

P0502003

Tosoh Automated Glycohemoglobin Analyzer HLC-723[®]G11

Instructions For Use

G11[®] β -Thalassemia Elution Buffer No.1 (S)

No.2 (S)

No.3 (S)



TOSOH CORPORATION

Safety Precautions

To help protect you and/or your property from potential damage and ensure personal safety, please read this IFU thoroughly before using the product.

[Notational Convention]

Notation	Explanation
 CAUTION	Indicates a hazard with a low level of risk which, if not avoided, could result in minor or moderate injury.

CAUTION

■ **Use only in well ventilated areas**

In case of insufficient ventilation, spilled solvents can cause harm.

■ **First Aid**

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.

Immediately call for medical attention.

Ingestion

Please wash mouth with excess water and immediately call for medical attention.

■ **Do not spill solvents**

Spillage and leakage can cause fire, electric shock, poisoning, injury, and corrosion.

Wear appropriate protective gear when cleaning up a spill.

■ **Wear eye protection and protective gloves**

Organic acids are harmful and should not come in direct contact with the skin.

■ **Handle package with care**

Inappropriate handling may cause rupturing and/or spattering of the product.

■ **Only use this product as intended**

This product is intended for *IN VITRO* DIAGNOSTIC USE ONLY for the measurement of Hemoglobin F and A₂ in blood specimens by healthcare professionals.

■ **Proper disposal**

Dispose in accordance with local, state and federal laws and regulations.

NOTE

Keep this IFU with the product for future reference.

EU rev. G11B-0202003



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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



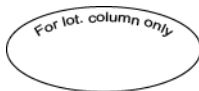
Use-by date / Use by



Batch code / Lot number



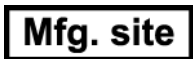
Temperature limitation



For specified
column lot only



Net volume
(after reconstitution for
lyophilized material)



Actual manufacturing site



Date of manufacture

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Revised in October, 2021

1. Intended Use

The G11 β -Thalassemia Elution Buffers are intended for *IN VITRO* DIAGNOSTIC USE for the quantitative percent determination of Hemoglobin F and A₂ and for the detection of the major hemoglobin variants, especially HbE, HbD, HbS and HbC, in whole blood samples using the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11, β -Thalassemia Analysis Mode (referred to as HLC-723G11 in this IFU), which is based on the principle of high-performance liquid chromatography assay, to aid in the diagnosis of β -thalassemia. It is not designed for and should never be used with any other type of system. The G11 β -Thalassemia Elution Buffers are intended for Healthcare Professionals Use Only.

2. Summary and Explanation of the Test

Hemoglobin(Hb) is a tetramer which is composed of 2 α -chains and 2 non α -chains. In the normal synthesis, α -chains and non α -chains (β -chain, γ -chain and δ -chain) are synthesized with no overproduction or underproduction.

Thalassemias are hereditary disorders that are caused by abnormally synthesized globin chains.

Since Thalassemia carriers are frequently found in a broad belt around the Mediterranean, it's sometimes called "Mediterranean anemia".

In Thalassemic disorders, due to a quantitative defect in synthesis of a specific chain, free α chains or single globin chains such as HbH (β 4), HbBart's (γ 4) of hemoglobin could be synthesized.

β -Thalassemia in an analogous manner means reduced or missing production of hemoglobin β -chains, which is compensated by overproduction of γ -chains and δ -chains. Consequently, HbA₂ (α 2 δ 2) and HbF (α 2 γ 2) are often elevated in β -Thalassemia.

3. Principle of the Procedure

The HLC-723G11 is based on the High-Performance Liquid Chromatography (HPLC) principle. Separation is obtained with a cation exchange column based on differences in ionic interactions between hemoglobin components within 5.0 min.

A step gradient elution is used to separate and assay HbF and HbA₂. The three-types of G11 β -Thalassemia Elution Buffers (G11 β -Thalassemia Elution Buffer No.1, 2, and 3 (S)) contain different salt concentrations and pH. HbF (%) and HbA₂ (%) are reported as a relative percentage of the integrated area of each Hb fraction against the sum of those hemoglobin fractions, after being calibrated using the calibration curve established with G11 F&A2 Calibrator Set or F&A2 Calibrator Set 2.

