Instructions For Use
Hemoglobin A1c Control Set

TOSOH CORPORATION

Attention: This IFU complies with IVD directive 98/79/EC and is intended for use by customers operating in a member state of the European Union

1. Introduction

This Hemoglobin A1c Control Set has been designed exclusively for the quality control of Tosoh Automated Glycohemoglobin Analyzers, Standard Analysis Mode and Variant Analysis Mode. This product is intended for evaluating and monitoring the performance of HbA_{1c} assays on those analysers by being assayed as samples.
This product consists of two levels of HbA_{1c} (% or mmol/mol) to cover the clinically significant range for diabetes control.

2. Before Use

Inspect the packaging and the exterior of the vial for any signs of damage before 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

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 Analyzers (HLC-723®G7, HLC-723G8, HLC-723GX, HLC-723G11), Standard Analysis Mode and Variant Analysis Mode.
3) After reconstitution, the product must be tightly sealed and stored in an upright position at 2 ℃ - 8 ℃.
4) Do not use the HbA1c Diluting Solution for reconstituting the controls but use purified water.
5) The reconstituted product can be stored under freezing condition. In such a case, it must be frozen immediately after reconstitution.
6) Repeated freeze-thaw cycles must be avoided.
7) In case this product is used in combination with HbA1c Calibrator Set (S) (Catalogue No. 0023502) or G8 HbA1c Calibrator Set (S) (Catalogue No. 0023528), the HbA1c Diluting Solution should be used for the dilution of this reconstituted control material.
8) In case an erroneous result is obtained with the reconstituted and frozen product, use another vial of the product freshly reconstituted.
9) 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. Since no test method can give 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 those used for patient samples.
10) Do not use this product beyond the expiry date.
11) In case of accidental ingestion, rinse the mouth and throat with excess water and immediately call for medical attention.
12) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state, and federal regulations.

4. Content

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

This product has been prepared from human blood cells with two significant levels of HbA_{1c} (% or mmol/mol) and lyophilized. The total haemoglobin concentration is about 40 g/L (4 g/dL) after reconstitution.

5. Related Components

	Catalogue No.
Hemoglobin A1c Calibrator Set	0018767
G8 HbA1c Calibrator Set (S)	0023528
HbA1c Calibrator Set (S)	0023502

	Catalogue No.
HbA1c Diluting Solution	0023503

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 should be stored at 2 ℃ - 8 ℃.
2) The product will remain stable 7 days after opening or reconstitution provided that the vial is kept tightly sealed and refrigerated at 2 ℃ - 8 ℃.
3) When the product is frozen after reconstitution, it should be stored at -20 ℃ or below. Then, it will be stable for up to 30 days.
4) The expiry date for this product is shown below.
   Expiry date: 20XX-XX (YYYY-MM)

7. Assigned Values

Lot No. ABXXXX

	Level 1	Level 2
IFCC aligned value (mmol/mol)	XX ± 3	XXX ± 5
NGSP aligned value (%)	X.X ± 0.3	XX.X ± 0.5

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:

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

Ref.: Geistanger A. et al. *Statistical Methods for Monitoring the Relationship between the IFCC Reference Measurement Procedure for Hemoglobin A1c and the Designated Comparison Methods in the United States, Japan, and Sweden*. Clin Chem 2008; 54: 1379-1385.

The assigned values are specific to each lot of the product. The observed values may vary during the life time of the product and may depend on the used instrument and reagents. 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 purified water when using Hemoglobin A1c Calibrator Set (Catalogue No. 0018767) or HbA1c Diluting Solution when using HbA1c Calibrator Set (S) (Catalogue No. 0023502) or G8 HbA1c Calibrator Set (S) (Catalogue No. 0023528)) before performing the assays.
6) Diluted samples with HbA1c Diluting Solution should be used within 30 minutes at 15° - 30 ℃.

9. Long Term Storage Procedure

When the reconstituted product is stored at -20 ℃ 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 is frozen by being dispensed into plastic tubes.
2) After dispensing, the tubes should be tightly sealed and immediately frozen at -20 ℃ or below.

3) Before assaying, slowly bring the frozen product to room temperature, and wait until it completely thaws. After that, dilute it by 51 times (10 µl of the thawed product to 0.5 mL of purified water when using Hemoglobin A1c Calibrator Set (Catalogue No. 0018767) or HbA1c Diluting Solution when using HbA1c Calibrator Set (S) (Catalogue No. 0023502) or G8 HbA1c Calibrator Set (S) (Catalogue No. 0023528)) and gently mix it.
4) Diluted samples with HbA1c Diluting Solution should be used within 30 minutes at 15° - 30 ℃.
5) Repeated freeze-thaw cycles must be avoided.

10. Assay Procedure

After reconstitution and dilution, the Hemoglobin A1c Control Set should be treated in the same manner as an unknown patient specimen manually diluted. It should be analysed on a Tosoh Automated Glycohemoglobin Analyzer following the instructions in the Operator's Manual.

Symbols on the HPLC products

Mfg. site

Actual manufacturing site

TOSOH

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