Elecsys NfL RUO

cobas®

REF		Σ	SYSTEM
09880488430	09880488520	100	**cobas e** 402 **cobas e** 801

English

For Research Use Only (RUO). Not for use in diagnostic procedures.

System-Information

Short name	ACN (application code number)
NfL v2	17080

Please ensure installation of the lot-specific efiles on the **cobas** link prior to running the assay.

Please note

The measured value of the protein *Neurofilament light chain* (NEFL, Gene ID: 4747) in a given sample, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. Values determined in samples by different assay methods cannot be used interchangeably.

Assay description

The Elecsys NfL RUO assay is a quantitative immunoassay for the in vitro determination of neurofilament light (NfL) protein in human plasma, serum and cerebrospinal fluid (CSF).

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

Test principle

The Elecsys NfL RUO assay is a quantitative, two-incubation step assay using sandwich assay principle.

Total duration of assay: 18 minutes.

- 1st incubation: 48 µL of sample, a biotinylated monoclonal NfL-specific antibody and a monoclonal NfL-specific antibody labeled with a ruthenium complex[a)] react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.
- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell II M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.
- Results are determined via a calibration curve which is instrument-specifically generated by 2-point calibration and a master curve provided via the reagent barcode or e-barcode.

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The **cobas e** pack (M, R1, R2) is labeled as NFL.

M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.4 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 Anti-NfL-Ab~biotin, 1 bottle, 7.0 mL:
Biotinylated monoclonal anti-NfL antibody (rabbit); HEPES[b)] buffer, pH 7.4; preservative.

R2 Anti-NfL-Ab~$Ru(bpy)_3^{2+}$, 1 bottle, 7.0 mL:
Monoclonal anti-NfL antibody (rabbit) labeled with ruthenium complex, HEPES buffer, pH 7.4; preservative.

b) HEPES = [4-(2-hydroxyethyl)-piperazine]-ethane sulfonic acid

Warnings and precautions

Do not run RUO assays in random access mode with IVD measurements. Instead, perform RUO assays in batch mode and follow the washing procedure to avoid any potential impact on IVD results.

Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

All human material should be considered potentially infectious and should be handled with the same level of care as a patient specimen.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Hazardous components:

- 2-methyl-2H-isothiazol-3-one hydrochloride

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Handling

The reagents in the kit (M, R1 and R2) are ready-for-use and are supplied in bottles compatible with the system.

All information required for correct operation is read in from the respective reagent labels or can be found in the package insert and on the associated Value Sheet.

Perform **only one** calibration procedure per aliquot.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Stability:	
unopened at 2-8 °C	up to the stated expiration date (see Value Sheet)
on the analyzers	112 days

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Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Plasma, Serum and CSF collected using standard sampling tubes.

Roller mix for 15 min after thawing.

Stable for 2 days at 2-8 °C and 1 day at 15-25 °C.

Freeze only once.

Do not use hemolyzed serum samples that are visibly colored red.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

Ensure the samples, calibrators and controls are at 15-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.

Close the cap when reagents are not in use.

Materials provided

See “Reagents – working solutions” section for reagents.

Materials required but not provided

- REF 09880496430, CalSet NfL RUO, for 2 x 1.0 mL
- REF 09880500430, PreciControl NfL RUO, for 3 x 1.0 mL
- REF 07299001190, Diluent Universal, 36.0 mL
- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- REF 03142949122, ControlSet Vials, 2 x 56 empty snap-cap bottles
- Distilled or deionized water
- General laboratory equipment
- **cobas e** analyzer

Additional materials for **cobas e** 402 and **cobas e** 801 analyzers:

- REF 06908799190, ProCell II M, 2 x 2 L system solution
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
- REF 06908853190, PreClean II M, 2 x 2 L wash solution
- REF 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- REF 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- REF 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- REF 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution
- REF 11298500160, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution (for USA)

Test procedure

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.

Resuspension of the microparticles takes place automatically prior to use.

Place the cooled (stored at 2-8 °C) **cobas e** pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the **cobas e** pack.

Read the test-specific parameters via the reagent label.

In case the barcode cannot be read, manually enter the 15-digit sequence of numbers.

Note: The assay name is displayed as *NFL* on the instrument.

Calibration

Traceability: The Elecsys NfL assay is traceable to the recombinant protein by weight which is traceable to NIST amino acid reference calibrators.

Every Elecsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analyzer).
Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

Renewed calibration is recommended as follows:

- every 12 weeks when using the same reagent lot
- every 4 weeks when using the same **cobas e** pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

Quality control

Use PreciControl NfL RUO or other suitable controls for routine quality control procedures.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

Values obtained should fall within the defined limits as stated in the Value Sheet.

Special care needs to be taken to ensure that the accuracy and precision of the testing stays within acceptable limits.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

If necessary, repeat the measurement of the samples concerned.

Follow the applicable government regulations and local guidelines for quality control.

Note: The controls are not barcode-labeled and therefore have to be run like external controls. All values and ranges have to be entered manually. Please refer to the section “QC” in the operator's manual or to the online help of the instrument software.

Non-barcode labeled controls: Only one target value and range for each control level can be entered in the analyzer. The reagent lot-specific target values have to be re-entered each time a specific reagent lot with different control target values and ranges is used. Two reagent lots with different control target values and ranges cannot be used in parallel in the same run.

The exact lot-specific target values and ranges are printed on the enclosed (or electronically available) value sheet in the reagent kit or PreciControl kit.

Please make sure that the correct values are used.

Calculation

The analyzer automatically calculates the analyte concentration of each sample in pg/mL.

Limits and ranges

Lower limits of measurement

Limit of Quantitation (LoQ) = 0.3 pg/mL

The Limit of Quantitation is defined as the lowest amount of analyte in a sample that can be accurately quantitated with a total allowable relative error of ≤ 20 %.

Measuring range

The Limit of Quantitation and the maximum of the master curve define a measuring range of 0.3-5000 pg/mL. Values below the Limit of Quantitation

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are reported as < 0.3 pg/mL. Values above the measuring range are reported as > 5000 pg/mL.

Dilution

CSF samples NFL concentrations above the measuring range can be diluted 1:10 with Diluent Universal.

After dilution, multiply the result by the dilution factor.

For further information, please refer to the appropriate user guide or operator's manual for the analyzer concerned, the respective application sheets and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see navifyportal.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution

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