P0401802

Tosoh Automated Glycohemoglobin Analyzer HLC-723®G11

Instructions For Use

TSKgel G11® β-Thal.

CE

TOSOH CORPORATION

2022/04/28

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 A_2 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-0201802

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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

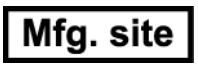
Batch code / Lot number

Temperature limitation

For specified column lot only

Serial number / Column number

Net volume (after reconstitution for lyophilized material)



Actual manufacturing site

CONTENTS

Revised in October, 2021

1. Intended Use

The TSKgel G11 β-Thal. is intended for *IN VITRO* DIAGNOSTIC USE for the quantitative percent determination of hemoglobin F and A_2 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 TSKgel G11 β-Thal. is 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 (β4), HbBart's (γ4) 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, HbA_2 (α2δ2) and HbF (α2γ2) 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 HbA_2. 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 HbA_2 (%) 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 column package and package components for any signs of damage before use. If any damages are visible, contact your local Tosoh sales representative.

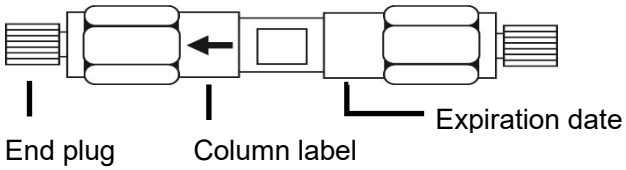
Confirm that the following two documents are included in the package.

- Instructions For Use 1 copy
- TSKgel Inspection Report 1 copy

5. Material Provided

Catalogue No.	Description	Package content
0023504	TSKgel G11 β-Thal.	1 piece

The TSKgel G11 β-Thal. is a pre-packed column with cation exchange resin. The names of the various parts of the column are shown below.



＜Illustration of TSKgel G11 β-Thal. column＞

6. Materials Required but Not Provided

The following materials are required to perform HbF and HbA_2 analysis using the HLC-723G11 β-Thalassemia Analysis Mode. They are available separately from Tosoh Corporation.

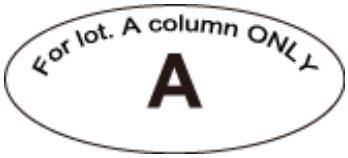
	Catalogue No.
G11 F&A2 Calibrator Set (*)	0023508
F&A2 Calibrator Set 2 (*)	0023550
G11 F&A2 Control Set	0023509
G11 β-Thalassemia Elution Buffer No. 1 (S)	0023505
G11 β-Thalassemia Elution Buffer No. 2 (S)	0023506
G11 β-Thalassemia Elution Buffer No. 3 (S)	0023507
HSi Hemolysis & Wash Solution (L)	0018431
HSi Hemolysis & Wash Solution (LL)	0019550

(*) 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 TSKgel G11 β-Thal. is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
2) The TSKgel G11 β-Thal. is designed exclusively for use in combination with the HLC-723G11 analyzer system, G11 β-Thalassemia Elution Buffers and HSi Hemolysis & Wash Solution indicated below, never in any other combination.
   - Tosoh Automated Glycohemoglobin Analyzer HLC-723G11
   - G11 β-Thalassemia Elution Buffer (No. 1, 2 and 3 (S))
   - HSi Hemolysis & Wash Solution (L) or (LL)
3) Do not use this product beyond the expiration date.
4) This Instructions For Use (IFU) must be read combined with the Operator's Manual of the HLC-723G11 β-Thalassemia Analysis Mode.
5) Carefully read the instructions contained in this IFU and those in the IFU provided with the G11 β-Thalassemia Elution Buffers.
6) The used column has been in contact with blood samples. Wear protective clothing (glasses, gloves, mask, etc.) and take sufficient care to prevent potential infection during installation and handling.
7) After replacing the column, be sure to assay three dummy samples to check the chromatogram results. Then calibrate the analyzer system.
8) Always use the TSKgel G11 β-Thal. in combination with the G11 β-Thalassemia Elution Buffers 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 column lot number, as shown below.



