

REF 20751995 190

→ 2 x 4 mL Calibrator

English

System information

For use on Roche/Hitachi and **cobas c** analyzers the calibrator code is 688.
For use on COBAS INTEGRA analyzers the system ID is 07 5199 5.

Intended use

Ammonia/Ethanol/CO₂ Calibrator is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

Ammonia/Ethanol/CO₂ Calibrator is a liquid ready-for-use calibrator based on a buffered aqueous solution. 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

Reactive components:

Aqueous buffer solution containing ammonia, ethanol and sodium bicarbonate

Non-reactive component:

Preservative

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, COBAS INTEGRA and **cobas c** 111 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.

The calibrator values were obtained via single determinations performed in different laboratories in separate runs. The calibrator value specified is the mean 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.

Handling

The product is ready-for-use. Mix carefully before use. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **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.

Criterion for the stability data stated by Roche:

Recovery within ± 10 % of initial value.*

Recovery within ± 5 % of initial value.**

Stability:

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

**Open vial: 2 hours at 15-25 °C.

**Sample cup: 30 minutes at 15-25 °C (ammonia is volatile – start the calibration as soon as possible).

**After opening: 8 weeks at 2-8 °C, provided that dispensing of the calibrator takes place 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 Ammonia/Ethanol/CO₂ Calibrator as specified in the relevant Method Sheet for the system reagents.

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.

	Contents of kit
	Calibrator
	Volume after reconstitution or mixing

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

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