

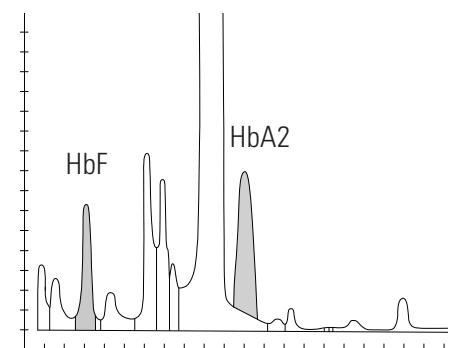
β -Thalassemia Diagnosis for a Diverse Population



Tosoh G11 HPLC Analyzer
G11 is not available in the US

HLC-723 *G11* β -Thal Mode

Gold Standard HPLC technology provides excellent chromatographic resolution for accurate HbF and HbA2 quantitation using Tosoh's proprietary HPLC column.



HbF and HbA2 results in 5 minutes



HbA2 Inter- and Intra-assay CV's of <2.0%



Ability to detect high concentrations of HbF (~ up to 50%)

TOSOH BIOSCIENCE



Performance Data

Sample Chromatogram

Normal

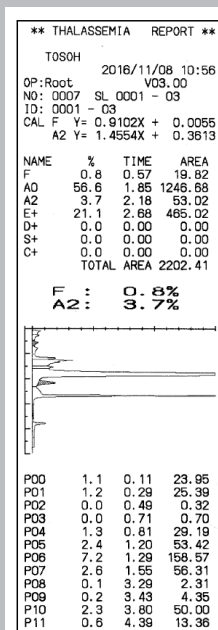
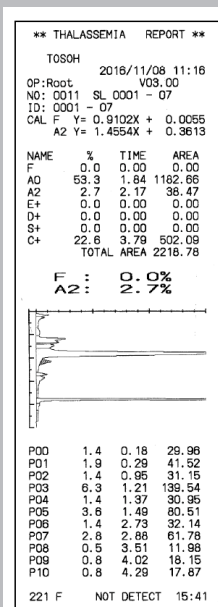
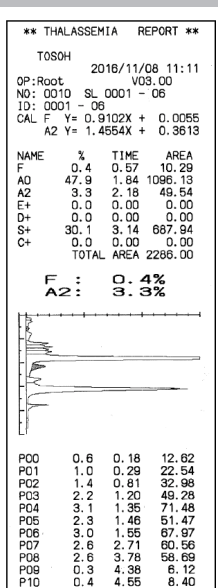
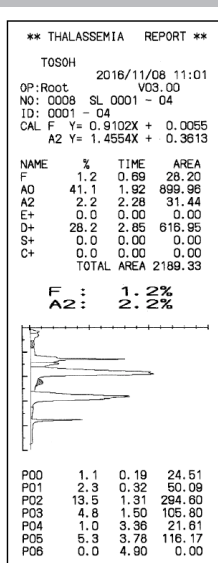
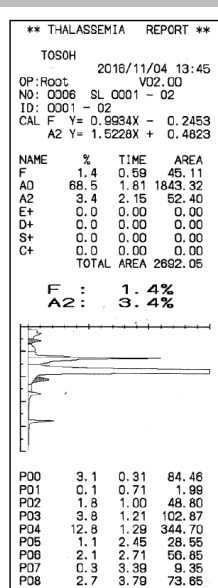
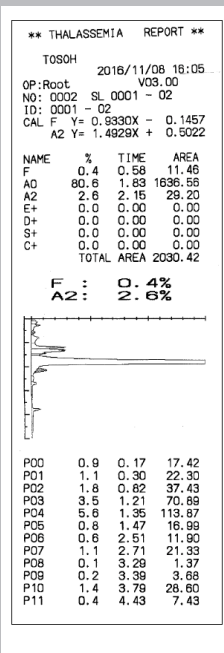
β -Thal Trait

AD

AS

AC

AE



High Accuracy

Intra-assay Precision (n=20)

