

**REF** 05144701 190

→ 4 x 1.0 mL

**English**

**Intended use**

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

**Summary**

PIGF CalSet is a lyophilized buffered equine serum matrix with added recombinant human PIGF-1 in two concentration ranges. The CalSet can be used with all reagent lots.

**Reagents - working solutions**

- PIGF Cal1: 2 bottles, each for 1.0 mL of calibrator 1
  - PIGF Cal2: 2 bottles, each for 1.0 mL of calibrator 2
- PIGF-1 (mucin, human, recombinant, from E. coli) in two concentration ranges (approximately 5 pg/mL and approximately 1200 pg/mL) in a buffered 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 PIGF assay has been standardized against a commercially available PIGF assay.

**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 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: |                               |
| at -20 °C                                   | 1 month (freeze only once)    |
| on the analyzers at 20-25 °C                | up to 2 hours (use only once) |

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

**Materials provided**

- PIGF 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

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

This product or portions thereof is manufactured under license from ThromboGenics and Geymonat under European Patent Number 550519 and US Patent Number 7314734 and foreign equivalents of these patent rights.

Additional US patents pending.

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.

|                   |   |
|-------------------|---|
| <b>CONTENT</b>    | Contents of kit                                     |
| <b>SYSTEM</b>     | Analyzers/Instruments on which reagents can be used |
| <b>REAGENT</b>    | Reagent   |
| <b>CALIBRATOR</b> | Calibrator  |
| <b>→</b>          | Volume after reconstitution or mixing               |
| <b>GTIN</b>       | Global Trade Item Number                            |

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

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