9) Care must be taken to ensure that the Elution Buffers are delivered in a column only in the direction indicated by the arrow on the column label.
10) In case the column is not used for more than one week, remove the column from the analyzer, reattach its end plugs to the column to protect it from drying out and store in a cool and dark place between 4 and 15 °C.
11) Please handle the column with care. Do not drop or give a shock to the column.
12) If the pressure is more than 4 MPa higher than the pressure which is indicated on the TSKgel Inspection Report of the column, replace the filter. If the pressure still does not drop, please contact your local Tosoh representative.
13) If you use the Lot management function on the HLC-723G11, please enter the barcode

information printed on the box label. Please refer to the Operator's Manual of the HLC-723G11 β-Thalassemia Analysis Mode for detailed procedure.

14) For safe waste disposal, it is recommended that each laboratory complies with established laboratory procedures and local, state and federal regulations.
15) Patient samples (clinical specimens) must always be considered as potentially infectious and should be handled using established laboratory procedures and/or institutional guidelines.
16) 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.
17) 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

Before opened, The TSKgel G11 β-Thal. is stable until the expiration date when stored at 4 to 15 °C. The expiration date is indicated on the product box and column label.
The product remains stable even after opened until the expiration date when stored at 4 to 15 °C with the end plugs in place.

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 G11 β-Thalassemia Elution Buffers, 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. Reagent preparation

Set the following reagents (Buffers) appropriately to the analyzer. These reagents are provided ready for use.

- G11 β-Thalassemia Elution Buffer (No. 1 (S), 2 (S) and 3 (S))
- HSi Hemolysis & Wash Solution (L) or (LL)

II. Column installation

1) Take the column from out of its box and let it return to room temperature before use.
2) Remove the end plugs from the both ends of the column. Keep the plugs in case the

column is separately stored after being de-installed from the analyzer.

3) Confirm that the analyzer is in STAND-BY state (a “STAND-BY” is displayed on the Main screen (First screen)) without running Buffers. If it is not in STAND-BY state, wait for the ongoing analysis to end and a “STAND-BY” to be displayed, or press the STOP key to stop the ongoing analysis.
4) Open the column oven and remove the used column and replace by the new column.

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 HbA_2. 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

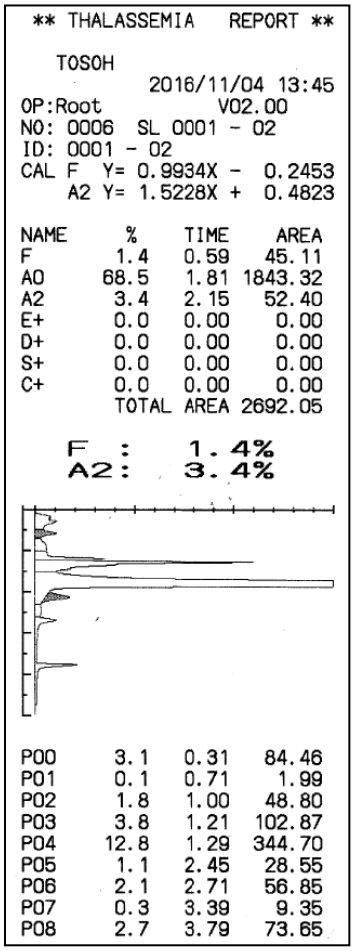
In order to monitor and evaluate the precision and analytical performance, it is recommended that at least two levels of controls be run at least once per day.

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).



** THALASSEMIA REPORT **

TOSOH

2016/11/04 13:45

OP:Root V02.00

NO: 0006 SL 0001 - 02

ID: 0001 - 02

CAL F Y= 0.9934X - 0.2453

A2 Y= 1.5228X + 0.4823

NAME	%	TIME	AREA
F	1.4	0.59	45.11
A0	68.5	1.81	1843.32
A2	3.4	2.15	52.40
E+	0.0	0.00	0.00
D+	0.0	0.00	0.00
S+	0.0	0.00	0.00
C+	0.0	0.00	0.00
	TOTAL AREA		2692.05

F : 1.4%

A2: 3.4%

P00	3.1	0.31	84.46
P01	0.1	0.71	1.99
P02	1.8	1.00	48.80
P03	3.8	1.21	102.87
P04	12.8	1.29	344.70
P05	1.1	2.45	28.55
P06	2.1	2.71	56.85
P07	0.3	3.39	9.35
P08	2.7	3.79	73.65

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 HbA_2 values should not be reported.

High concentrations of hemoglobin may cause the Total Area of the chromatogram to be > 5000 in which HbF and HbA_2 values should not be reported.

