

# β-CrossLaps CalSet

cobas®

REF 11972316 122

4 x 1.0 mL

For USA: Elecsys β-CrossLaps CalSet

## English

### Intended use

β-CrossLaps CalSet is used for calibrating the quantitative Elecsys β-CrossLaps/serum assay on the Elecsys and **cobas e** immunoassay analyzers.

### Summary

β-CrossLaps CalSet is a ready-for-use equine serum matrix with added synthetically prepared β-CTx peptide in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

- CROSSL Cal1: 2 bottles, each containing 1.0 mL of calibrator 1
  - CROSSL Cal2: 2 bottles, each containing 1.0 mL of calibrator 2
- β-CTx (synthetic peptide) in two concentration ranges (approximately 0.05 ng/mL or 50 pg/mL and approximately 2.0 ng/mL or 2000 pg/mL) in an equine serum matrix.

**cobas e 801** analyzer: The exact lot-specific calibrator values are encoded in the electronic barcode and available via the **cobas** link.

All other analyzers: 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 β-CrossLaps/serum assay has been standardized against peptide reference standards precisely defined by weighing out synthetic peptide.

### 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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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



### Warning

- |      |                                      |
|------|--------------------------------------|
| H315 | Causes skin irritation.              |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation.       |

### Prevention:

- |      |   |
|------|---|
| P261 | Avoid breathing dust/fume/gas/mist/vapours/spray.                             |
| P280 | Wear protective gloves/ protective clothing/ eye protection/ face protection. |

### Response:

- |             |  |
|-------------|--|
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention. |
| P337 + P313 | If eye irritation persists: 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. |
|------|--|

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

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

### Handling

The calibrators are supplied ready-for-use in bottles compatible with the system.

**cobas e 411** analyzer: The calibrators should only be left on the analyzer 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.

MODULAR ANALYTICS E170, **cobas e 601**, **cobas e 602** and **cobas e 801** analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °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.

Stability:	
unopened at 2-8 °C	up to the stated expiration date
after opening at 2-8 °C	12 weeks
on <b>cobas e 411</b> analyzer at 20-25 °C	up to 5 hours
on MODULAR ANALYTICS E170, <b>cobas e 601</b> , <b>cobas e 602</b> and <b>cobas e 801</b> analyzers at 20-25 °C	use only once

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

### Materials provided

- β-CrossLaps CalSet, barcode card, calibrator barcode sheet, 2 x 4 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-CrossLaps/serum assay reagents

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

### Assay

Place the bottles 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 (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

# $\beta$ -CrossLaps CalSet

**cobas<sup>®</sup>**

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

**FOR US CUSTOMERS ONLY: LIMITED WARRANTY**

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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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim  
[www.roche.com](http://www.roche.com)



Distribution in USA by:

Roche Diagnostics, Indianapolis, IN

US Customer Technical Support 1-800-428-2336