

Tosoh Automated Glycohemoglobin Analyzer HLC-723®G11

Instructions For Use

## **F&A2 Calibrator Set 2**



**TOSOH**

**TOSOH CORPORATION**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
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| <b>hu</b> A Használati utasítás több nyelven elérhető webszájlunkon: <a href="http://www.tosohbioscience.eu">www.tosohbioscience.eu</a> , a "Service & Support" (Szolgáltatás és Támogatás) szekció alatt. Nyomtatott változat igényelhető faxon a +32 13 66 47 49-es telefonszámon vagy e-mailben: <a href="mailto:info.raqa.eu@tosoh.com">info.raqa.eu@tosoh.com</a> . Aktuális Változat: FA2CAL2-020722<br> Ez a termék emberi vagy állati forrásanyagokat tartalmaz, ezért lehetségesen fertőzőként kell kezelni.                                                      | <b>tr</b> Bir çok dilde Kullanma Talimatları'na, <a href="http://www.tosohbioscience.eu">www.tosohbioscience.eu</a> adresindeki web sitemizin, "Service & Support" bölümünden ulaşabilirsiniz. Basılı sürümünü +32 13 66 47 49 numaralı faks ya da <a href="mailto:info.raqa.eu@tosoh.com">info.raqa.eu@tosoh.com</a> e-posta adresinden isteyebilirsiniz. Mevcut Sürüm: FA2CAL2-020722<br> Bu ürün, insan ya da hayvan kaynaklı maddeler içerebilir ve enfeksiyon olasılığı bulunduğundan gözetimle bulundurulacak ele alınmalıdır.                         |

## 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



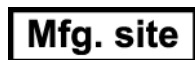
Batch code / Lot number



Temperature limitation



Net volume  
(after reconstitution for  
lyophilized material)



Actual manufacturing site



Date of manufacture



For specified  
column lot only



Imported and Marketed  
in India by



a carrier containing unique  
device identifier information

## 1. Intended Use

The F&A2 Calibrator Set 2 is intended for *IN VITRO* DIAGNOSTIC USE for the calibration of the Tosoh Automated Glycohemoglobin Analyzer HLC-723G11  $\beta$ -Thalassemia Analysis Mode.

The F&A2 Calibrator Set 2 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
- Barcode Sheets 1 copy

## 3. Material Provided

| Catalogue No. | Description           | Package content                                                        |
|---------------|-----------------------|------------------------------------------------------------------------|
| 0023550       | F&A2 Calibrator Set 2 | Level-1 : 2 vials $\times$ 0.2 mL<br>Level-2 : 2 vials $\times$ 0.2 mL |

The F&A2 Calibrator Set 2 is prepared from human blood cells and then lyophilized. The total hemoglobin concentration is about 8 g/dL after reconstitution.

Assay mode :  $\beta$ -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 HbA<sub>2</sub> analysis using the HLC-723G11  $\beta$ -Thalassemia Analysis Mode. They are available separately from Tosoh Corporation.

|                                                  | Catalogue No. |
|--------------------------------------------------|---------------|
| G11® F&A2 Control Set                            | 0023509       |
| TSKgel G11 $\beta$ -Thal.                        | 0023504       |
| G11 $\beta$ -Thalassemia Elution Buffer No.1 (S) | 0023505       |
| G11 $\beta$ -Thalassemia Elution Buffer No.2 (S) | 0023506       |
| G11 $\beta$ -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 F&A2 Calibrator Set 2 is intended for *IN VITRO* DIAGNOSTIC USE ONLY.
- 2) This product is intended for use on Tosoh Automated Glycohemoglobin Analyzer HLC-723G11  $\beta$ -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) Use the F&A2 Calibrator Set 2 in combination with the TSKgel G11  $\beta$ -Thal. of the lot number specified by "For lot xx columns only" on the label of F&A2 Calibrator Set 2. The column lot number is indicated by a single uppercase alphabetical character (A, B, etc.) on the label of column box.

## 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 F&A2 Calibrator Set 2 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 0.7 to 3.5 % for HbF and 2.0 to 4.0 % HbA<sub>2</sub> and those of level-2 are 5.2 to 8.0 % for HbF and 4.8 to 7.5 % HbA<sub>2</sub>.

The specific values and the lot number of the calibrator are printed on the labels.

The assigned values of the calibrators have been standardized to WHO Reference Reagent (NIBSC code: 89/666) for HbA<sub>2</sub> values.

## 8. Procedure

Be sure to read the IFU included with the TSKgel G11  $\beta$ -Thal., G11  $\beta$ -Thalassemia Elution Buffer, G11 F&A2 Control Set and HSi Hemolysis & Wash Solution as well as the Operator's Manual of the HLC-723G11  $\beta$ -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 calibrator with distilled water by 51 times (10  $\mu$ L of the calibrator to 0.5 mL of distilled water) into the designated sample cups before performing assay.

### II. Calibration

The analyzer must be recalibrated every 30 days and after service maintenance, column replacement, and if control values assayed are out of range.

Each laboratory must monitor QC results to determine when to recalibrate. If the QC values are out of range, the system should be calibrated according to the procedures provided in the IFU.

