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Progesterone II CalSet

cobas®

REF **12145391** 122 → **4 x 1.0 mL**

For USA: Elecsys Progesterone II CalSet

English

Intended use

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

Summary

Progesterone II CalSet is a lyophilized human serum with added progesterone in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

Progesterone (from plant material) in two concentration ranges (approximately 0.6 nmol/L or 0.2 ng/mL and approximately 169 nmol/L or 53 ng/mL) in a human 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 Progesterone II assay has been standardized using ID-GC/MS (isotope dilution-gas chromatography/mass spectrometry).[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.

For USA: For prescription use only.

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.

Product safety labeling primarily follows EU GHS guidance.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[2,3]

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 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.

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

Stability of the reconstituted calibrators:	
at 2-8 °C	12 weeks
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

- Progesterone II CalSet, barcode card, calibrator barcode sheet, 4 empty labeled snap-cap bottles, 2 x 4 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 Progesterone 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.

References

1 Thienpont LM, Verhseghe PG, Van Brussel KA, et al. Efforts by industry toward standardization of serum estradiol-17β measurements. Clin Chem 1998;44(3):671-674.

2 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

3 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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
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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