	HbF		HbA2	
	Level 1	Level 2	Level 1	Level 2
Mean (%)	1.5	5.12	3.19	6.48
SD (%)	0	0.04	0.03	0.04
CV%	0	0.78	0.94	0.62

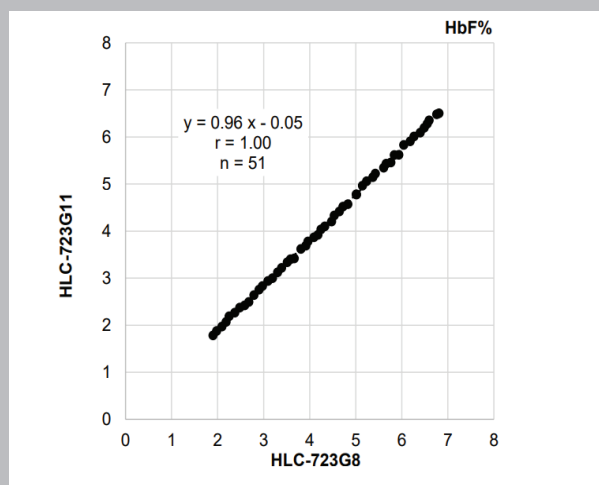
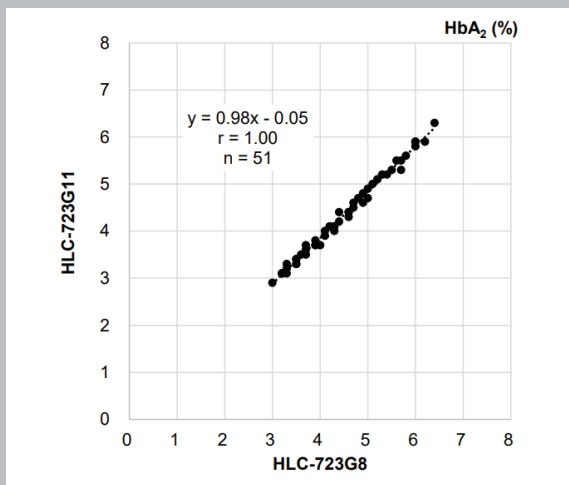
Inter-assay Precision (n=20)

	HbF		HbA2	
	Level 1	Level 2	Level 1	Level 2
Mean (%)	1.51	4.69	3.17	5.78
SD (%)	0.02	0.03	0.06	0.11
CV%	1.32	0.64	1.89	1.9

This data was produced using Tosoh F & A2 controls

Consistency

Correlation between G8 and G11 for patient samples with HbA2 and HbF



Tosoh G11 β -Thalassemia Screening and Diagnosis

β -Thalassemia is a hereditary disorder, that is characterized by reduced or missing production of hemoglobin β -chains, which is compensated by overproduction of γ -chains and δ -chains. The G11 quantitates the HbA2 ($\alpha\delta\delta$) and HbF ($\alpha\gamma\gamma$) that are elevated in β -Thalassemia.

Tosoh's value proposition:

- Over 35 years of experience in HPLC
- Proprietary non-porous cation exchange HPLC column offers excellent quality separation of hemoglobin components based on differences in ionic charge
- Small footprint and easy to use analyzers with very low maintenance
- Ability connect with third party laboratory automation trackline



Assay

Speed

- HbF and HbA2 results in 5 minutes

Precision

- HbA2 and HbF Inter- and Intra-assay CV's of <2.0%

Result Reliability

- Excellent chromatographic resolution
- Gold standard HPLC Technology
- Reportability of HbA2 and HbF in the presence of heterozygous HbS, HbC, HbD and HbE
- Ability to detect high concentrations of HbF (~ up to 50%)

Analyzer

Compact Bench Top Size

- Small Footprint saves space in laboratory
- Fit for all laboratory types and sizes

