P0600713US

“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

Hemoglobin A1c Control Set

Part # 0021974

For use in the U.S. with Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01

TOSOH CORPORATION

Contents

Revised in March, 2026

1. Introduction

This Hemoglobin A1c Control Set has been designed exclusively for the quality control of Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01. This product is intended for evaluation and monitoring of the performance of HbA1c assays on those analyzers by being assayed as samples.

This product consists of two levels of HbA1c (% or mmol/mol) to cover the clinically significant range for diabetes control.

2. Prior to Use

Inspect the packing and the exterior of the vial for any signs of damage prior to use. If any damage is visible, contact your local Tosoh representative.
Confirm that the following documents are included in the package.

1 copy each of:

- Instructions For Use (this document)
- 2D Barcode Sheet

3. Warnings and Precautions

1) This product is for *IN VITRO* DIAGNOSTIC USE ONLY.
2) This product is intended for use on Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01.
3) Use purified water for reconstituting the control.
4) After reconstitution, the product must be tightly sealed and stored in an upright position at 2 - 8 °C.
5) In case of freezing: Reconstitute the product. Immediately dispense aliquots of samples into aliquot tubes. Care must be taken to freeze the tubes immediately. Thereafter, repeated freeze-thaw cycles must be avoided.
6) Prepare the QC for analysis using the HbA1c Diluting Solution (Part # 0023503), which is used only with the HbA1c Calibrator Set (S) (Part # 0023502). Do not use water.
7) In case an erroneous result is obtained with the reconstituted frozen product, use another freshly reconstituted vial of the product .
8) Human blood used in the preparation of this product has been tested by FDA-approved methods and found negative for the presence of HBsAg and antibodies to HCV and HIV-1. Because no test method can offer complete assurance that products derived from human blood will not transmit infectious agents, it is recommended that this product be handled with the same precautions as used for patient specimens.
9) Do not use this product beyond the expiration date.
10) In case of accidental ingestion, rinse the mouth and throat with excess water and immediately call for medical attention.
11) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

4. Content

Catalog No.	Description	Package content
0021974	Hemoglobin A1c Control Set	HbA1c Control Level 1: 4 vials×0.5 mL HbA1c Control Level 2: 4 vials×0.5 mL

This product has been prepared from human blood cells with two significant levels of HbA1c (% or mmol/mol) and lyophilized. The total hemoglobin concentration is about 40 g / L (4 g / dL) after reconstitution.

5. Related Components

Refer to the Calibrator Set IFU for information on HbA1c Calibrator Set (S) Part # 0023502 and HbA1c Diluting Solution Part # 0023503. The HbA1c Diluting Solution is used to dilute the reconstituted control.

Traceable to the IFCC reference method. The NGSP values are assigned using the Master equation (See Section 7 below).

6. Storage and Stability

1. Before opening, Hemoglobin A1c Control Set must be stored at 2 - 8 °C.
2. The product is stable for 7 days after opening or reconstitution provided that the vial is kept tightly sealed and refrigerated at 2 - 8 °C.
3. When the product is frozen after reconstitution, it must be stored at – 20 °C or lower. Stored under these conditions, it will be stable for up to 30 days.

7. Assigned Values

Values are provided on the document “Assigned Values for Hemoglobin A1c Control Set Part # 0021974 IFU, U.S. Only” on the webpage www.tosohbioscience.us.

IFCC: International Federation of Clinical Chemistry and Laboratory Medicine
The IFCC aligned values are traceable to the IFCC reference method.
NGSP: National Glycohemoglobin Standardization Program
The NGSP aligned values were calculated using the following conversion equation (Master equation) from the IFCC aligned values:

$$NGSP\ (\%) = 0.09148 \times IFCC\ (mmol/mol) + 2.152$$

Ref. : Geistanger A. et al. Clin Chem 2008; 54: 1379-1385.

The assigned values are specific to each lot of the product.
Observed values may vary during the product’s lifetime and are dependent on the instrument and reagents used.
Each laboratory should establish its own criteria for acceptable range of variations.

8. Preparation

1. Tear off the metal seal with plastic flip top and carefully remove the rubber cap.
   (NOTE) A sudden rush of air can result in a loss of lyophilized material.
2. Using volumetric pipettes, accurately reconstitute the lyophilized material with 0.5 mL of purified water.
3. Place the removed cap at step 1 on the vial and let the material stand at room temperature for 30 minutes.
4. Swirl gently but thoroughly before use to ensure homogeneity.
5. Dilute the reconstituted product by 51 times (10 µL of the reconstituted product to 0.5 mL of HbA1c Diluting Solution) (Part # 0023503) before performing the assays.
6. Samples diluted with HbA1c Diluting Solution must be used within 30 minutes when stored at 15-30 °C.

9. Long Term Storage Procedure

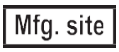
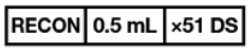
When the reconstituted product is stored at – 20 °C or below, it will remain stable for up to 30 days. The reconstituted product must be frozen immediately after reconstitution.

1. It is recommended that the reconstituted product be frozen by being dispensed into plastic tubes.
2. After dispensing, the tubes must be tightly sealed and immediately frozen at – 20 °C or lower.
3. Prior to assay, slowly bring the frozen product to room temperature, and wait until it completely thaws. Dilute the reconstituted product by 51 times (10 µL of the reconstituted product to 0.5 mL of HbA1c Diluting Solution (Part # 0023503) before performing the assay and gently mix it.
4. Diluted samples with HbA1c Diluting Solution must be used within 30 minutes when stored at 15-30 °C.
5. Repeated freeze-thaw cycles must be avoided.

10. Assay Procedure

After reconstitution (with purified water) and dilution (with HbA1c Diluting Solution), the Hemoglobin A1c Control Set must be treated in the same manner as an unknown patient specimen that is manually diluted. It must be analyzed on the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 following the instructions in the Operator’s Manual.

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)	 Actual manufacturing site	 Date of manufacture
 Imported and Marketed in India by	 A carrier containing unique device identifier information	 Reconstitute the content of a vial by adding 0.5 mL of purified water and then dilute 51 times with HbA1c Diluting Solution for use
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