4. Before Use

Inspect the packaging and the exterior of the aluminum pack for any signs of damage before use. If any damages are visible, contact your local Tosoh sales representative.

Confirm that the following document is included in the package.

- Instructions For Use 1 copy (in each box)

5. Material Provided

Catalogue No.	Description	Content (per one pack)
0023505	G11 β -Thalassemia Elution Buffer No. 1 (S)	800 mL
0023506	G11 β -Thalassemia Elution Buffer No. 2 (S)	800 mL
0023507	G11 β -Thalassemia Elution Buffer No. 3 (S)	800 mL

G11 β -Thalassemia Elution Buffers are organic acid buffers, each of which contains less than 0.05 % sodium azide as a preservative.

6. 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
G11 F&A2 Control Set	0023509
TSKgel G11® β -Thal.	0023504
HSi Hemolysis & Wash Solution (L)	0018431
HSi Hemolysis & Wash Solution (LL)	0019550

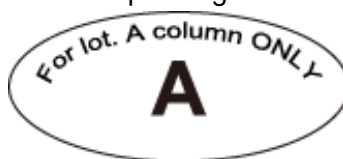
(*) G11 F&A2 Calibrator Set and F&A2 Calibrator Set 2 cannot be used interchangeably.

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.

7. Warnings and Precautions

- 1) The G11 β -Thalassemia Elution Buffer No.1, No.2 and No.3 (S) are intended for *IN VITRO* DIAGNOSTIC USE ONLY.
- 2) The G11 β -Thalassemia Elution Buffer is designed exclusively for use in combination with the HLC-723G11 analyzer system, TSKgel G11 β -Thal. and HSi Hemolysis & Wash Solution indicated below, never in any other combination.
 - Tosoh Automated Glycohemoglobin Analyzer HLC-723G11
 - TSKgel G11 β -Thal.
 - HSi Hemolysis & Wash Solution (L), (LL)
- 3) Do not use this product beyond the expiration date.
- 4) Note that G11 β -Thalassemia Elution Buffers must be used within 90 days after opening (provided that the pack is being squeezed and capped so that the air will not enter it).
- 5) This Instructions For Use (IFU) must be read combined with the Operator's Manual of the HLC-723G11 β -Thalassemia Analysis Mode.
- 6) Carefully read the instructions contained in this IFU and those in the IFU provided with TSKgel G11 β -Thal..
- 7) Always use the G11 β -Thalassemia Elution Buffers in combination with the TSKgel G11 β -Thal. of the identical lot number. The column lot number is indicated by a single uppercase alphabetical character (A, B, etc.) on the label of column box. The Elution Buffer label displays an alphabetic character corresponding to the column lot number, as shown below.



- 8) When there is leftover buffer in the aluminum pack that is used again but is once removed from the analyzer and stored, gently squeeze the aluminum pack by hand to remove all excess air, and store it at a temperature between 4 and 30 °C firmly tightening the cap so that the air will not enter it.
- 9) Do not refill an aluminum pack with any leftover Elution Buffer.
- 10) If you use the Lot management function on the HLC-723G11, please enter the barcode information printed on the box/pack labels of Elution Buffers. Please refer to the Operator's Manual of the HLC-723G11 β -Thalassemia Analysis Mode for detailed procedure.
- 11) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state and federal regulations.
- 12) Patient samples (clinical specimens) must always be considered as potentially infectious and should be handled using established laboratory procedures and/or institutional guidelines.
- 13) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authorities in the country where the HLC-723G11 is running.
- 14) HLC-723G11 β -Thalassemia Analysis Mode can use G11 F&A2 Calibrator Set and F&A2 Calibrator Set 2, but these cannot be used interchangeably. Please consult your local Tosoh representative for which calibrator should be used.

8. Storage and Stability

All unopened materials are stable until the expiration date on the label when stored at 4 to 30 °C. The expiration date is indicated on the package box and aluminum pack labels.

The G11 β -Thalassemia Elution Buffer No. 1, No. 2 and No. 3 (S) are stable for 90 days after opening when stored at 4 to 30 °C.

9. Specimen Collection and Handling

A venous whole blood sample collected in a primary tube containing EDTA is required for the analysis.

