

REF 04528417190

04528417500

→ 3 x 2 mL Calibrator

English**System information**

For use on **cobas c** and COBAS INTEGRA analyzer systems, refer to the corresponding method sheet of the assay for the identification on the systems.

Intended use

C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheets.

Summary

C.f.a.s. HbA1c is a lyophilized calibrator based on hemolyzed sheep blood. 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:**

Hemolyzed sheep blood with chemical additives and material of biological origin as specified. The origin of the biological additives is as follows:

Analyte	Origin
Hemoglobin	Sheep blood
HbA1c	Human blood

Non-reactive components:

Preservatives and stabilizers

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

For Tina-quant Hemoglobin A1cDx Gen.3 on the **cobas c** 513 analyzer and on the **cobas c** 303/503 analyzer, C.f.a.s. HbA1c calibrator values are reagent lot matched. For each application and each combination of C.f.a.s. HbA1c calibrator lot and Tina-quant Hemoglobin A1cDx Gen.3 reagent lot, the exact calibrator values are given in the electronically available or enclosed value sheet.

For all other systems (**cobas c** 111, COBAS INTEGRA 400 plus analyzer, **cobas c** 311/501 and **cobas c** 502 analyzers) for Tina-quant Hemoglobin A1c Gen.3, C.f.a.s. HbA1c calibrator values are not reagent lot matched.

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 calibrators according to the standardization plan of the respective assay.

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 relevant Method Sheets for the system reagent.

Precautions and warnings

For in vitro diagnostic use for laboratory 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 or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 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}

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

**Danger**

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Prevention:

P261 Avoid breathing dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. + P310 Continue rinsing. Immediately call a POISON CENTER/ doctor.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P391 Collect spillage.

Hazardous components:

- tetradonium bromide
 - 2-methyl-2H-isothiazol-3-one hydrochloride
- Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590

Handling

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 2.0 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 **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 ± 10 % 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

C.f.a.s. HbA1c

at 2-8 °C 2 days
 at (-15)-(-25) °C 3 months (when frozen once)

Store calibrator tightly capped when not in use.

Materials provided

See "Reagents – working solutions" section for reagents.

Barcoded labels

Materials required (but not provided)

Roche system reagents and clinical chemistry analyzers
 General laboratory equipment

Assay

Use C.f.a.s. HbA1c 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:

	Contents of kit
	Calibrator
	Volume for reconstitution
	Global Trade Item Number

Rx only For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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

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