Reading

Donor	Lot 1					
	Plasma Conc. (pg/mL)	CV	Serum Conc. (pg/mL)	CV	CSF Conc. (pg/mL)	CV
1	22.3	11%	31.5	5.4%	499	6.4%
2	13.3*	44%	8.55*	52%	1480	10%
3	13.1*	47%	8.66*	19%	1139	8.3%
4	12.1*	28%	8.66*	21%	1390	4.0%
5	9.86*	12%	6.92*	47%	1163	6.2%
6	23.7	25%	31.4	8.9%	812	6.7%
7	15.6*	45%	17.1*	5.8%	771	14%
8	28.2	18%	20.0*	10%	1026	8.8%
9	12.1*	14%	7.46*	43%	1031	2.3%
10	13.6*	27%	13.8*	22%	840	4.5%
11	7.48*	6.0%	10.3*	32%	1440	3.0%
12	10.6*	78%	15.2*	23%	904	3.2%
13	8.13*	39%	2.95*	86%	925	11%
14	22.4	43%	22.7	21%	626	17%
15	3.36*	19%	6.85*	33%	677	6.0%
16	3.79*	72%	4.73*	17%	789	4.2%
17	6.64*	50%	7.81*	29%	1125	6.4%
18	7.17*	19%	7.60*	55%	1179	7.5%
19	29.9	5.3%	28.9	21%	2618	5.2%
20	5.16*	56%	5.42*	62%	951	8.5%
Mean **	**25.3 pg/mL**		**28.6 pg/mL**		**1069 pg/mL**	
Median **	**23.7 pg/mL**		**30.2 pg/mL**		**989 pg/mL**	
Range	**3.36 – 29.9 pg/mL**		**2.95 –31.5 pg/mL**		**499 – 2618 pg/mL**	

*Sample concentration below LLOQ

** Values below LLOQ are not included in the mean and median.

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