2) Measuring Range

The measuring range of HbF is from 0.3 % to 50.0 % and HbA_2 is from 1.8 % to 9.9 %.

13. Expected Values

Reference Range (β-Thalassemia trait):

$HbA_2 \geqq 3.5\%$

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 HbA_2 (%) 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:

Carryover (%) = (Total area of the blank sample) / (Total area of the sample) × 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 HbA_2 (%) 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 HbA_2 (%).

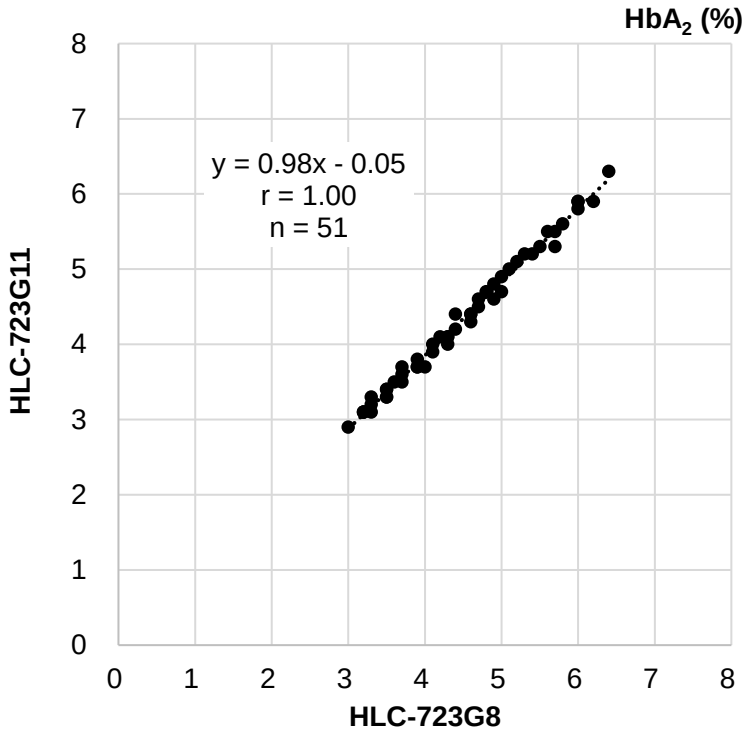
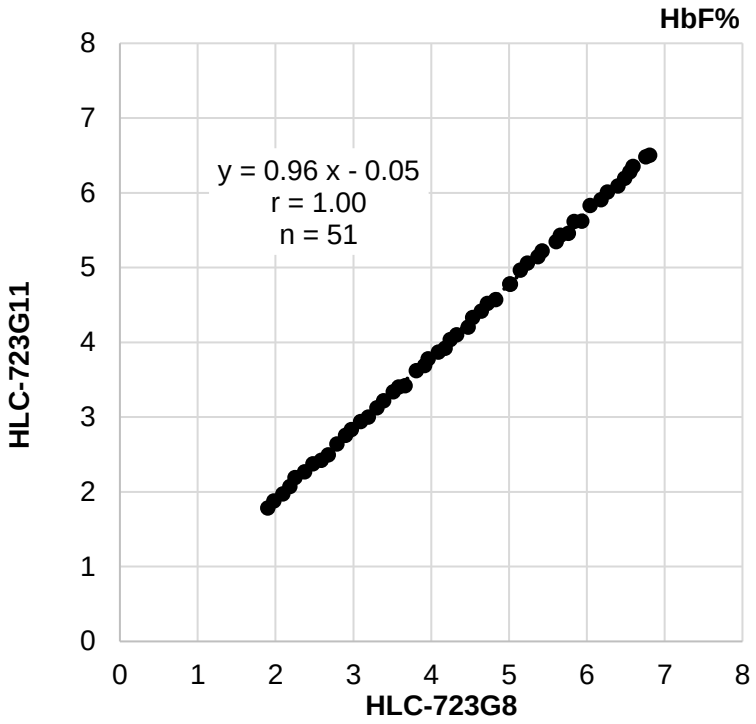


Fig. 2 Method comparison study between HLC-723G11 and HLC-723G8 on HbF (%).



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.

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

HbA_2

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 HbA_2 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 HbA_2, and HbF value and HbA_2 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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