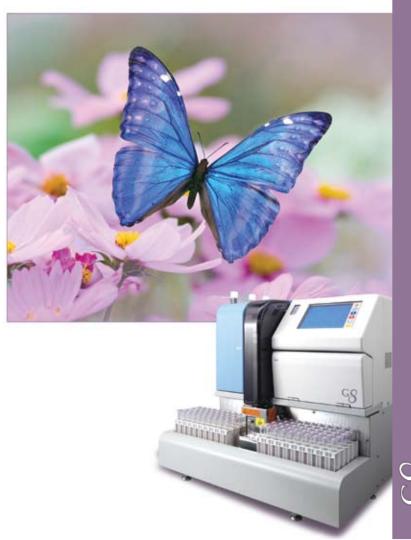


GS HPLC ANALYZER

Gold Standard Accuracy by Ion-Exchange HbA1c



PRECISE CHROMATOGRAPHIC DETAIL

TOSOH BIOSCIENCE, INC.



GS HPLC ANALYZER

HbA1c analysis in 1.6 minutes

Direct determination of stable HbA1c

Less than 2% CVs

Compact footprint - 21"w x 20"d x 19"h

Simple touch-screen operation

Automated daily maintenance

Flexible tube sizes

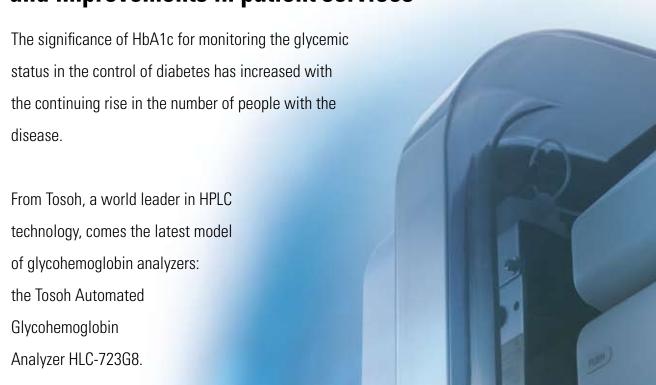




Evolution at its best... Faster, Easier, Smaller



Contributing to team-based diabetes care and improvements in patient services



Providing fast HbA1c results, with CVs of less than 2%, the G8 is the perfect solution for improving diabetic patient care.

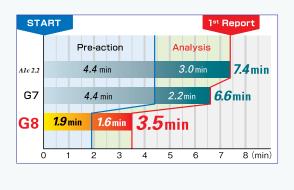




Alternative/STAT Position

Fast

The time to first result is 3.5 minutes. Analysis time is only 1.6 minutes.



Simple Operation

- Touch screen
- Direct primary tube sampling/cap-piercing
- Automatic start-up
- No sample pre-treatment



Main screen (first screen)

Feature Enhancements

90 Sample Loader

A new calibration check function utilizes a pop-up window to display standard values during calibration. Features also include a flag check function with user-selectable levels, buffer monitoring and an automatic prime function. Tosoh designed G8 functions from the user perspective, enhancing overall safety and convenience of operation.



Standard value input screen

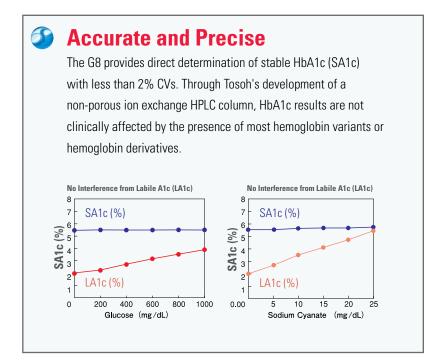


Main screen (second screen)

Gold Standard Technology

Ion-exchange HPLC is the gold standard for HbA1c measurement. Ion-exchange HPLC was used in the DCCT* study undertaken in the United States.

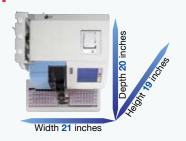
*Diabetes Control and Complications Trial





Compact Benchtop Size

The instrument has a footprint of ~ 20 square inches and weighs only 75 lbs. The G8's compact size makes it an easy fit into any location.





