

ISE Reference Electrolyte

Order information

REF		CONTENT	Analyzer(s) on which reagents can be used
08392013190	08392013500	ISE Reference Electrolyte (2 × 2000 mL)	cobas ISE neo, cobas pro ISE
08392013214	08392013500	ISE Reference Electrolyte (2 × 2000 mL)	cobas ISE neo, cobas pro ISE
10820652216	08392013500	ISE Reference Electrolyte (1 × 500 mL)	cobas c 303 ISE, cobas 8000 ISE
11360981216	08392013500	ISE Reference Electrolyte (5 × 300 mL)	cobas c 311, cobas c 501

* Some kits shown may not be available in all countries.

English

Intended use

The ISE Reference Electrolyte is intended for closing the measurement circuit on the **cobas c** ISE analytical unit for the quantitative determination of sodium, potassium, and chloride in human origin serum, plasma or urine.

Reagents - working solutions

1 mol/L potassium chloride

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.

Reagent handling

Use the ISE Reference Electrolyte according to the instructions in the ISE section of the corresponding Operator's Manual/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:

cobas ISE neo, **cobas** pro ISE, **cobas c** 303 ISE, **cobas** 8000 ISE: up to expiration date

cobas c 311, **cobas c** 501: 4 weeks

NOTE: Dissolved gases can cause performance problems if present in high amounts in the Reference Electrolyte. In this case, mix the contents of the bottle gently before use.

NOTE: If one of the reagent bottles is nearly empty, do not just refill the bottle with new reagent. Discard the old reagent bottle, including any remaining reagent.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

Roche system reagents and clinical chemistry analyzer with **cobas c** ISE analytical units.

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 navifyportal.roche.com for definition of symbols used):

Contents of kit

REAGENT

Reagent



Volume for reconstitution

GTIN

Global Trade Item Number

Rx only

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

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.

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For USA: Rx only



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

+800 5505 6606



Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256, USA

+1 800 4282336

