

REF 06505970 190

→ 4 x 1.0 mL

## English

### Intended use

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

### Summary

ProGRP CalSet is a lyophilized equine serum matrix with added proGRP protein (recombinant from E. coli) in two concentration ranges.

The CalSet can be used with all reagent lots.

### Reagents - working solutions

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

ProGRP (recombinant from E. coli) in two concentration ranges (approximately 20 pg/mL and approximately 294 pg/mL) in an equine serum matrix; preservative.

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 ProGRP assay has been standardized against the Architect ProGRP method from Abbott Diagnostics.

### 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.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

2-methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.

Product safety labeling primarily follows EU GHS guidance.

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 an aliquot of the reconstituted calibrator into an empty labeled snap-cap bottle (CalSet Vial) supplied. Attach the supplied labels to the additional bottles. Use the aliquot immediately and perform **only one** calibration procedure per aliquot. Close the glass vial carefully and freeze the remainder of the reconstituted calibrator immediately at -20 °C for later use. Do not freeze the aliquots in the snap-cap bottles!

Due to possible evaporation effects, not more than 3 calibration procedures per bottle set should be performed.

**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:	
at -20 °C	2 months (may be frozen twice)
on the analyzers at 20-25 °C	up to 5 hours

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the snap-cap.

### Materials provided

- ProGRP 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
- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers and Elecsys ProGRP 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.



ProGRP used in the Roche ProGRP products is licenced by Fujirebio Diagnostics, Inc.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

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

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Additions, deletions or changes are indicated by a change bar in the margin.

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