

A1CD

Hemolyzing reagent**Order information**

REF		CONTENT		Analyzer(s) on which cobas c pack(s) can be used
08463107190	08463107500	Hemolyzing reagent (50 mL)	System-ID 2069 001	cobas c 303, cobas c 503

English**System information****A1CD:** ACN 20690**Intended use**

The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c assays on **cobas c** systems.

Summary

The hemolyzing reagent is used as a diluent to hemolyze whole blood samples (whole blood application) and for the dilution of the calibrator (whole blood application and hemolyzate application). During predilution the TTAB^{a)} in the hemolyzing reagent serves as a detergent to eliminate interference from leukocytes (TTAB does not lyse leukocytes).

A1CD Hemolyzing reagent is concentrated fourfold and is automatically diluted by the analyzer prior to use.

a) Tetradecyltrimethylammonium bromide

Reagents - working solutions

Aqueous buffered matrix, pH 7.25; TTAB: 36 g/L; phosphate buffer: 80 mmol/L; stabilizer; preservative

The reagent is in position B.

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.

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 mist or vapours.

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

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C:

See expiration date on

cobas c pack label.

On-board in use and refrigerated on the analyzer:

4 weeks

When storing at temperatures below 3 °C the reagent may become cloudy. This has no effect on the function of the reagent and is reversible at higher temperatures. It is therefore recommended to equilibrate the reagent to room temperature for approximately 10 minutes and mix thoroughly prior to use.

Materials provided

See "Reagents – working solutions" section for reagents.

Assay

Use A1CD Hemolyzing reagent as specified in the relevant Method Sheet for the system reagents.

The hemolyzing reagent is used for the predilution of whole blood samples (whole blood application) and for the dilution of the calibrator (whole blood application and hemolyzate application). A1CD Hemolyzing reagent must be available on the analyzer otherwise the calibration cannot be performed. The exact volumes are programmed in the respective test settings on the system.

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard:

 CONTENT

Contents of kit



Volume for reconstitution

 GTIN

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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