

REF 05144701190

→ 4 x 1.0 mL

English

Intended use

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

Summary

PIGF CalSet is a lyophilized buffered equine serum matrix with added recombinant human PIGF-1 in 2 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 (human, recombinant, from *E. coli*) in 2 concentration ranges (approximately 5 pg/mL and approximately 1200 pg/mL) in a buffered equine serum matrix.

Calibrator values

The calibrator values are encoded either in the barcode or in the electronic barcode (which is available via the **cobas** link).

Traceability: The Elecsys PIGF assay has been standardized against a commercially available PIGF assay.

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.

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



Warning

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

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 402**, **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:	
at -20 °C (± 5 °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, 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
- 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.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets 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.

The Summary of Safety & Performance Report can be found here: <https://ec.europa.eu/tools/eudamed>

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

ms_05144701190V7.0

PIGF CalSet

cobas[®]

CALIBRATOR

Calibrator



Volume for reconstitution

GTIN

Global Trade Item Number

COBAS, COBAS E and ELECSYS are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

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

© 2022, Roche Diagnostics

 0123



Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim
www.roche.com

+800 5505 6606

