

# A1CD

Hemolyzing reagent

Order information

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

## English

### System information

A1CD: ACN 20690

### Intended use

The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay 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<sup>a)</sup> 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 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.

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/fume/gas/mist/vapours/spray.

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.

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 (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	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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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim  
www.roche.com

+800 5505 6606

