Elecsys GFAP RUO bx

cobas®

Materials provided

REF		Σ	SYSTEM
10151897430	10151897520	100	**cobas** e 402 **cobas** e 801

For reagents, refer to the "Reagents" section.

Materials required (but not provided)

REF	Description
10151927430	CalSet GFAP RUO bx, for 2 × 0.5 mL
10151951430	PreciControl GFAP RUO bx, for 2 × 0.5 mL
11776576322	CalSet Vials, 2 × 56 empty snap-cap bottles
03142949122	ControlSet Vials, 2 × 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	Description
06908799190	ProCell II M, 2 × 2 L system solution
04880293190	CleanCell M, 2 × 2 L measuring cell cleaning solution
07485409001	Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
06908853190	PreClean II M, 2 × 2 L wash solution
05694302001	AssayTip/AssayCup tray, 6 magazines × 6 magazine stacks × 105 assay tips and 105 assay cups, 3 wasteliners
07485425001	Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution / Elecsys SysClean for Liquid Flow Cleaning Detection Unit
07485433001	PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution / Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
11298500316	ISE Cleaning Solution / Elecsys SysClean, 5 × 100 mL system cleaning solution

Disclaimer

For professional use only.

For research use only (RUO). Not for use in diagnostic procedures. No clinical decision or patient notification may be made based on results using this research assay.

Note

The measured value of GFAP (Glial fibrillary acidic protein) in a given sample, determined with assays from different manufacturers, can vary due to differences in assay methods and reagent specificity. Values determined on samples by different assay methods cannot be used interchangeably.

System information

Short name	ACN (application code number)
GFAP	17813

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

Designated use

The Elecsys GFAP RUO bx is an in vitro quantitative immunoassay for the measurement of GFAP in human serum, plasma 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

Sandwich principle. Total duration of assay: 18 minutes.

- First incubation: 30 µL of sample, a biotinylated monoclonal GFAP-specific antibody, and a monoclonal GFAP-specific antibody labeled with a ruthenium complex[a)] react to form a sandwich complex.

- Second incubation: After streptavidin-coated microparticles have been added, 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 that is instrument-specifically generated by 2-point calibration and a leading calibration curve provided via the reagent barcode or e-barcode.

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

Reagents

cobas *e pack (M, R1, R2)*

M	Streptavidin-coated microparticles (transparent cap), 1 bottle, 7.2 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservatives.
R1	Anti-GFAP-Ab~biotin (black cap), 1 bottle, 7.2 mL: Biotinylated monoclonal anti-GFAP antibody (recombinant); Sodium phosphate buffer 80 mmol/L, pH 7.4; preservatives.
R2	Anti-GFAP-Ab~$Ru(bpy)_3^{2+}$ (black cap), 1 bottle, 7.2 mL: Monoclonal anti-GFAP antibody (recombinant) labeled with ruthenium complex; Sodium phosphate buffer 80 mmol/L, pH 7.4; preservatives.

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 safe disposal.

The Safety Data Sheet is available for professional users on request.

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

Warning

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Prevention:

P261	Avoid breathing mist or vapours.
P273	Avoid release to the environment.
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:

- reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

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

Product safety labeling follows EU GHS guidance.

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

All human material should be considered potentially infectious.

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

Storage and technical stability

Store at 2-8 °C.

Do not freeze.

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

Technical stability of the product is provided as a guidance for the user.

Technical stability	
unopened at 2-8 °C	up to the stated expiration date (see Value Sheet)
on the analyzers	28 days

Calibration

Traceability: No WHO standard is available for GFAP. The GFAP assay is traceable to the recombinant protein by weight.

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

Calibration intervals are to be defined and adopted to the specific technical use of the product based on, e.g., quality control findings outside the defined limits.

Quality control

For routine quality control procedures, use PreciControl GFAP RUO bx or other suitable controls.

It is recommended to run the controls for the various concentration ranges individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

Adjust the limits and control intervals based on the laboratory's individual requirements. If values fall outside the limits, each laboratory is advised to establish corrective measures.

