

# ISE Compensator

REF 11489828 216

10 x 1 mL

## English

### System information

For use on **cobas c** analyzers the calibrator code is 504.

### Intended use

ISE Compensator is for use in the calibration of Ion Selective Electrodes on Roche/Hitachi analyzers and **cobas c** analyzers.

### Summary

ISE Compensator is a stabilized liquid human serum preparation with defined Na<sup>+</sup>, K<sup>+</sup> and Cl<sup>-</sup> concentrations.

The concentrations of the calibrator components have been adjusted to ensure optimal calibration of the appropriate Roche methods on clinical chemistry analyzers.

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

### Reagents – working solutions

10 bottles, each with 1 mL ISE Compensator.

#### Reactive components:

Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>

#### Non-reactive components:

Stabilizer

The concentrations of the calibrator components are lot-specific. The exact calibrator values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed calibrator barcode sheets for Roche/Hitachi MODULAR analyzers.

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.

### Calibrator values

The calibrator values were determined using the method stated in the electronically available or enclosed value sheets. Determinations were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator.

The calibrator values were obtained via single determinations performed in different laboratories, in several separate runs. The calibrator value specified is the median of all values obtained.

Traceability information is given in the relevant Method Sheets for the system reagents.

### 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.

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 applied were FDA-approved 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.<sup>1,2</sup>

### Handling

Use contents undiluted.

Bring to 20-25 °C before use. Mix well immediately prior to use by occasional swirling while avoiding the formation of foam.

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.

### Storage and stability

Store at 2-8 °C.

### Stability:

Unopened:

Up to the stated expiration date at 2-8 °C.

After opening:

2 weeks at 2-8 °C, provided that dispensing of the calibrator occurs without microbial contamination, e.g. by pouring out.

Store calibrator tightly capped when not in use.

### 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 Compensator as specified in the Roche/Hitachi operator’s manual.

### References

- 1 Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.
- 2 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.

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.

CONTENT	Contents of kit
CALIBRATOR	Calibrator
➔	Volume after reconstitution or mixing

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Significant additions or changes are indicated by a change bar in the margin.

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