

Tosoh Automated Glycohemoglobin Analyzer HLC-723®G11

Instructions For Use

G11® F&A2 Control Set



TOSOH CORPORATION

Symbols on the product labels



Manufacturer



Catalogue number / Part number



In vitro diagnostic medical device



Consult instructions for use



Use-by date
/ Use by



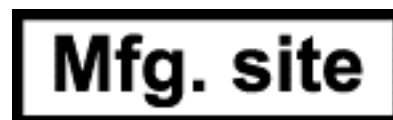
Batch code / Lot number



Temperature limitation



Net volume
(after reconstitution for
lyophilized material)



Actual manufacturing site



Date of manufacture



Imported and Marketed
in India by

1. Intended Use

The G11 F&A2 Control Set is intended for *IN VITRO* DIAGNOSTIC USE for performing quality control procedure with the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 β -Thalassemia Analysis Mode. These controls can be used to evaluate and monitor the precision of the performance of an assay in the same way as an unknown specimen. Two concentration levels are provided to cover the entire clinical range.

The G11 F&A2 Control Set is intended for Healthcare Professionals Use Only.

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 1 copy
- Assignment value sheet 1 copy

3. Material Provided

Catalogue No.	Description	Package content
0023509	G11 F&A2 Control Set	Level-1 : 2 vials $\times$ 0.2 mL Level-2 : 2 vials $\times$ 0.2 mL

The G11 F&A2 Control Set is prepared from human blood cells with the constituents of two significant concentrations and then lyophilized. The total hemoglobin concentration is about 8 g/dL after reconstitution.

Assay mode : β -Thalassemia Analysis Mode

Applicable analyzers : Tosoh Automated Glycohemoglobin Analyzer HLC-723G11

4. Materials Required but Not Provided

The following materials are required to perform HbF and HbA₂ analysis using the HLC-723G11 β -Thalassemia Analysis Mode. They are available separately from Tosoh Corporation.

	Catalogue No.
G11 F&A2 Calibrator Set	0023508
F&A2 Calibrator Set 2	0023550
TSKgel G11 β -Thal.	0023504
G11 β -Thalassemia Elution Buffer No.1 (S)	0023505
G11 β -Thalassemia Elution Buffer No.2 (S)	0023506
G11 β -Thalassemia Elution Buffer No.3 (S)	0023507
HSi Hemolysis & Wash Solution (L)	0018431
HSi Hemolysis & Wash Solution (LL)	0019550

Only materials obtained from Tosoh Corporation should be used.

Materials obtained elsewhere should not be used as substitute since assay performance is characterized based strictly on Tosoh Corporation materials.

For detailed information about these materials, contact your local Tosoh sales representative.

5. Warnings and Precautions

- 1) The G11 F&A2 Control Set is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
- 2) This product is intended for use on Tosoh Automated Glycohemoglobin Analyzer HLC-723G11 β -Thalassemia Analysis Mode only.
- 3) Each human blood used in the preparation of this product has been tested by standard, 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 should be handled with the same precautions as patient specimens.
- 4) Do not use this product beyond the expiration date.
- 5) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state and federal regulations.

6. Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at 2 to 8 °C. The expiration date is indicated on the package box and individual materials.

The G11 F&A2 Control Set is stable for 5 days after reconstitution when stored at 2 to 8 °C.

After reconstitution, even when stored as stated above, it cannot be used beyond their expiration dates.

7. Assigned Values

The assigned values of level-1 are 0.3 to 3.5 % for HbF and 2.0 to 4.0 % for HbA₂ and those of level-2 are 3.5 to 8.0 % for HbF and 4.8 to 7.5 % for HbA₂. The ranges, determined on a lot-to-lot basis, are target ranges generated from limited data and are meant to serve as guidelines. Since the assay values are dependent upon assay procedures as well as several other factors, each laboratory should establish its own range for the assay procedure being monitored. The assigned value is determined by comparing with internal reference standard.

8. Procedure

Be sure to read the IFU included with the TSKgel G11 β -Thal., G11 β -Thalassemia Elution Buffer, G11 F&A2 Calibrator Set or F&A2 Calibrator Set 2, and HSi Hemolysis & Wash Solution as well as the Operator's Manual of the HLC-723G11 β -Thalassemia Analysis Mode for detailed description.

I. Reconstitution and Dilution

- 1) Tear off the metal seal with plastic flip top and carefully remove the rubber cap.
(NOTE: A sudden rush of air could result in a loss of lyophilized material.)
- 2) Using volumetric pipettes, accurately reconstitute the lyophilized material with 0.2 mL of distilled water.
- 3) Place the cap 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 control with distilled water by 51 times (10 μ L of the control to 0.5 mL of distilled water) into the designated sample cups before performing assay.

II. Analysis

The control should be treated in the same manner as an unknown patient specimen and must be analyzed according to descriptions stated in the Operator's Manual of the HLC-723G11 β -Thalassemia Analysis Mode.



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