Data Sheet

Neurofilament Light (NfL_LDT) Assay

siemens-healthineers.us/nfl-testing-service

Test description

The Neurofilament Light (NfL) assay is a laboratory-developed test (LDT) used to quantify neurofilament light chain (NfL) in human serum, EDTA plasma, and cerebrospinal fluid using the Atellica® Solution Immunoassay Analyzer (Atellica IM Analyzer).

Test code	NFLS_LDT, NFLP_LDT, NFLC_LDT
Units	pg/mL
Assay range	Serum: 3.9 to 500 pg/mL EDTA plasma: 4.9 to 477 pg/mL Cerebrospinal fluid: 85.5 to 25,700 pg/mL
Sample type	Serum, plasma, or cerebrospinal fluid
Sample size	1.0 mL serum or plasma (min 0.7 mL) 0.5 mL cerebrospinal fluid (min 0.3 mL)

Sample collection and handling

Serum: Observing universal precautions, collect blood samples by venipuncture into a serum or serum separator tube. Allow samples to clot adequately before centrifugation. Separate serum by centrifugation according to manufacturer's instructions.

Plasma: Observing universal precautions, collect blood samples by venipuncture into an EDTA plasma tube. Mix well by inversion. Separate plasma by centrifugation at 2000 xg for 10 minutes or according to manufacturer's instructions.

Cerebrospinal Fluid: Collect CSF specimens preferably in the morning at level L3/L4 or L4/L5. Discard the first 20 drops of CSF or until bleeding has diminished before collecting. **Do not allow specimen contact with glass or polystyrene. Do not centrifuge or mix samples.**

Aliquot serum, plasma, or cerebrospinal fluid into a 3.5 mL 13 x 92 mm screw cap polypropylene tube (Sarstedt 62.617) or a 5.0 mL 15.3 x 92 screw cap polypropylene tube (Sarstedt 62.611.300)

Storage

Freeze serum and plasma at ≤ –20°C in a non-frost-free freezer or, preferably, –60 to –90°C for long-term storage. See Sample Stability for long-term storage stability.

Sample stability

Storage Condition/ Treatment	EDTA Plasma	Serum	CSF
Freeze/thaw	Up to 6 freeze/thaw cycles		
Room temperature	Up to 1 week		
Refrigerated 4–8°C	Up to 2 weeks		Up to 1 week
Frozen –15 to –25°C*	3 months	1 year	3 months
Frozen –60 to –90°C*	6 months	1 year	

**Stability studies ongoing.*

Shipping instructions

Send electronic manifest along with airway information to **dx.scl.healthcare@siemens-healthineers.com** and enclose a copy of the shipping manifest/packing list in each shipment box.

Ship on sufficient dry ice to last 72 hours in case of delayed shipment. Package and label in compliance with federal and international regulations covering the transport of clinical samples and etiological agents.

Ship specimens overnight express to allow for receipt on Monday through Friday. **We cannot receive packages on Saturday or Sunday.**

Shipping address

Siemens Healthcare Laboratory
725 Potter Street
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Phone: +1 800-434-2447 (+1 510-982-4200)
Fax: +1 510-982-4203
Email: dx.scl.healthcare@siemens-healthineers.com

Intended use

The Neurofilament Light (NfL_LDT) assay is used for the quantitative detection of NfL in serum, plasma, and cerebrospinal fluid.

Additional information

For technical questions, please call +1 800-434-2447

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Summary of analytical performance characteristics of the Neurofilament Light (NfL) assay

Characteristic	Performance
Reportable range	The reportable range for each sample type is as follows: • Serum: 3.9 to 500 pg/mL • EDTA plasma: 4.9 to 477 pg/mL • Cerebrospinal fluid: 85.5 to 25,700 pg/mL **Note:** The upper limit is based on the highest concentration tested in validation studies. The actual upper limit could be higher.
Reproducibility	Across the assay reporting range, the ranges of total %CVs observed for each sample type were as follows: • Serum: 4.9 to 8.4% • EDTA plasma: 7.7 to 18.1% • Cerebrospinal fluid: 4.0 to 16.5%
Sensitivity	**LoB** • Serum: 0.5 pg/mL • EDTA plasma: 0.6 pg/mL • Cerebrospinal fluid: 32.3 pg/mL **LoD** • Serum: 0.7 pg/mL • EDTA plasma: 1.7 pg/mL • Cerebrospinal fluid: 54.2 pg/mL **LLoQ** • Serum: 3.9 pg/mL • EDTA plasma: 4.9 pg/mL • Cerebrospinal fluid: 85.5 pg/mL
Interfering substances	Assay interference was not observed in samples with the following substances and concentrations: • Hemoglobin below 500 mg/dL • Direct bilirubin below 60 mg/dL • Indirect bilirubin below 40 mg/dL • Albumin below 6 g/dL • Triglycerides below 2000 mg/dL • RF below 193 U/mL • Biotin below 3500 ng/mL • Neurofilament heavy chain • Neurofilament medium chain
Drug interference	Drug interference testing was performed using the following drugs used to treat Alzheimer's and multiple sclerosis patients: • Donepezil • Rivastigmine • Memantine • Galantamine • Citalopram • Mirtazapine • Sertraline • Bupropion • Duloxetine • Imipramine • Ibuprofen • Siponimod • Acetaminophen • Aspirin • Beta interferon 1a • Beta interferon 1b • Fingolimod • Dimethyl fumarate • Teriflunomide • Ocrelizumab • Mitoxantrone • Caldribine • Alemtuzumab • Glucose Assay interference was observed in the presence of mitoxantrone at concentrations greater than 0.113 mg/dL. No interference was observed in the presence of the other drugs tested.
Normal range (EDTA plasma)	The normal range for NfL in EDTA plasma is ≤14.4 pg/mL.
Specimen equivalency	Equivalency testing using 7 spiked and 40 donor-matched sets of serum, EDTA plasma, and lithium heparin plasma was performed. It was determined that NfL results are equivalent across the different sample types (slope = 1.0 ± 0.1, Y-int ≤LLoQ).
Method comparison	Good correlation was observed between the NfL assay on the Atellica IM Analyzer and the Quanterix and ADVIA Centaur® XP systems. Results are as follows: **Quanterix vs. Atellica IM Analyzer** • Serum average quantitation difference: –8% Slope = 1.28 Pearson correlation R = 0.995 • CSF average quantitation difference: –29% Slope = 1.71 Pearson correlation R = 0.994 **ADVIA Centaur XP System vs. Atellica IM Analyzer** • Serum average quantitation difference: 9% Slope = 0.88 Pearson correlation R = 1.00 • CSF average quantitation difference: –13.2% Slope = 0.943 Pearson correlation R = 0.996

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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