



04542312001V5.0

Hemolyzing Reagent Gen.2

cobas®

Order information

REF	CONTENT	Analyzer(s) on which kit(s) can be used
04528328 190	Hemolyzing Reagent Gen.2 (6 × 10 mL)	System-ID 07 6851 0 COBAS INTEGRA 400 plus COBAS INTEGRA 800

English

Intended use

The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.2 assay on COBAS INTEGRA 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 hemolysate application). During predilution the TTAB^a in the hemolyzing reagent serves as a detergent to eliminate interference from leukocytes (TTAB does not lyse leukocytes).

Hemolyzing Reagent Gen.2 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

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.

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

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

2-methyl-2H-isothiazol-3-one hydrochloride

EUH 208 May produce an allergic reaction.



Danger

H318 Causes serious eye damage.

H410 Very toxic to aquatic life with long lasting effects.

Prevention:

P273 Avoid release to the environment.

P280 Wear 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.

P391 Collect spillage.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

Reagent handling

Ready for use

Storage and stability

Shelf life at 2-8 °C

See expiration date on bottle label

COBAS INTEGRA 400 plus/800 systems

On-board in use, ISE rack, closed bottles 4 weeks

On-board in use, multi rack, open bottles 2 days

COBAS INTEGRA 800 CTS system

On-board in use, ISE rack, open bottles 2 days

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 Hemolyzing Reagent Gen.2 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 hemolysate application). Hemolyzing Reagent Gen.2 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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see <https://usdiagnostics.roche.com> for definition of symbols used):

CONTENT	Contents of kit
REAGENT	Reagent
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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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