



05234727001V2.0

Homocysteine Calibrator Kit

cobas®

REF 05385504 190

2 × 3 mL Calibrator

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the calibrator code is 590.

For use on COBAS INTEGRA analyzers the system ID is 07 7493 6.

Intended use

The Homocysteine Calibrator Kit is intended for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Summary

The Homocysteine Calibrator Kit is a ready-for-use calibrator based on human serum.

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

Reagents – working solutions

Reactive components:

Human serum with chemical additives.

Non-reactive components:

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.

Please note: Roche Diagnostics is not responsible for the assigned values and the application on the **cobas c** 111 analyzer.

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.^{1,2}

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 stability data stated by Roche:
Recovery within ± 10 % of initial value.

Stability:

Unopened:

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

After opening:

2 hours at 15-25 °C or 28 days 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 the Homocysteine Calibrator Kit as specified in the relevant Method Sheet for the system reagents.

References

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

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

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