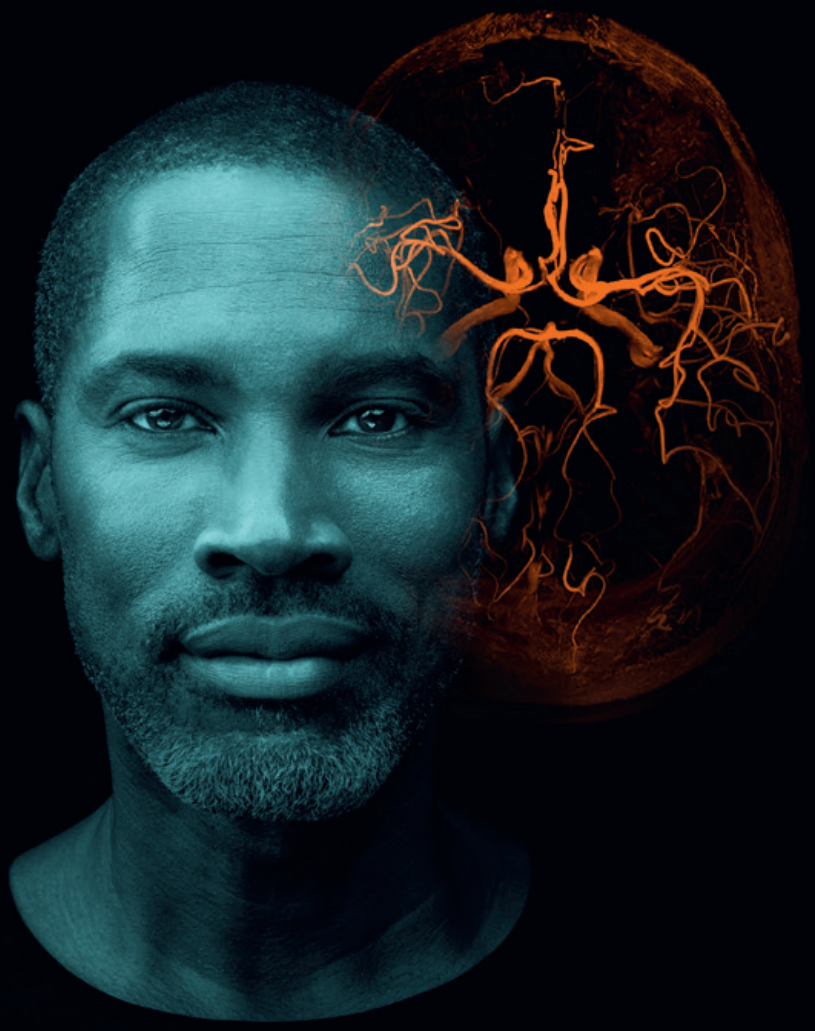
Neurofilament Light Chain (NfL) Testing Service

Siemens Healthcare Laboratory,
Berkeley, CA

siemens-healthineers.us/nfl-testing-service



SIEMENS Healthineers

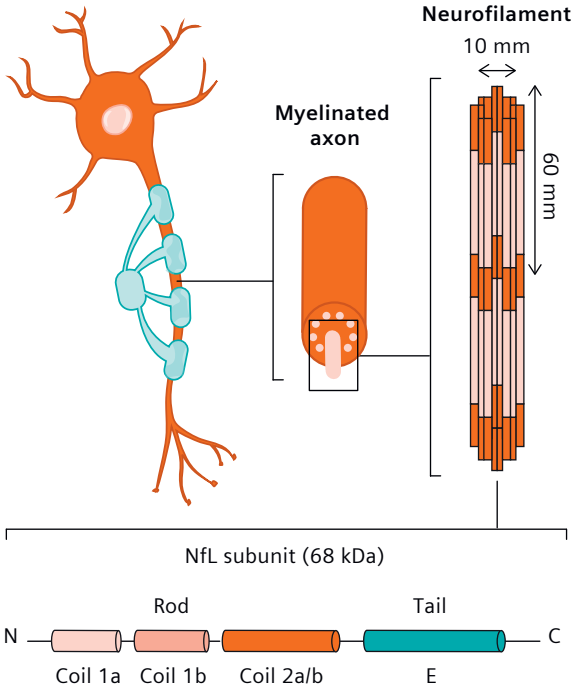
Neurofilament Light Chain

Neurodegenerative diseases often progress stealthily with a prolonged subclinical stage.[1] Noninvasive biomarkers are needed that can detect underlying pathologies and monitor disease activity.[1]

Neurofilament light chain (NfL) is a structural protein found in neurons. Axonal injury and degeneration of neurons results in the release of NfL into CSF and blood,[2] making it a candidate-specific biomarker for a range of neurodegenerative diseases.

