



1217460001V10.0

# FSH CalSet II

**cobas®**

REF 03032680 122

→ 4 x 1.0 mL

## English

### Intended use

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

### Summary

FSH CalSet II is a lyophilized equine serum matrix with added FSH in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

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

FSH (human) in two concentration ranges (approximately 1 mIU/mL and approximately 55 mIU/mL) 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 FSH assay has been standardized against the Enzygnost-Test FSH method. This in turn was standardized via the 2nd IRP WHO Reference Standard 78/549.

### 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.

Materials of human origin were tested for HIV, hepatitis B, and hepatitis C infections. The findings were negative.

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.<sup>1,2</sup>

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.

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 -20 °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

- FSH CalSet II, 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 FSH 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.

### References

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