

P0502210US

"For users in the United States: Please refer to the Web IFU posted on www.tosohbioscience.us"

CAUTION : US federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Instructions For Use

HbA1c Diluting Solution

Part # 0023503

For use in the US with Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01



TOSOH CORPORATION

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1. Intended Use

The HbA1c Diluting Solution is intended for *IN VITRO* DIAGNOSTIC USE ONLY on the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01.

This product is intended for Healthcare Professionals Use Only.

2. Summary and Explanation

The HbA1c Diluting Solution is a dilution agent specifically designed for use in combination with the HbA1c Calibrator Set (S) and Hemoglobin A1c Control Set indicated in "5. Related Components".

3. Prior to Use

Inspect the packaging and the exterior of the vial for any signs of damage prior to use. If any damage is visible, contact your local Tosoh sales representative.

Confirm that the following document is included in the package.

- Instructions For Use (this document) 1 copy

4. Content

Catalog No.	Description	Package content
0023503	HbA1c Diluting Solution	100 mL × 2 bottles

This product contains deionized water, EDTA and Tween 20.

Each contains less than 0.02% sodium azide as a preservative.

5. Related Components

Catalog No.

HbA1c Calibrator Set (S)	0023502
Hemoglobin A1c Control Set	0021974

6. Warnings and Precautions

- 1) This product is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
- 2) This product is intended for use on Tosoh Automated Glycohemoglobin Analyzers (HLC-723GR01).
- 3) Do not use this product beyond the expiration date.
- 4) After opening, the HbA1c Diluting Solution must be used within 180 days, even if this product is still within the expiration date after 180 days of opening.
- 5) This product contains less than 0.02% sodium azide as a preservative.

For safety, adopt the following first aid in case of an accident and call for medical attention.

Skin exposure: Wash exposed area with plenty of soap and water.

Eye exposure: Open eyes as wide as possible and wash with clean water for at least 15 minutes.

Ingestion: Rinse the mouth and throat with excess water.

- 6) Remaining HbA1c Diluting Solution after use must not be combined with contents of another bottle. Prior to disposal, add excess water to the bottle to support safe and appropriate disposal practices.
- 7) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state and federal regulations.

7. Storage and Stability

- 1) Always store the HbA1c Diluting Solution in an upright position.
- 2) The HbA1c Diluting Solution must be stored at 4 to 30 °C while unopened. It will remain stable for use up to the expiration date indicated on the package box and bottle label.
- 3) After opening, the bottle of HbA1c Diluting Solution must be kept tightly sealed with a clean cap and stored at 4 to 30 °C.
- 4) The HbA1c Diluting Solution must not be used beyond 180 days after opening.

8. Installation and Diluting

For detailed description of procedures for using the HbA1c Calibrator Set (S) and Hemoglobin A1c Control Set, refer to the respective Instructions For Use and the Operator's Manual for the Tosoh Automated Glycohemoglobin Analyzers HLC-723GR01.

Reconstitution of HbA1c Calibrator Set (S) (Catalog No. 0023502)

- 1) Remove the metal seal with plastic flip top and carefully remove the rubber cap.
- 2) Reconstitute HbA1c Calibrators (1) and (2) by adding 1 mL of the HbA1c Diluting Solution to each and place the removed rubber cap at step 1 on the vial.
Thoroughly mix by gentle inverting.
- 3) After reconstitution, HbA1c Calibrator Set (S) will remain stable for use up to 30 minutes at 30 °C and 8 hours at 2 to 8 °C.

Dilution of Hemoglobin A1c Control Set (Catalog No. 0021974)

- 1) Remove the metal seal with plastic flip top and carefully remove the rubber cap.
- 2) Using volumetric pipettes, accurately reconstitute the lyophilized material with 0.5 mL of deionized water.
- 3) Replace the rubber cap that was removed in step 1 on the vial and let the material stand at ambient temperature for 30 minutes.
- 4) Swirl gently but thoroughly before use to ensure homogeneity.
- 5) Dilute the reconstituted product with HbA1c Diluting Solution by 51 times (10 µL of the reconstituted product to 0.5 mL of HbA1c Diluting Solution) before performing the assays.
- 6) Diluted control samples must be used within 30 minutes at 15-30 °C.

CAUTION: To avoid deterioration of reconstituted controls, deionized water must be used for reconstitution in step 2.

Dilution of frozen Hemoglobin A1c Control Set

- 1) Slowly bring the frozen product to room temperature, and wait until it completely thaws.
- 2) Dilute thawed product with HbA1c Diluting Solution by 51 times (10 µL of the thawed product to 0.5 mL of HbA1c Diluting Solution) and gently mix.
- 3) Diluted control samples must be used within 30 minutes at 15-30 °C.

CAUTION: Repeated freeze-thaw cycles must be avoided.

9. Limitations

The HbA1c Dilution Solution is designated for use only with the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 in the US.

Symbols on the product labels



European Conformity



Manufacturer



Authorized representative in the European Community



Catalogue number / Part number



In vitro diagnostic medical device



Consult instructions for use



Use-by date



Batch code / Lot number



Temperature limitation



Net volume (after reconstitution for lyophilized material)



A carrier containing unique device identifier information



Supplied by



製造販売元

東ソー株式会社

バイオサイエンス事業部

東京都中央区八重洲 2-2-1 〒104-0028
TEL (03) 6636-3734 FAX (03) 6636-3627



TOSOH CORPORATION

BIOSCIENCE DIVISION

2-2-1 Yaesu, Chuo-ku, Tokyo 104-0028 Japan
Phone: +81 3 6636 3734 Fax: +81 3 6636 3627

EC REP

TOSOH EUROPE N.V.

Transportstraat 4
3980 Tessenderlo-Ham, Belgium
Phone: +32 13 66 88 30 Fax: +32 13 66 47 49

Supplied by

TOSOH BIOSCIENCE, INC.

3600 Gantz Road, Grove City, OH 43123 USA
Phone: +1 650 615 4970 Fax: +1 650 615 0415

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