

# Calibrator for automated systems **cobas**<sup>®</sup>

REF 10759350 190

→ 12 x 3 mL Calibrator

## English

### System information

For use on Roche/Hitachi MODULAR analyzers and **cobas c** analyzers the calibrator code is 401.

For use on Roche/Hitachi **cobas c** 513 analyzers the calibrator code is 30401.

For use on COBAS INTEGRA analyzers the system ID is 07 3718 6.

### Intended use

Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

### Summary

C.f.a.s. is a lyophilized calibrator based on human serum.

The concentrations and activities 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 in the lyophilizate:*

Human serum with chemical additives and material of biological origin as specified.

The origin of the biological additives is as follows:

Analyte	Origin
ALT (GPT)	porcine heart
AST (GOT)	human, recombinant
Acid phosphatase	human prostate/potato
Albumin	bovine plasma
Aldolase	rabbit muscle
Alkaline phosphatase	human placenta (recombinant)
Amylase, total	porcine pancreas
Amylase, pancreatic	porcine pancreas
Cholesterol	bovine plasma
Cholinesterase	human serum
Creatine kinase	rabbit muscle
γ-GT	human, recombinant
GLDH	bacterial, recombinant
LD (LDH)	porcine heart
Lipase	human pancreas (recombinant)
Triglycerides	chicken egg yolk

*Non-reactive components:*

#### Stabilizers

The concentrations and activities 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 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 mean of all values obtained.

Traceability information is given in the respective instructions for use of the system reagents.

### 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.

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 use assays that have been approved by the FDA or that are in compliance with the legal rules applicable to placing in vitro diagnostic medical devices for human use on the market in the European Union.

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

Carefully open one bottle avoiding the loss of lyophilizate, and pipette in exactly 3.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for Roche/Hitachi MODULAR automated analyzers and **cobas c** systems (except for the **cobas c** 513 analyzer) 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 ± 5 % of initial value.

Stability of the lyophilized calibrator at 2-8 °C:

Up to the stated expiration date.

Stability of the components in the reconstituted calibrator\*:

at 15-25 °C	8 hours
at 2-8 °C	2 days
at (-15)-(-25) °C	4 weeks (when frozen once)

\*Exceptions: see below

Stability of acid phosphatase and prostatic acid phosphatase in the reconstituted calibrator (criterion: ± 10 % of initial value):

at 15-25 °C	4 hours
at 2-8 °C	1 day
at (-15)-(-25) °C	2 weeks (when frozen once)

Stability of total bilirubin in the reconstituted calibrator (when stored protected from light):

at 15-25 °C	6 hours
at 2-8 °C	1 day
at (-15)-(-25) °C	2 weeks (when frozen once)

Stability of direct bilirubin in the reconstituted calibrator (when stored protected from light):

at 15-25 °C	3 hours
at 2-8 °C	8 hours
at (-15)-(-25) °C	2 weeks (when frozen once)

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Store calibrator tightly capped (and protected from light) 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 C.f.a.s. as specified in the relevant Method Sheet for the system reagents.

## 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.

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](http://dialog.roche.com) for definition of symbols used):

	Contents of kit
	Calibrator
	Volume after reconstitution or mixing
	Global Trade Item Number

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Additions, deletions or changes are indicated by a change bar in the margin.

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