A venous blood sample should be collected aseptically. No special preparation is necessary. Blood samples collected in primary tubes containing EDTA may be stored at 25 °C for 24 hours or at 2-8 °C for 14 days prior to analysis.

10. Procedure

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

I. Column and reagent installation

Set the following column and reagent appropriately on the analyzer. The column and reagent are provided ready for use.

- TSKgel G11 β -Thal.
- HSi Hemolysis & Wash Solution (L) or (LL)

II. Buffers installation

- 1) Return the Elution Buffer to room temperature before use.
- 2) Press the "STOP" key on the HLC-723G11 system operation panel to go back to the STAND-BY state.
- 3) Uncap the Elution Buffer packs. Keep the caps in case the Elution Buffers are separately stored after being de-installed from the analyzer.
- 4) Make sure to insert the tube matching the color of the Elution Buffer pack being installed.
- 5) Gently squeeze the Elution Buffer pack by hand to remove all excess air inside, and firmly tighten the cap so that the air will not enter during operation.

III. Calibration

Calibration frequency should be determined based upon QC results and chromatogram quality at each laboratory. For recalibration details, please refer to the Operator's Manual of the HLC-723G11 and Instructions For Use of G11 F&A2 Calibrator Set or F&A2 Calibrator Set 2.

The G11 F&A2 Calibrator Set and the F&A2 Calibrator Set 2 are prepared to be traceable to the values of WHO reference reagent, NIBSC code: 89/666 on HbA₂. The G11 F&A2 Calibrator Set is prepared to be traceable to the value of WHO reference reagent, NIBSC code: 85/616 on HbF.

IV. Quality Control Procedure

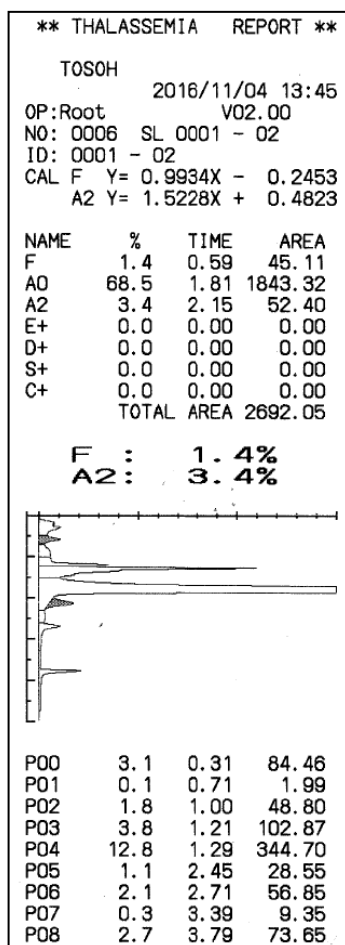
In order to monitor and evaluate the precision and analytical performance, it is recommended that at least two levels of controls be run at least once per day.

G11 F&A2 Control Set is provided lyophilized. Refer to the IFU of G11 F&A2 Control Set for detailed instructions.

Assay quality control materials as instructed in the Operator's Manual of the HLC-723G11 β -Thalassemia Analysis Mode.

If one or more control samples are out of the established ranges, it is necessary to investigate the validity of the calibration curve before reporting patient results. Follow the recommendations of local, state, and federal regulatory agencies as well as laboratory policies.

A sample chromatogram for G11 F&A2 Control Set, Level (1).



11. Results

Measurement values (%) indicate the percentage of each peak in relation to the Total Area. Note the minimum unit of measurement displayed is 0.1 %.

12. Limitations of the Procedure

1) Sample Dilution

Low concentrations of hemoglobin may cause the Total Area of the chromatogram to be < 900 in which HbF and HbA₂ values should not be reported.

High concentrations of hemoglobin may cause the Total Area of the chromatogram to be > 5000 in which HbF and HbA₂ values should not be reported.

2) Measuring Range

The measuring range of HbF is from 0.3 % to 50.0 % and HbA₂ is from 1.8 % to 9.9 %.