If necessary, repeat sample measurement.

Follow the applicable government regulations and local guidelines.

Note: The controls are not barcode-labeled and therefore have to be run like external controls. All ranges and values have to be entered manually. Refer to the section "QC" in the User Guide or to the online help of the instrument software.

Non-barcode-labeled controls: Only 1 range and target value for each control level can be entered in the analyzer. The reagent-lot-specific target values must be re-entered each time when a specific reagent lot with different control ranges and control target values is used. 2 reagent lots with different control ranges and control target values cannot be used in parallel in the same run. Ensure that the correct values are used.

The exact lot-specific target values and ranges are listed in the Value Sheet of the corresponding reagent kit.

Ensure that the correct ranges and target values are used.

Specimen collection and preparation

Recommended specimen:

Serum: Collect serum using standard sampling tubes.

EDTA plasma.

CSF.

Stability in plasma: 48 hours at 2-8 °C

The samples may be frozen 3 times.

Stability in CSF: 48 hours at 15-25 °C, 48 hours at 2-8 °C

Multiple freeze/thaw cycles have to be avoided.

Note: CSF samples could only be tested from frozen sources; one additional freeze/thaw cycle may already result in a loss of up to 28 %.

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, analyze and measure samples, calibrators, and controls on the analyzers within 2 hours.

Close the cap when reagents are not in use.

Test procedure

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

All information required for correct operation is read into the analyzer from the corresponding reagent barcode or listed in the corresponding Method Sheet and Value Sheet.

Perform **only 1** calibration procedure per vial.

For optimum performance of the assay, follow the instructions given in this document for the corresponding analyzer.

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 in the test-specific parameters via the reagent RFID code.

Calculation

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

Technical measuring range

LDL - Upper Limit of Calibration (ng/mL)

Lower Limit of Quantitation (LLoQ)

$LLoQ_{Plasma}$ = 0.00307 ng/mL

$LLoQ_{CSF}$ = 0.00338 ng/mL

The LLoQ is defined as the lowest amount of analyte in a sample that can be accurately quantitated with a coefficient of variation of ≤ 20 %. Results obtained in individual laboratories may differ.

Dilution

Plasma, Serum and CSF samples with GFAP concentrations above the measuring range can each be manually diluted with Plasma, Serum and CSF samples of low GFAP concentration.

Additional information

Additions, deletions, or changes are indicated by a change bar in the margin.

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

Symbols

For USA: For definition of symbols used, refer to navifyportal.roche.com.

In addition to the ISO 15223-1 standard, Roche Diagnostics uses the following symbols and signs:

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

Elecsys GFAP RUO bx

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim, Germany
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Changelog

For this document version only:

Due to technical reasons, changes that have been made since the last version of this document are listed in the following table instead of indicated by change bars in the margin.

Section headers are indicated in bold letters.

In addition to the changes listed in the table below, this Method Sheet version contains several editorial and layout updates.

Section	Current version	Previous version
Materials required (but not provided)	**Materials required (but not provided)**	**Order information** **Materials required (but not provided)**
Disclaimer	For professional use only. For research use only (RUO). Not for use in diagnostic procedures. No clinical decision or patient notification may be made based on results using this research assay.	For Research Use Only (RUO). Not for use in diagnostic procedures.
Designated use	**Designated use**	**Assay description**
Reagents	**Reagents**	**Reagents - working solutions**
Reagents	M: Streptavidin-coated microparticles (transparent cap), 1 bottle, 7.2 mL:	M: Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.4 mL:
Storage and technical stability	**Storage and technical stability**	**Storage and stability**
Storage and technical stability	Technical stability of the product is provided as a guidance for the user.	
Storage and technical stability	Technical stability	Stability:
Calibration	Section updated	
Specimen collection and preparation	Section updated	
Test procedure	**Test procedure**	**Handling** **Test procedure**
Limits and ranges	section deleted	
Technical measuring range	**Technical measuring range**	**Measuring range**
Additional information	sentence deleted	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).