NfL as a specific neurobiomarker has been reported in inflammatory, neurodegenerative, traumatic, and cerebrovascular diseases. Testing for levels of NfL may provide valuable data in clinical trials for neurological disorders such as amyotrophic lateral sclerosis (ALS), Alzheimer's disease, Huntington's disease, multiple sclerosis, and Parkinson's disease.[2]

1. Barro C, Chitnis T, Weiner HL. Blood neurofilament light: a critical review of its application to neurologic disease [eng]. Ann Clin Transl Neurol. 2020;7:2508-23. doi: 10.1002/acn3.51234
2. Gaetani L, Blennow K, Calabresi P, et al. J Neurol Neurosurg Psychiatry. 2019;90:870-881.



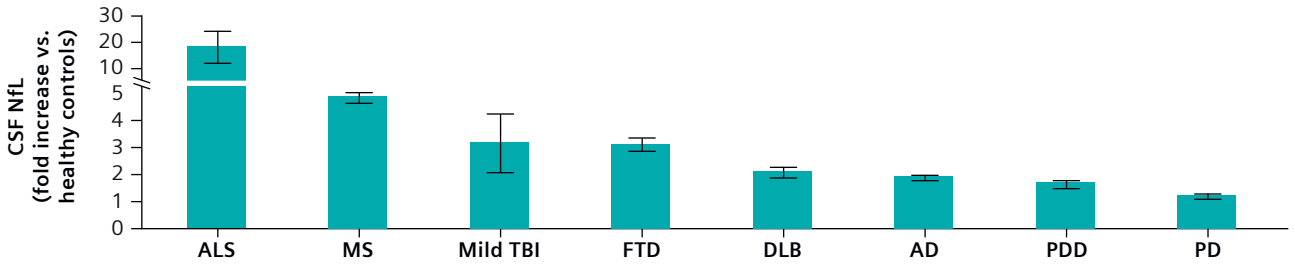
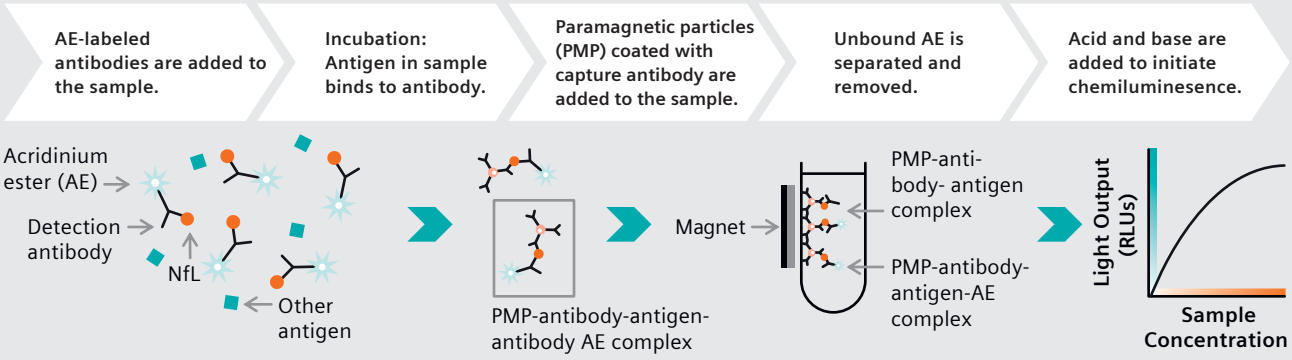


Figure 1. The increase of CSF NfL in a variety of neurological diseases associated with axonal damage. ALS: amyotrophic lateral sclerosis; MS: multiple sclerosis; mild TBI: mild traumatic brain injury; FTD: frontotemporal dementia; DLB: dementia with Lewy bodies; AD: Alzheimer's disease; PDD: Parkinson's disease dementia; PD: Parkinson's disease.(Adapted from Figure 2 of Gaetani L, Blennow K, Calabresi P, et al. J Neurol Neurosurg Psychiatry. 2019;90:870-881.)

Our Assay

Siemens Healthineers blood-based NfL assay* uses high-sensitivity acridinium ester (AE) technology designed to run on the Atellica® Solution Immunoassay Analyzer for serum, plasma, or CSF samples. We have extensive experience in NfL assay development on our proprietary immunoassay platforms and with clinical trial assay testing, supporting clinical trials conducted by NIH and top pharmaceutical companies. Our NfL testing service is available to support clinical trials through our CLIA-certified lab in Berkeley, CA, USA.



