



06688004001V2.0

Calcitonin CalSet

cobas[®]

REF 06445861 190

→ 4 x 1.0 mL

English

Intended use

Calcitonin CalSet is used for calibrating the quantitative Elecsys Calcitonin assay on the Elecsys and **cobas e** immunoassay analyzers.

Summary

Calcitonin CalSet is a lyophilized equine serum with added calcitonin (hCT) in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

Calcitonin (synthetic) in two concentration ranges (approximately 2.0 pg/mL or 0.585 pmol/L and approximately 500 pg/mL or 146 pmol/L) in an equine serum matrix.

The exact lot-specific calibrator values are encoded in the barcode as well as printed on the enclosed (or electronically available) calibrator barcode sheet.

Calibrator values

Traceability: The Elecsys Calcitonin assay has been standardized against the IRP WHO Reference Standard 89/620.

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.

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.

Elecsys 2010 and **cobas e** 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C. 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.

Storage and stability

Store at 2-8 °C.

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

Stability of the reconstituted/thawed calibrators:	
at 2-8 °C	72 hours (3 days)
at -20 °C	84 days (12 weeks) (freeze only once)
on Elecsys 2010 and cobas e 411 analyzers at 20-25 °C	up to 5 hours
on MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers	use only once

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

Materials provided

- Calcitonin CalSet, 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
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Calcitonin assay reagents
- Distilled or deionized water

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

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.

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.

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

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Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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