ms_08838534190V2.0

total PSA CalSet II

cobas®

REF 08838534190 → **4 x 1.0 mL**

English

Intended use

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

Summary

total PSA CalSet II is a lyophilized human serum with added human PSA in two concentration ranges.

The CalSet can be used with all reagent lots.

Reagents - working solutions

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

PSA (human) in two concentration ranges (approximately 0 ng/mL and approximately 60 ng/mL) in a human serum matrix.

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 total PSA assay has been standardized against the Stanford Reference Standard/WHO 96/670 (90 % PSA-ACT + 10 % free PSA).[1,2,3]

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:

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

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 used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

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.[4,5]

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.

cobas e 411 analyzer: The reconstituted calibrators should only be left on the analyzer during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.

Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed.

If necessary, freeze in aliquots; see section on **cobas e** 601, **cobas e** 602 and **cobas e** 801 analyzers.

cobas e 601, **cobas e** 602 and **cobas e** 801 analyzers: 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 2-8 °C or -20 °C (± 5 °C) for later use.

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)	12 weeks (freeze only once)
or at 2-8 °C	6 weeks
on **cobas e** 411 analyzer at 20-25 °C	up to 5 hours
on **cobas e** 601, **cobas e** 602 and **cobas e** 801 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

- total PSA CalSet II, 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
- **cobas e** immunoassay analyzers and Elecsys total PSA 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 Stamey TA. Second Stanford conference on international standardization of prostate-specific antigen immunoassays: September 1 and 2, 1994. Urology 1995;45:173-184.

2 Stamey TA, Chen Z, Prestigiacomo AF. Reference Material for PSA: The IFCC Standardization Study. Clin Biochem 1998;31:475-481.

3 WHO Technical Report Series, No. 904, 2002.

4 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

5 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.

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):

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

CE 0123

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