13. Expected Values

Reference Range (β -Thalassemia trait):

$$\text{HbA}_2 \geq 3.5 \%$$

Ref National Health Service (UK). NHS Sickle Cell and Thalassemia Screening Program.
November, 2006

14. Performance Characteristics

Performance Characteristics shown in this section are all obtained using HLC-723G11 calibrated by G11 F&A2 Calibrator Set except Fig. 2 in Sec. IV Method comparison.

I. Dilution Linearity

A study was performed with G11 F&A2 Calibrator Level 2 diluted with various ratios of HSi Hemolysis & Wash Solution to determine linearity of HbF (%) and HbA₂ (%) values against Total Area. The results demonstrate that it is linear in samples with Total Area from 900 to 5000. It is recommended that measurement be done with Total Area from 1000 to 4500 to give more reliable results.

Total area	HbF%	HbA ₂ %
853	4.5	6.3
1720	4.6	6.4
2238	4.7	6.3
2789	4.7	6.4
3465	4.7	6.4
3977	4.8	6.5
4483	4.8	6.5
5318	4.8	6.5

II. Linearity

The table below shows the recovery for samples prepared by mixing two types of samples at different ratios.

High HbF sample (ratio)	Low HbF sample (ratio)	Measured value HbF (%)	Theoretical value HbF (%)	Recovery (%)
0	10	0.33	—	—
2	8	10.08	10.26	98
4	6	20.87	20.19	103
6	4	30.33	30.12	101
8	2	41.04	40.05	102
10	0	49.98	—	—

High HbA ₂ sample (ratio)	Low HbA ₂ sample (ratio)	Measured value HbA ₂ (%)	Theoretical value HbA ₂ (%)	Recovery (%)
0	10	1.76	-	-
2	8	3.22	3.38	95
4	6	4.96	5.00	99
6	4	6.54	6.62	99
8	2	8.44	8.24	102
10	0	9.86	-	-

III. Carryover

Carryover of samples was checked by measuring 2 successive blank samples set just after a sample with high Total area. Carryover (%) was calculated as:

$$\text{Carryover (\%)} = (\text{Total area of the blank sample}) / (\text{Total area of the sample}) \times 100$$

Total area			Carryover (%)	
Sample	Blank-1	Blank-2	Blank-1	Blank-2
7608.74	31.51	34.15	0.4	0.4

Based on these results, the carryover is not clinically significant.

IV. Method comparison

A method comparison study was performed on 51 patient samples, with HbA₂ (%) values ranging from 2.9 % to 6.3 %, between the HLC-723G11 and HLC-723G8 analyzers in β -Thalassemia Analysis Mode.

Fig.1 illustrates the results.

Fig. 2 illustrates the method comparison study results on HbF (%) between the HLC-723G8 and HLC-723G11 calibrated with F&A2 Calibrator Set 2.

Fig. 1 Method comparison study between HLC-723G11 and HLC-723G8 analyzers on HbA₂ (%).