The analyzer has a two-point automatic calibration function. Refer to the Operator's Manual of the HLC-723G11  $\beta$ -Thalassemia Analysis Mode for detailed procedures.

- 1) Verify whether TSKgel G11  $\beta$ -Thal. is set on the analyzer.
- 2) Verify the volume of G11  $\beta$ -Thalassemia Elution Buffers and HSi Hemolysis & Wash Solution. Replace if necessary.
- 3) Check the analyzer status.
  - If the analyzer is off, press the POWER key which is located on the right side of the control panel. The G11 begins its warming up. After warming up, the status becomes STAND-BY automatically.
  - If the analyzer is in STAND-BY status, proceed to step 4.
- 4) Press the CALIB key on the Main screen (first screen).
- 5) The key is highlighted and the calibrator's assigned value input screen is displayed.
- 6) Press CALIB\_1 (F) and enter the assigned value for HbF of level-1. Press Enter to input the value.
- 7) Enter the assigned value for HbF of level-2 into CALIB\_2 (F), HbA<sub>2</sub> of level 1 into CALIB\_1 (A2) and level 2 into CALIB\_2 (A2) in the same way as for CALIB\_1 (F).
- 8) Confirm that the correct values are entered.
- 9) Close the list.
- 10) Place Calibrators level-1 and level-2 on position No. 1 and No. 2 of the first rack.  
(NOTE: At least 500  $\mu$ L of each diluted calibrator is required for calibration.)
- 11) Press the START key to start automatic calibration.

The Calibrator level-1 will be automatically measured three times and Calibrator level-2 will be automatically measured twice to

calculate calibration coefficients "a" and "b" for HbF and HbA<sub>2</sub>. These calibration coefficients will be used to calculate HbF and HbA<sub>2</sub> values.

Note that a calibration error occurs in the following cases:

- If the difference in results between the replicates for HbF or HbA<sub>2</sub> is more than 0.3 %.
- The HbF% result differs from its assigned value by 50 % or more.
- The HbA<sub>2</sub>% result differs from its assigned value by 50 % or more.

Refer to the Operator's Manual of the HLC-723G11  $\beta$ -Thalassemia Analysis Mode for detailed description.

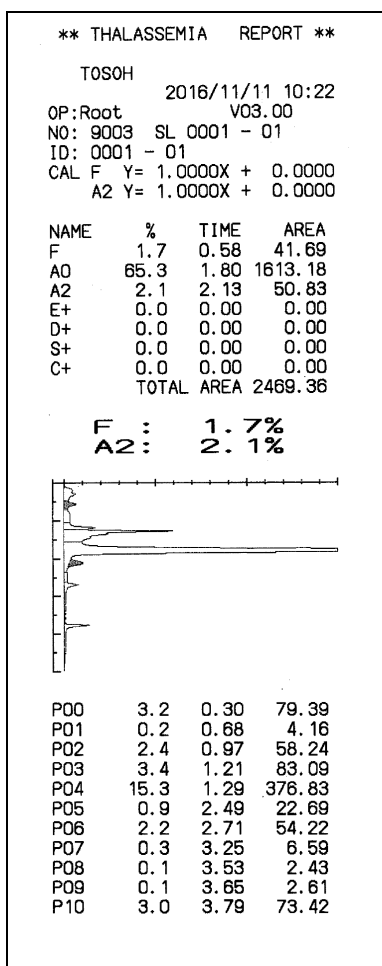
### F&A2 Calibrator Set 2 Barcode Sheets

Calibrator's assigned value, lot number and expiry date are automatically entered by scanning Barcode Sheets with and optional handy barcode scanner connected to the HLC-723G11.

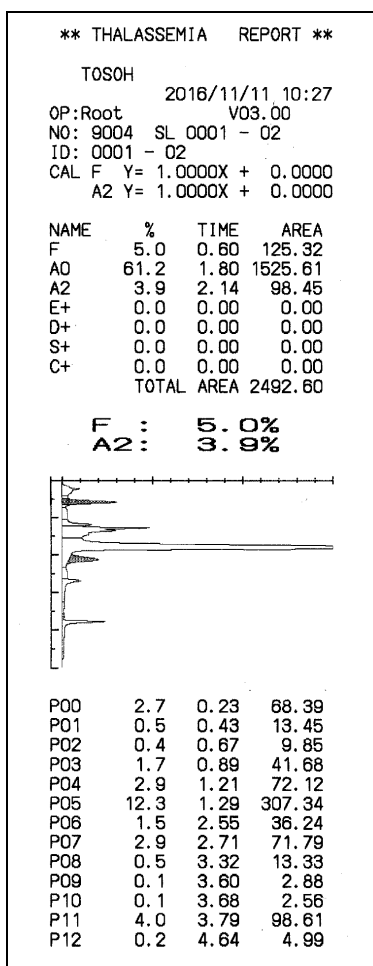
Refer to the HLC-723G11 Operator's Manual for detailed description.

< A report output from the HLC-723G11 >

Level-1



Level-2





TOSOH



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