**The SHL NfL testing service is available through our CLIA-accredited lab in Berkeley, CA, USA to support clinical trials.*

Assay Validation

Our NfL Assay demonstrated equivalence with serum, K2 EDTA plasma, and lithium heparin plasma samples:

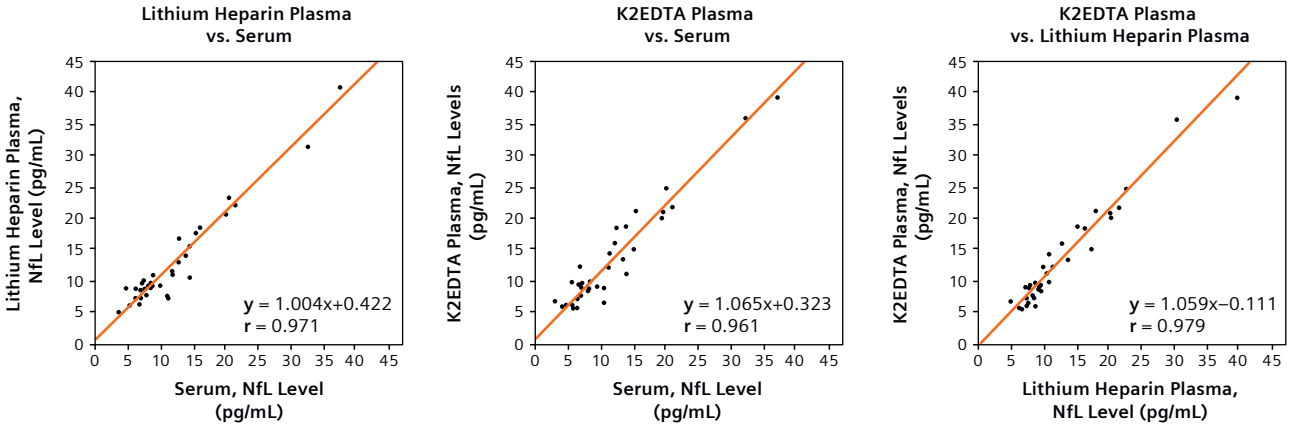


Figure 2. Serum and plasma equivalence.† Matched serum, heparin plasma, and EDTA plasma from 40 individual donors were tested. NfL concentrations in plasma and serum were determined to be equivalent.

Qiu X et al. Equivalence of serum and plasma neurofilament light chain levels using a highly sensitive automated immunoassay. Poster presented at: Alzheimer's Association International Conference (AAIC); July 27–31, 2020; Virtual meeting

Our NfL assay† values are similar to those observed with SIMOA NfL Assay:

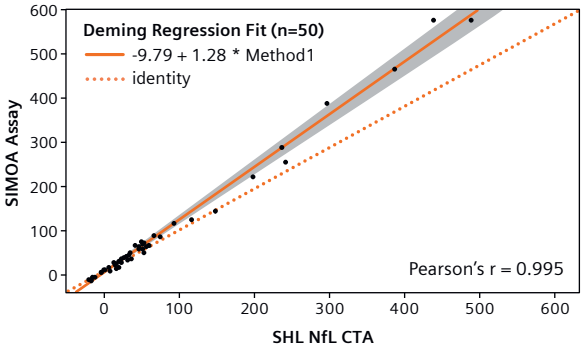


Figure 3. Deming regression analysis: Siemens Healthcare Laboratory NfL Clinical Trial Assay (SHL NfL CTA) vs SIMOA NfL assays

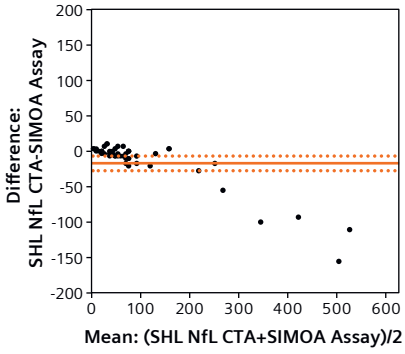


Figure 4. Bland-Altman difference plot: SHL NfL CTA vs SIMOA NfL assays

- There was a high level of agreement, with a Pearson's correlation coefficient of 0.995 (Figure 3).
- At higher NfL concentrations (>200 pg/mL), the SIMOA NfL assay produced higher values (Figure 4).

†Data on File. Performed on the Atellica Solution Immunoassay Analyzer. The SHL NfL testing service is available through our CLIA-accredited lab in Berkeley, CA, USA to support clinical trials.

Key Facts About the NfL Test

Test Description	The Neurofilament Light (NfL) assay is a laboratory-developed test (LDT) used to quantify NfL in human serum, plasma, or cerebrospinal fluid (CSF) using the Atellica Solution Immunoassay Analyzer.
Sample type	Serum, EDTA plasma, or CSF
Sample size	1.0 mL Serum or EDTA plasma 0.5 mL of CSF
Specimen Storage	Freeze serum and plasma at ≤ −20°C in a non-frost-free freezer or, preferably, −60 to −90°C for long-term storage.

Contact your Siemens Healthcare Laboratory Representative for more details.

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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Published by Siemens Healthcare Diagnostics Inc. · Order No. 30-22-DX-1367-76 · 03-2022 · ©Siemens Healthcare Diagnostics Inc., 2022