Flexible

A variety of different sized tubes can be loaded continuously. The operator can also run primary and secondary tubes in the same rack. The G8 easily adapts to changing laboratory workloads by offering a choice of either a 90 sample loader or a 290 sample loader. With the optional LA model linked via a sample belt line, no workload is too large.

SPECIFICATIONS

Analytes HbA1c (SA1c), HbF, HbA1 (Total A1)

Principle lon-exchange high performance liquid chromatography

Visible two-wavelength absorption

Whole blood or diluted blood (Preserved with EDTA) Sample requirement

Sampling volume Whole blood: 4 µL Diluted blood: 80 uL Throughput 1.6 minutes per sample

Data storage On-board memory: up to 800 samples

Main unit

Sampling Cap-piercing of primary sample tubes Whole blood Automatic dilution by Hemolysis and Wash solution in the dilution port Thermomodule in aluminum block Column oven

Colulmn connection Finger-tight type LED colorimetric detector Detector unit

Sample loading units

Sample loading capacity G8-90SL: 90 samples plus one STAT sample

G8-290SL: 290 samples plus one STAT sample

Sample holding 10 samples/rack

Sample vial 12-15 mm x 75-100 mm primary tubes and Tosoh vials

Barcode specifications NW-7, CODE39, ITF, CODE128, JAN, COOP 2 of 5, Industrial 2 of 5

System control/Data processing

Display & Input Liquid crystal display touch panel

Thermal printer (roll paper), SmartMedia or LIS Output

Communication RS-232C standard serial (bi-directional)

Operating temperature 15 - 30 ° C

AC 100 - 240 V, 50/60 Hz, 180 VA Power requirement

Dimensions/Weight 90SL model:

W 21" (530 mm) x D 20" (515 mm) x H 19" (482 mm)

75 lbs (34.0 kg) 290SL model

W 44" (1120 mm) x D 21" (530 mm) x H 19" (482 mm)

114 lbs (51.5 kg)

PART NUMBERS/DESCRIPTION

021560 HLC-723G8 (Main Unit) 021561 G8-90SL (90 Sample Loader) G8-290SL (290 Sample Loader) 021562 021955 TSKgel G8 Variant HSi (Analysis Column)

G8 Variant Elution Buffer HSi No. 1 (S) 021956 021957 G8 Variant Elution Buffer HSi No. 2 (S) 021858 G8 Variant Elution Buffer HSi No. 3 (S) 018431US HSi Hemolysis & Wash Solution (L)

Hemoglobin A1c Calibrator Set 018767 Hemoglobin A1c Control 992133



G8 90 Sample Loader





Tosoh Bioscience, Inc. 6000 Shoreline Court, Suite 101 South San Francisco, CA 94080 Tel: (800) 248-6764 Fax: (650) 615-0415 www.tosohbioscience.us

Analysis Column



Elution Buffers (Variant Analysis Mode) and Hemolysis & Wash Solutions



HbA1c Calibrator Set

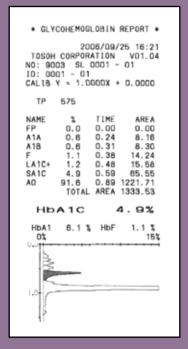


HbA1c Control

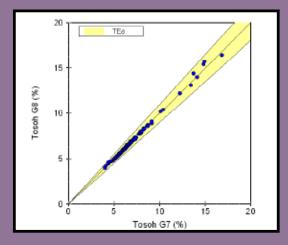


PERFORMANCE DATA

SAMPLE CHROMATOGRAM



SA1c% CORRELATION



REPRODUCIBILITY

INTRA-ASSAY PRECISION

	Number of Replicates	Mean (%HbA1c)	Standard Deviation	Coefficient of Variation (%)
Whole blood (Low)	20	5.07	0.05	0.93
Whole blood (Medium)	20	7.39	0.03	0.42
Whole Blood (High)	20	13.54	0.06	0.44

INITED ACCAY DECICION

INTER-ASSAT I REGISTOR						
Number of Replicates	Mean (%HbA1c)	Standard Deviation	Coefficient of Variation (%)			
20	5.01	0.03	0.61			
20	7.04	0.05	0.70			
20	12.18	0.04	0.36			
	Replicates 20 20	Replicates (%HbA1c) 20 5.01 20 7.04	Replicates (%HbA1c) Deviation 20 5.01 0.03 20 7.04 0.05			