

# Elecsys pT217p RUO



## Materials provided

REF			SYSTEM
10285583430	10285583520	100	cobas e 402 cobas e 801

For reagents, refer to the "Reagents" section.

## Materials required (but not provided)

REF	Description
10285656430	CalSet pT217p RUO, for 2 × 1.0 mL
10285664430	PreciControl pT217p RUO, for 3 × 1.0 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
	<b>cobas e analyzer</b>

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
11298500160	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 phosphorylated Tau (217P) (pTau) 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)
pT217PEV	17068/17081/17082

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

## Designated use

The Elecsys pT217p RUO is an in vitro quantitative immunoassay for the measurement of tau phosphorylated at amino acid 217 (pT217P) in human plasma.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.

## Test principle

Sandwich principle. Total duration of assay: 18 minutes.

- First incubation: 60 µL of sample, a biotinylated monoclonal antibody specific for phosphorylation at threonine 217 (numbering based on Tau 4R2N) and a monoclonal Tau-specific antibody labeled with a ruthenium complex<sup>a)</sup> 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)  $\text{Tris}(2,2\text{'-bipyridyl})\text{ruthenium(II)-complex } (\text{Ru}(\text{bpy})_3^{2+})$

## 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-pT217p-Ab~biotin, 1 bottle, 5.1 mL: Biotinylated monoclonal anti-pT217p antibody (rabbit/mouse) 6.0 µg/mL; Tris buffer 50 mmol/L, pH 7.6; preservative.
R2	Anti-Tau-Ab~Ru(bpy) <sub>3</sub> <sup>2+</sup> , 1 bottle, 5.1 mL: Monoclonal anti-Tau antibody (mouse/human) labeled with ruthenium complex 4.0 µg/mL; Tris buffer 50 mmol/L, pH 7.6; preservative.

## 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.

### 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

# Elecsys pT217p RUO



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	16 weeks

## Calibration

Traceability: No WHO standard is available for phosphorylated Tau (217P). This method has been standardized against a purified reference material, absolutely quantified via amino acid analysis (AAA).

Calibrator values are based on weighted pTau reference material, 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 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 pT217p RUO 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 ranges and control target values is used. 2 reagent lots with different ranges and control target values cannot be used in parallel in the same run.

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

Ensure that the correct values are used.

## Specimen collection and preparation

Recommended specimen:

EDTA plasma.

Freeze only once.

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.

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## 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 aliquot.

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.

## Calculation

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

## Technical measuring range

0.0560-2.40 pg/mL. Values below the Limit of Quantitation are reported as < 0.0560 pg/mL. Values above the measuring range are reported as > 2.40 pg/mL.

## 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](http://navifyportal.roche.com).

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

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

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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.

# Elecsys pT217p RUO



Section	Current version	Previous version
<b>Materials required (but not provided)</b>	<b>Materials required (but not provided)</b>	<b>Order information</b> <b>Materials required (but not provided)</b>
<b>Disclaimer</b>	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.
<b>Designated use</b>	<b>Designated use</b>	<b>Assay description</b>
<b>Reagents</b>	<b>Reagents</b>	<b>Reagents - working solutions</b>
<b>Storage and technical stability</b>	<b>Storage and technical stability</b>	<b>Storage and stability</b>
<b>Storage and technical stability</b>	Technical stability of the product is provided as a guidance for the user.	
<b>Storage and technical stability</b>	Technical stability	Stability:
<b>Storage and technical stability</b>	on the analyzers: 16 weeks	on the analyzers: 28 days
<b>Calibration</b>	Section updated	
<b>Specimen collection and preparation</b>	Section updated	
<b>Test procedure</b>	<b>Test procedure</b>	<b>Handling</b> <b>Test procedure</b>
<b>Test procedure</b>	sentence deleted	Read the test-specific parameters into the analyzer via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers.
<b>Limits and ranges</b>	section deleted	
<b>Technical measuring range</b>	<b>Technical measuring range</b>	<b>Measuring range</b>
<b>Additional information</b>	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).