

ISE Standard High

REF 11183982216

11183982500

10 x 3 mL

English

System information

For use on **cobas c** analyzers the calibrator codes are:
ISE Standard High as S2: Code 503
ISE Standard High as S3: Code 763

Intended use

ISE Standard High is for use in the calibration of Ion Selective Electrodes on **cobas c** analyzers.

Summary

ISE Standard High is an aqueous preparation with gravimetrically defined electrolyte levels.

This product is for use in standardization of sodium, potassium, and chloride values on the Ion Selective Electrodes.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

10 ampules, 3 mL each

Reactive components:

160 mmol/L Na⁺, 7 mmol/L K⁺, 120 mmol/L Cl⁻

For ISE Standard High as S2: For the **cobas c** analyzers (except for the **cobas c 111** analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

For ISE Standard High as S3: The values must be entered manually.

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.

Handling

Wear protective glasses when handling the ampule. Using a piece of gauze or other protective material, carefully snap the top off the ampule.

Use according to instructions in the ISE sections of your **cobas c** operator's manual.

The enclosed barcoded labels are intended exclusively for **cobas c** systems to identify the calibrator. Attach the barcoded labels to the tubes carrying the sample cups containing the calibrator material.

NOTE: When the barcoded tube is only used as a cup holder, it can be reused if the lot number of the ISE standard does not change.

Storage and stability

Store at 15-25 °C.

Stability:

Unopened: Up to the stated expiration date at 15-25 °C.
After opening: Opened ampules should be used immediately. Remaining content must not be stored to avoid inaccurate calibrations.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Use ISE Standard High as specified in the **cobas c** operator's manual.

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):

CONTENT	Contents of kit
CALIBRATOR	Calibrator
→	Volume for reconstitution
GTIN	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.

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