

P0601705US

“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 Calibrator Set (S)

Part # 0023502

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



TOSOH CORPORATION

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1. Intended Use

The HbA1c Calibrator Set (S) is intended for *IN VITRO* DIAGNOSTIC USE ONLY for the calibration of the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01.

The HbA1c Calibrator Set (S) is intended for Healthcare Professionals Use Only.

2. Summary and Explanation

The HbA1c Calibrator Set (S) is a reference agent specifically designed for use in the calibration of the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01 which reports HbA1c (SA1c). For detailed procedures for use of the HbA1c Calibrator Set (S), refer to the Operator's Manuals of the Tosoh Automated Glycohemoglobin Analyzer HLC-723GR01.

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 representative.

Confirm that the following documents are included in the package.

1 copy of each:

- Instructions For Use (this document)
- Barcode Sheets

4. Content

Catalog No.	Description	Package content
0023502	HbA1c Calibrator Set (S)	HbA1c Calibrator (1) : 4 vials × 1 mL HbA1c Calibrator (2) : 4 vials × 1 mL

This product contains processed and lyophilized human blood cells with two distinct levels of HbA1c (% or mmol/mol).

5. Related Components

	Catalog No.
Hemoglobin A1c Control Set	0021974
HbA1c Diluting Solution (*)	0023503

(*) Not provided but is required to reconstitute HbA1c Calibrator Set (S).

6. Warnings and Precautions

1. This product is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
2. See the Operator's Manual for guidance on when to recalibrate the analyzer.
3. Do not use this product beyond the expiration date.
4. Human blood used for the preparation of the HbA1c Calibrator Set (S) has been tested by standard, approved methods and found to be 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 taken for patient samples.
5. For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state and federal regulations.

7. Reconstitution of Reagent

1. Carefully remove the cap from the calibrator vials.
2. Add 1 mL of the HbA1c Diluting Solution to each HbA1c Calibrator (1) and (2) and place the cap again. Reconstitute the calibrators thoroughly by rotating and inverting them.
3. Reconstituted HbA1c Calibrator (1) and (2) can be used immediately.

CAUTION : Only the HbA1c Diluting Solution should be used for reconstitution of the HbA1c Calibrator (1) and (2).

8. Storage and Stability

1. The HbA1c Calibrator Set (S) must be stored at 2 to 8 °C while unopened. It will remain stable for use up to the expiration date indicated on the vial.
2. After reconstitution, the HbA1c Calibrator Set (S) will remain stable for use for up to 30 minutes at 30 °C and 8 hours at 2 to 8 °C.

9. Assigned Values

Values are provided on the document “Assigned Values for HbA1c Calibrator Set (S) Part # 0023502 IFU, U.S. only” on the webpage www.tosohbioscience.us.

IFCC^(*1) Aligned Value: traceable to IFCC HbA1c Calibrator Set provided from IFCC Working Group on Standardization of HbA1c.

(*1) IFCC: International Federation of Clinical Chemistry and Laboratory Medicine

NGSP^(*2) Aligned Value: calculated using the following conversion equation.

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

(*2) NGSP: National Glycohemoglobin Standardization Program

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

10. Calibration Procedure

1. Dispense 500 µL, reconstituted HbA1c Calibrator (1) and (2), respectively, into the designated sample cups.
2. Place HbA1c Calibrator (1) and (2) in positions No. 1 and No. 2 of the first rack.
3. Tap the calibration reserve button on the main screen.
4. Enter the assigned value for HbA1c Calibrator (1) and (2). Refer to the document “Assigned Values for HbA1c Calibrator Set (S) Part # 0023502 IFU, U.S. only” on the webpage www.tosohbioscience.us for the assigned values of HbA1c Calibrator (1) and (2).

5. Make sure that the correct assigned values are displayed in the [CAL1 asg. value] and [CAL2 asg. value] fields and that the calibrators are set properly as indicated in the diagram. Then, tap the calibration register button.
6. Check the reserved calibration contents on the calibration reservation confirmation dialog. Then, tap the set button.
7. "Calibration reserved." appears at a lower part of the analysis start button. Tap the analysis start button to start calibration.
8. HbA1c Calibrator (1) will be automatically measured three times and HbA1c Calibrator (2) will be automatically measured two times to calculate calibration coefficients "a" and "b".

Note that calibration will have to be performed again if the following results are produced.

- Difference between the 2nd and 3rd SA1c (%) value exceeds 0.3 %.
- Difference between the 4th and 5th SA1c (%) value exceeds 0.3 %.
- Any of the four calibrator results differ from its assigned value by 30 % or more.

Refer to the HLC-723GR01 Operator's Manual for detailed description.

HbA1c Calibrator Set (S) Barcode Sheets

Calibrator's assigned value, Lot. No. and expiration date are automatically entered by scanning Barcode Sheets with an optional handheld barcode scanner connected to the HLC-723GR01.

Refer to the HLC-723GR01 Operator's Manual for detailed description.

11. Limitations

The HbA1c Calibrator Set (S) is designated only for use with the Tosoh Automated Glycohemoglobin Analyzer (HLC-723GR01).

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



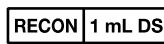
Batch code / Lot
number



Temperature limitation



Net volume
(after reconstitution for
lyophilized material)



Reconstitute the
content of a vial by
adding 1 mL of HbA1c
Diluting Solution for use



A carrier containing
unique device identifier
information



Supplied by



TOSOH



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