

Prolactin II CalSet

REF 03277356190

→ 4 x 1.0 mL

For USA: cobas Elecsys Prolactin II CalSet

English

Intended use

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

Summary

Prolactin II CalSet is a lyophilized buffered equine serum matrix with added recombinant prolactin in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

Prolactin (human, recombinant, from *E. coli*) in two concentration ranges (approximately 2 μ U/mL or 0.09 ng/mL and approximately 2000 μ U/mL or 94 ng/mL) in a buffered 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 Prolactin II assay has been standardized using the 3rd IRP WHO Reference Standard 84/500.

1 μ U/mL corresponds to 0.0472 ng/mL.

Precautions and warnings

For in vitro diagnostic use for health care professionals. 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 the safe disposal.

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

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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.

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

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 aliquots of the reconstituted calibrators into empty labeled snap-cap bottles (CalSet Vials). Attach the supplied labels to the additional bottles. Store the aliquots immediately at -20 °C (\pm 5 °C).

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

Please note for **cobas e** 602 and **cobas e** 801 analyzers: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. Please turn the vial cap 180° into the correct position so that the barcode between the yellow markers can be read by the system. Place the vial on the analyzer 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:	
at -20 °C (\pm 5 °C)	3 months (freeze only once)
on the 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

- Prolactin II 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
- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Prolactin II 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.

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.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used

Prolactin II CalSet



- 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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