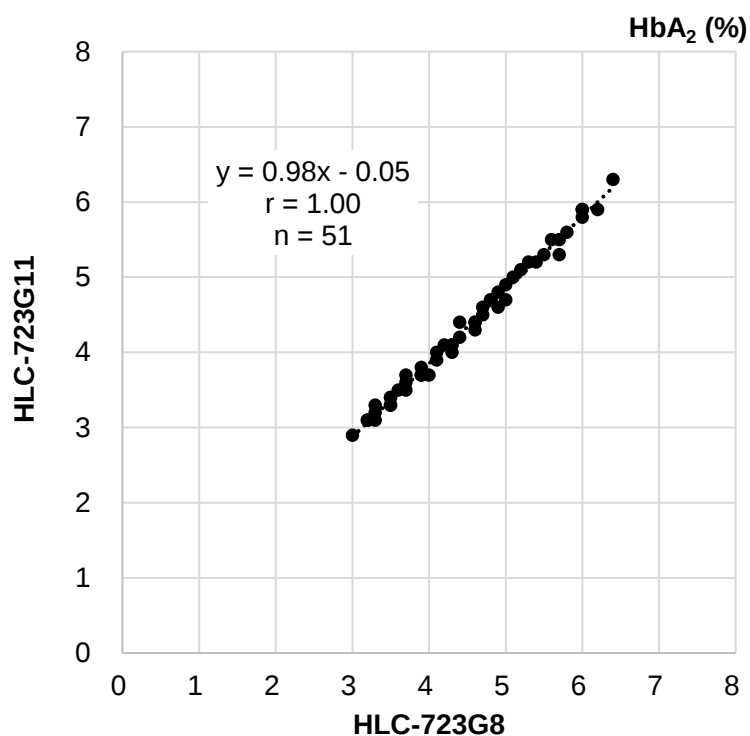
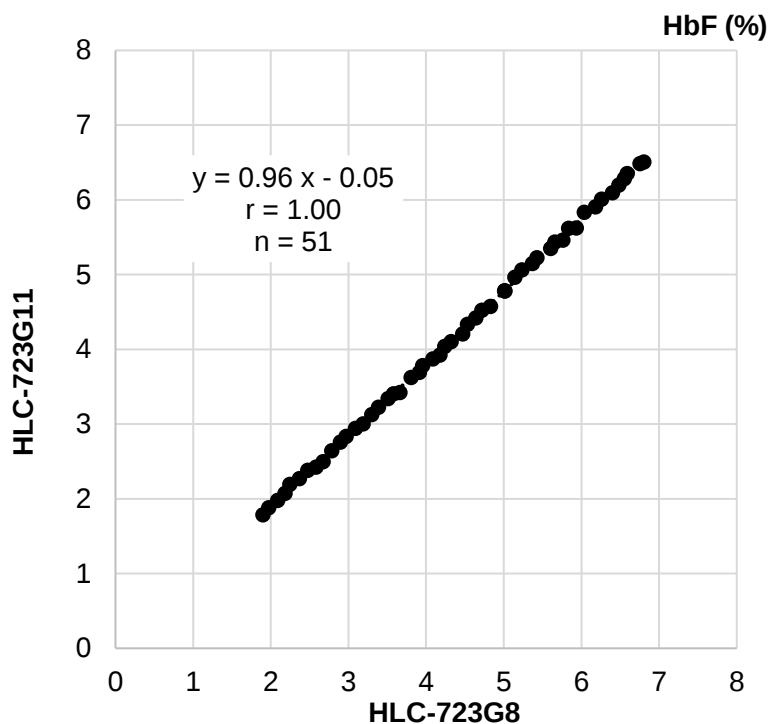


Fig. 2 Method comparison study between HLC-723G11 and HLC-723G8 on HbF (%).



V. Precision

1) Intra-assay precision (or within-run precision, n=20)

An intra-assay precision study (n=20) was done on 2 levels of G11 F&A2 Control Set and.

HbF			
Sample	Mean (%)	Standard Deviation (%)	Coefficient of Variation (%)
Control Material Level 1	1.50	0.00	0.00
Control Material Level 2	5.12	0.04	0.78

HbA ₂			
Sample	Mean (%)	Standard Deviation (%)	Coefficient of Variation (%)
Control Material Level 1	3.19	0.03	0.94
Control Material Level 2	6.48	0.04	0.62

2) Inter-assay precision (or between-day precision, n=20)

An inter-assay precision study (n=20) was done in which 2 levels of G11 F&A2 Control Set were measured once a day for 20 operating days. The following results were obtained.

HbF

Sample	Mean (%)	Standard Deviation (%)	Coefficient of Variation (%)
Control Material Level 1	1.51	0.02	1.32
Control Material Level 2	4.69	0.03	0.64

HbA₂

Sample	Mean (%)	Standard Deviation (%)	Coefficient of Variation (%)
Control Material Level 1	3.17	0.06	1.89
Control Material Level 2	5.78	0.11	1.90

VI. Interferences

Glucose/Triglyceride

No effect was observed below 10 g/L for glucose and 5 g/L for triglyceride.

Sodium cyanate/ Acetaldehyde

The presence of these substances may reduce the HbA₂ value. Care should be taken when interpreting alcoholic or nephritic patient specimens.

Variant hemoglobin

The variant hemoglobin HbE, HbD, HbS and HbC are separated from HbF and HbA₂, and HbF value and HbA₂ value are calculated. Since a high number of Hb Variants is observed worldwide, care should be taken when interpreting the results. Designation of a particular name cannot exclude the presence of other variants.

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