

β -Thalassemia Diagnosis for a Diverse Population

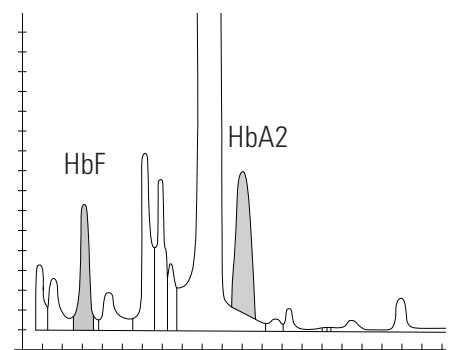


HLC-723 *G11* β -Thal Mode



Tosoh G11 HPLC Analyzer
G11 is not available in the US

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

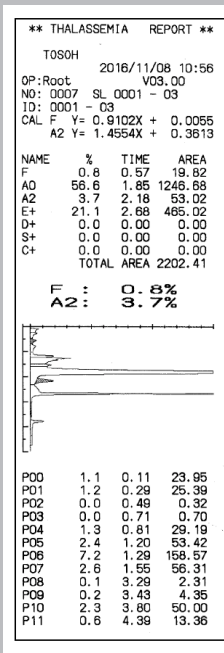
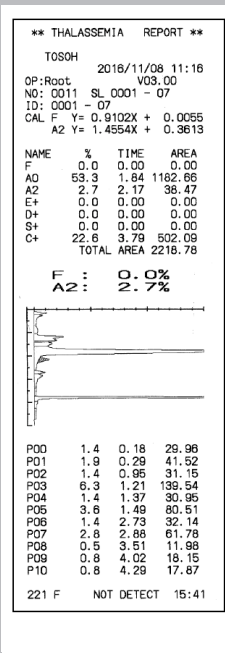
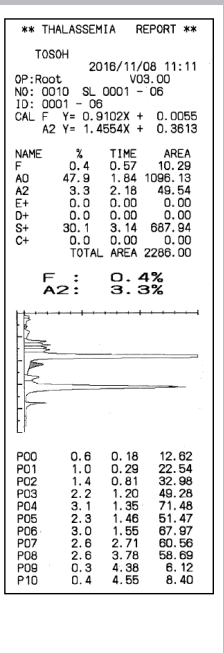
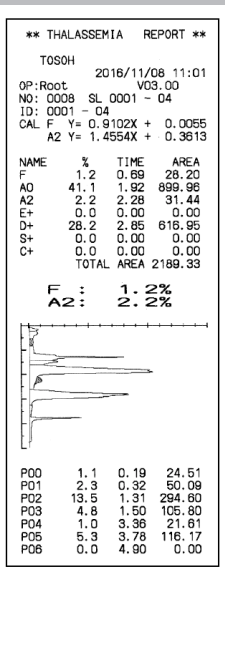
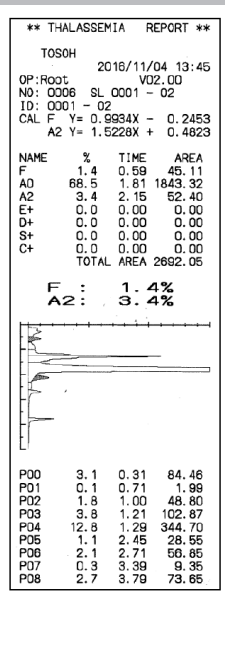
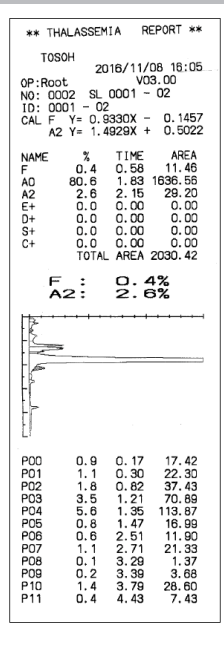
β -Thal Trait

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

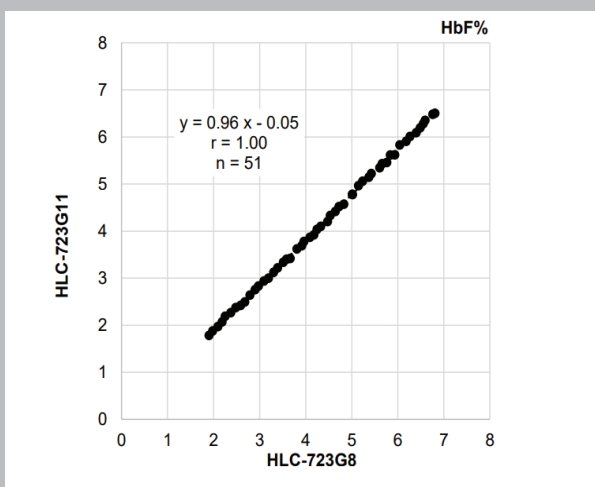
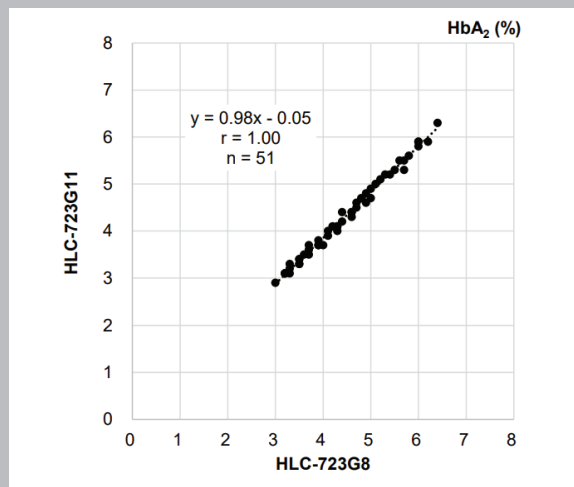
Inter-assay Precision (n=20)

	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 ($\alpha_2\delta_2$) and HbF ($\alpha_2\gamma_2$) 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

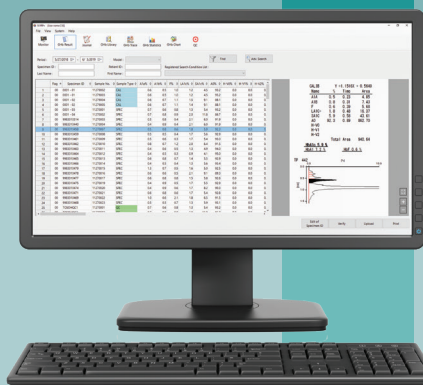
- One touch automated start-up and stop function
- Column change in seconds
- User Friendly
- Low maintenance

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)
018431US	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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