

# Folate III CalSet

REF 07560001 190

→ 4 x 1.0 mL

For USA: Elecsys Folate III CalSet

## English

### Intended use

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

### Summary

Folate III CalSet is a lyophilized human serum with added folate in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

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

Folate in two concentration ranges (< 9.1 nmol/L or < 4.0 ng/mL and approximately 38.5 nmol/L or 17.0 ng/mL) in human serum.

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 Folate III assay has been standardized against the WHO International Standard NIBSC Code: 03/178.

### 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:

H412 Harmful to aquatic life with long lasting effects.

### Prevention:

P273 Avoid release to the environment.

### Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

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.<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 30 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.

*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: |                             |
|---|-----------------------------|
| either at -20 °C                            | 3 months (freeze only once) |
| or at 2-8 °C                                | 3 days                      |
| 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

- Folate III 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
- MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys Folate III 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

- 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               |
| GTIN       | Global Trade Item Number                            |

# Folate III CalSet



## 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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