



12177226001V9.0

HCG STAT CalSet

cobas[®]

REF 03303071 190

→ 4 x 1.0 mL

English

Intended use

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

Summary

HCG STAT CalSet is a lyophilized human serum with added hCG in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

Human chorionic gonadotropin (from urine) in two concentration ranges (approx. 10 mIU/mL and approx. 5000 mIU/mL) in a buffered human serum matrix.

The exact lot-specific calibrator values are encoded in the barcode.

Calibrator values

Traceability: The Elecsys HCG STAT assay has been standardized against the 4th International Standard for Chorionic Gonadotropin from the National Institute for Biological Standards and Control (NIBSC) code 75/589.

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.

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.^{1,2}

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 at 2-8 °C.

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

cobas e 601 and **cobas e** 602 analyzers: Unless the entire volume is necessary for calibration on the analyzer, 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 2-8 °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 calibrators:	
at 2-8 °C	12 weeks
on Elecsys 2010 and cobas e 411 analyzers at 20-25 °C	up to 5 hours

Stability of the reconstituted calibrators:

on cobas e 601 and cobas e 602 analyzers	use only once
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Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

Materials provided

- HCG STAT CalSet, barcode card, 4 empty labeled snap-cap bottles, 2 x 6 bottle labels

Materials required (but not provided)

- Elecsys 2010 or **cobas e** immunoassay analyzers and Elecsys HCG STAT 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.

All the information necessary for calibrating the assay is automatically read into the analyzer.

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

References

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

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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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