

# proBNP II STAT CalSet



REF 05390117 190

→ 4 x 1.0 mL

For USA: Elecsys proBNP II STAT CalSet

## English

### Intended use

proBNP II STAT CalSet is used for calibrating the quantitative Elecsys proBNP II STAT assay on the **cobas e 601** and **cobas e 602** immunoassay analyzers.

### Summary

proBNP II STAT CalSet is a lyophilized equine serum matrix with added synthetic NT-proBNP (1-76) in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

- PRO-BNP II STAT Cal1: 2 bottles, each for 1.0 mL of calibrator 1
- PRO-BNP II STAT Cal2: 2 bottles, each for 1.0 mL of calibrator 2

ProBNP in two concentration ranges (approximately 16.6 pmol/L or 140 pg/mL and approximately 320 pmol/L or 2700 pg/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 proBNP II STAT assay has been standardized against the proBNP II assay (REF 04842464).

### 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.

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.

Unless the entire volume is necessary for calibration on the analyzers, 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 -20 °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: |                             |
|---|-----------------------------|
| either at -20 °C                            | 3 months (freeze only once) |
| or at 2-8 °C                                | 2 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

- proBNP II STAT CalSet, 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
- cobas e 601**, **cobas e 602** immunoassay analyzers and Elecsys proBNP II STAT 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.

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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