Simple Operation

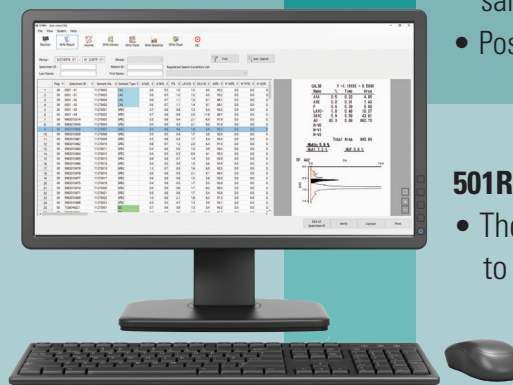
- One touch automated start-up and stop function
- Column change in seconds
- User Friendly
- Low maintenance

Workflow Enhancements

- Reagent lot traceability (input Lot # and expiration date using optional handheld barcode reader)
- Up to 5 user Log-ins with different priority levels
- Bidirectional LIS interface
- Automated cap piercing, closed primary tube sampling
- Positive sample ID

501RP+ Reporting Middleware

- The advanced middleware is a powerful tool to assist in result management



SPECIFICATIONS

Analytes	HbF, HbA2
Applicable samples	Whole blood and diluted samples
Assay principle	Ion exchange high performance liquid chromatography
Detection method	2-wavelength absorbance (detection wavelength: 415 nm)
Processing throughput	5 min/sample

Main unit

Column connection	Finger-tight-type
Sampling volume	6 µL for whole blood and 150 µL for diluted samples
Sample aspiration	by Nozzle
Pump unit	Single plunger pump

System control / Data processing

Display	320 × 240 dot matrix color LCD
Input	Pressure-sensitive touch panel / operation keys
Output	Thermal printer
Storage	USB stick
Data processing unit	RS-232C serial communication port (bi-directional) Data storage by internal memory (for up to 800 samples) Recalculation (reprinting) of achieved result Automatic startup by timer Error flag function for abnormal results
Calibration	2-point calibration by calibrators
Data extraction	Extract by date or sample type (max 800 samples)
Control for quality control	Distinguished by barcode ID (max 4 controls)

Sampling Unit

Sample loading capacity	90 samples or 290 samples
Sample rack	10 primary tubes or cups per rack
Sample dilution	Dilution by Hemolysis & Wash Solution in the dilution port
Sample tubes or cups	12 - 15 mm diameter × 75 - 100 mm primary tubes / Sample cups
Sample ID recognition	Barcode with maximum of 20 digits
Barcode specifications	NW-7 (Codabar), CODE39, ITF and CODE128 (initial setting), or JAN (UPC/EAN), Industrial 2 of 5 and COOP 2 of 5 (requires setting change)
Temperature	15 - 30 °C

Power requirement AC100 - 240 V, 50 / 60 Hz, 200 VA

Dimensions / weight 90SL model: 530 (W) × 515 (D) × 482 (H) mm / 37 kg
290SL model: 1120 (W) × 530 (D) × 482 (H) mm / 54 kg

PART NUMBERS/DESCRIPTION

0023850	HLC-723G11 (Main Unit)
0023851	HLC-723G11LA (Main Unit) *
0023852	G11-90SL (90 Sample Loader)
0023853	G11-290SL (290 Sample Loader)
* Possible to connect with Laboratory Automation Belt line	

B-Thalassemia Analysis Mode

0023504	TSKgel G11 β-Thal. (Analysis Column)
0023505	G11 β-Thalassemia Elution Buffer No. 1 (S)
0023506	G11 β-Thalassemia Elution Buffer No. 2 (S)
0023507	G11 β-Thalassemia Elution Buffer No. 3 (S)
0018431US	HSi Hemolysis & Wash Solution (L)
0023550	F&A2 Calibrator Set 2
0023509	G11 F&A2 Control Set



Analysis Column



Elution Buffers and Hemolysis & Wash Solutions



G11 F&A2 Control Set



G11 F&A2 Calibrator Set



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