

CalSet β -Amyloid (1-42)

cobas®

REF 06986838 190

→ 4 x 1.0 mL

English

Intended use

CalSet β -Amyloid (1-42) is used for calibrating the quantitative Elecsys β -Amyloid (1-42) CSF assay on the Elecsys and cobas e immunoassay analyzers.

Summary

CalSet β -Amyloid (1-42) is a lyophilized artificial CSF matrix with added β -Amyloid (1-42) in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

- Abeta42 Cal1: 2 bottles, each for 1.0 mL of calibrator 1
- Abeta42 Cal2: 2 bottles, each for 1.0 mL of calibrator 2

Abeta42 in two concentration ranges (approximately 50 pg/mL and approximately 700 pg/mL) in an artificial CSF matrix; preservative.

Calibrator values

Traceability: The Elecsys β -Amyloid (1-42) CSF assay has been standardized by means of the candidate reference measurement procedure, traceable to NIST SRM2389a.¹

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

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

2-Methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.



Warning

H319 Causes serious eye irritation.

Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear eye protection/ face protection.

Response:

P305 + P351
+ P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

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

Carefully dissolve the contents of one bottle by adding exactly 1.0 mL of distilled or deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation.

Transfer the reconstituted calibrators into the supplied empty labeled snap-cap bottles.

Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed.

If necessary, freeze in aliquots; see section on MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers.

MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers:

Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the reconstituted calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at -20 °C for later use.

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

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for cobas 8000 systems only. If using a cobas 8000 system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

Storage and stability

Store at 2-8 °C.

The lyophilized calibrators are stable up to the stated expiration date.

Stability of the reconstituted calibrators:	
either at -20 °C	31 days
or at 2-8 °C	24 hours
on MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers at 20-25 °C	up to 2 hours

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Materials provided

- CalSet β -Amyloid (1-42), barcode card, calibrator barcode sheet, 4 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- REF 11776576322, CalSet Vials, 2 x 56 empty snap-cap bottles
- MODULAR ANALYTICS E170 or cobas e immunoassay analyzers and Elecsys β -Amyloid (1-42) CSF assay reagents
- Distilled or deionized water

See the assay Method Sheet and the operator's manual for additionally required materials.

Assay

Place the reconstituted calibrators (in the system-compatible bottles with barcoded labels) in the sample zone.

Read in all the information necessary for calibrating the assay.

Ensure the calibrators are at 20-25 °C prior to measurement.

References

- Leinenbach A, Pannee J, Dülffer T, et al. Mass spectrometry-based candidate reference measurement procedure for quantification of amyloid- β in cerebrospinal fluid. ClinChem 2014;987-994.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information 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 <https://usdiagnostics.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 after reconstitution or mixing
GTIN	Global Trade Item Number

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cobas®

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