

ISE Internal Standard Gen.2 conc. **cobas**[®]

Order information

REF		CONTENT	Analyzer(s) on which reagents can be used
09137742190	09137742500	ISE Internal Standard Gen.2 conc. (1 x 510 mL)	cobas ISE neo

English

System information

For use on cobas ISE neo analytical unit.

Intended use

The ISE Internal Standard Gen.2 conc. is intended for the monitoring of electrode potential on **cobas c** ISE analytical unit for the quantitative determination of sodium, potassium, and chloride in human origin serum, plasma or urine.

Reagents - working solutions

HEPES buffer: 310 mmol/L
 Triethanolamine: 217 mmol/L
 Sodium chloride: 95 mmol/L
 Sodium acetate: 45 mmol/L
 Potassium chloride: 5 mmol/L
 Preservatives

The cobas ISE neo analyzer automatically dilutes the Internal Standard Gen.2 conc. to the appropriate dilution ratio for actual measurements.

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.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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.

EUH 208 Contains mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Product safety labeling follows EU GHS guidance.

Reagent handling

Use the ISE Internal Standard Gen.2 conc. according to the instructions in the ISE section of cobas pro integrated solutions <ISE neo> User Guide.

Storage and stability

Store at 15-25 °C.

Stability:

Unopened: up to expiration date at 15-25 °C. See label for expiration date.
 On-board stability: 6 weeks

NOTE:

Dissolved gases can cause performance problems if present in high amounts in the ISE Internal Standard conc. In this case mix the contents of the bottle gently before use.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

Roche system reagents and clinical chemistry analyzer with cobas ISE neo analytical unit.

General laboratory equipment

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
	Reagent
	Volume for reconstitution
	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.

COBAS and COBAS C 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.

© 2023, Roche Diagnostics

09137742500V1.0

ISE Internal Standard Gen.2 conc. **cobas**[®]

CE 0123



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

+800 5505 6606



Distribution in USA by:
Roche Diagnostics, Indianapolis, IN
US Customer Technical Support 1-800-428-2336