Sales sheet

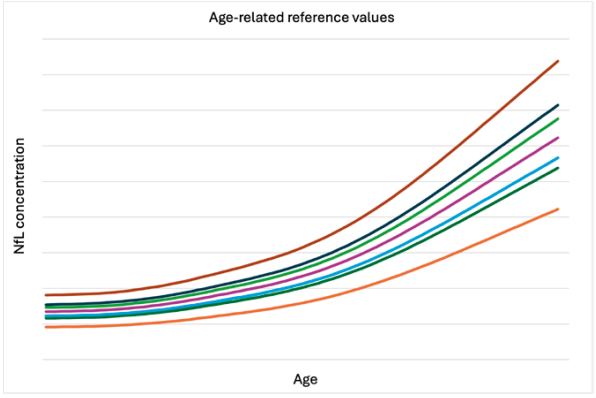
LUMIPULSE® G NFL BLOOD <CE>

FOR RELIABLE MEASUREMENT ACROSS VARIOUS NEUROLOGICAL DISEASES

Background - Neurofilament light chain (NfL) is a biologically grounded biomarker of neuroaxonal damage that can support disease activity monitoring, and may be helpful in prognosis, and therapeutic evaluation across a wide range of neurological diseases.[1,2]
Its clinical utility depends on interpretation by clinicians within standardized reference frameworks, including age-related reference ranges, defined clinical decision rules, and longitudinal assessment of change over time.[3,4]
Advances in highly sensitive, fully automated random-access immunoassays have enabled reliable quantification of NfL in blood, thereby facilitating its transition from a research biomarker to a clinically applicable routine tool.[1,5] Across neurological diseases of diverse causes - including i.e. neurodegenerative, inflammatory, vascular, infectious, and traumatic conditions - NfL concentrations consistently reflect the extent of axonal injury, largely independent of the underlying pathogenic mechanisms.[1,6,7,8,9]

Lumipulse® G NfL Blood (CE) provides robust results

- Highly sensitive immunoassay — 100 % detection rate in 858 samples from healthy and affected cohorts
- Serum and plasma equivalence across the analytical measurement interval — y = 0,001 + 1,005 x
- Wide analytical measurement interval — up to 2500 pg/mL
- High lot-to-lot consistency — 1.8 – 4.1% CV (3 lots tested)
- Easy to use and highly standardized automated processing with the LUMIPULSE G systems
- 2-point calibration master curve for less manual efforts and robust calibration



Given the well-established age-related increase in NfL concentrations, reference values stratified by individual years or decades are one important tool for meaningful assessment using the NfL as a biomarker of neuroaxonal damage.

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Overview

Feature	Characteristics
Assay design	Specific 2-step sandwich
Sample type	Serum, K_2EDTA plasma
Sample volume	100 µL
Analytical measuring range (AMI)	0.96 – 2500.00 pg/mL
Extended measuring range (EMI)	Up to 5000.00 pg/mL tested (1:2 dilution with sample diluent 1)
Limit of detection (LOD)	0.57 pg/mL
Limit of quantification (LOQ at 20 %CV)	0.96 pg/mL
Within-laboratory precision	1.8 – 6.4 %CV
Lot-to-lot consistency	1.8 – 4.1%CV
Calibration points, configuration	2 (master curve), liquid
Calibration curve stability	30 days
High dose Hook Effect	No effect up to 25000 pg/mL
Traceability	In-house reference calibrators
Controls (levels, configuration, target levels)	Low/High, liquid, approximately 15 and 800 pg/mL

Packaging and product codes

Cartridges, Calibrator & Controls*	Packaging / Labeling	Product code
Lumipulse G NfL Blood Immunoreaction Cartridges	3 x 14 T, CE	81632
Lumipulse G NfL Blood Calibrators	1 x 2 C, CE	81633
Lumipulse NfL Blood Controls	2 x 2 C, CE	81634

References

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4. *Delaby C et al. Clinical use and reporting of neurofilament quantification in neurological disorders: A global overview. Alzheimers Dement. 2025, 21(6), e70343.*
5. *Ashton NJ et al. A multicentre validation study of the diagnostic value of plasma neurofilament light. Nat Commun. 2021, 12(1), 3400.*
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8. *Davydow DS et al. Neurofilament Light Chain and Differentiation of Behavioral Variant Frontotemporal Dementia From Psychiatric Disorders: A Systematic Review. JAMA Psychiatry. 2026, 83(1), 85–98.*
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