

# Vitamin B12 II CalSet

REF 07212780 190

→ 4 x 1.0 mL

For USA: Elecsys Vitamin B12 II CalSet

## English

### Intended Use

Vitamin B12 II CalSet is used for calibrating the quantitative Elecsys Vitamin B12 II assay on the Elecsys and **cobas e** immunoassay analyzers.

### Summary

Vitamin B12 II CalSet is a lyophilized human serum matrix with added vitamin B12 in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

- B12 II Cal1: 2 bottles, each for 1.0 mL of calibrator 1

- B12 II Cal2: 2 bottles, each for 1.0 mL of calibrator 2

Vitamin B12 in two concentration ranges (approximately 185 pmol/L or 250 pg/mL and approximately 1107 pmol/L or 1500 pg/mL) in a human serum matrix, preservative.

**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 Vitamin B12 II assay (REF 07212771) has been standardized against the Elecsys Vitamin B12 assay (REF 04745736).

### 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.

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 use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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 (± 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:

either at -20 °C (± 5 °C)	84 days (freeze only once)
or at 2-8 °C	72 hours
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

- Vitamin B12 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 Vitamin B12 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 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.

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):

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

# Vitamin B12 II 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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