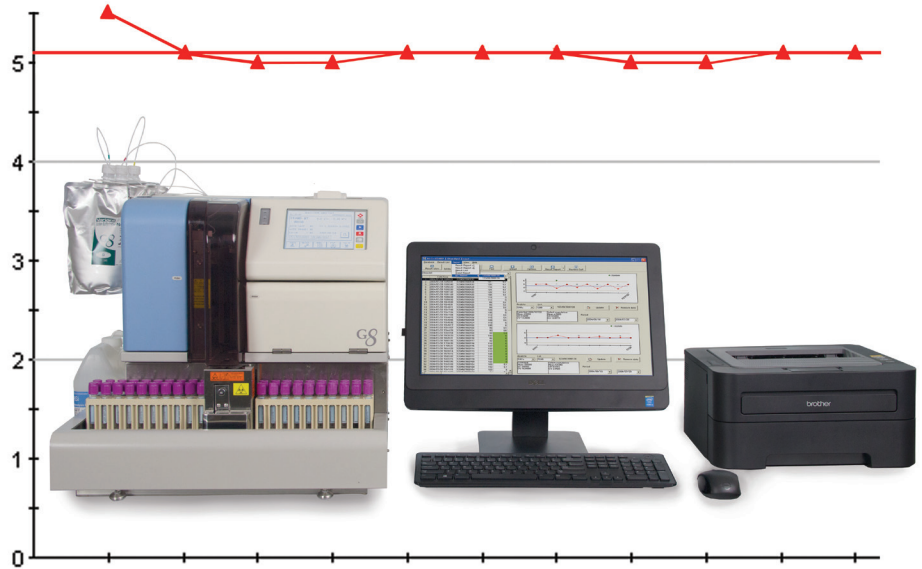




TOSOH

G8 HPLC ANALYZER

Gold Standard Accuracy by Ion-Exchange HbA1c



Precise Chromatographic Detail

FDA Cleared to Diagnose Diabetes

TOSOH BIOSCIENCE



TOSOH

G8 Features and Benefits

Trusted

- Gold Standard HPLC
- First HPLC Analyzer approved by the FDA to diagnose diabetes
- NGSP and IFCC Certified

Clinically Superior

- Directly measures stable and labile HbA1c
- Less than 2% CVs
- Flag level sophistication with increasing severity
- 20 customizable, user defined flags to assist with auto-verification

User Friendly, Flexible and Efficient

- Cap-piercing of primary tubes (1 mL minimum volume)
- Whole blood (50 uL minimum volume)
- Diluted samples (150 uL minimum volume)
- Various primary tube sizes 12-15 mm x 75-100 mm
- Batch or STAT mode
- Minimal maintenance
- Individual consumables – No kits
- 2500 injection column warranty
- Compact Footprint – 21" w x 20" d x 19" h
- Optional Reporting Software System for QC, result storage and multiple reporting options

Fast

- 1.6 minutes (96 seconds) per result
- 37 tests/hour throughput
- 3.5 minutes to first result from cold start
- 90 or 290 sample capacity with continuous loading



Tosoh G8 - The Gold Standard Accurate and Precise

HPLC Technology

High Performance Liquid Chromatography (HPLC) is considered the "Gold Standard" technology in the follow-up of the plasma glucose concentration of diabetic patients, via the measurement of HbA1c. Tosoh's G8 is the first HPLC analyzer cleared by the FDA to also diagnose diabetes.

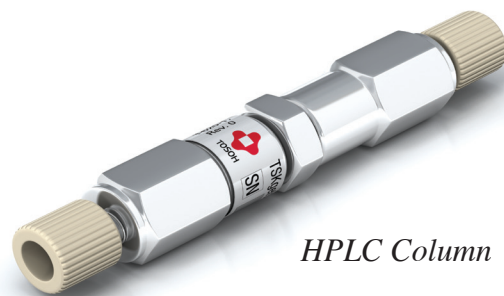
Through Tosoh's development of a non-porous ion-exchange column, HbA1c results are directly measured and not clinically affected by the presence of most hemoglobin variants or hemoglobin derivatives.

Direct Measurement vs. Calculation of HbA1c

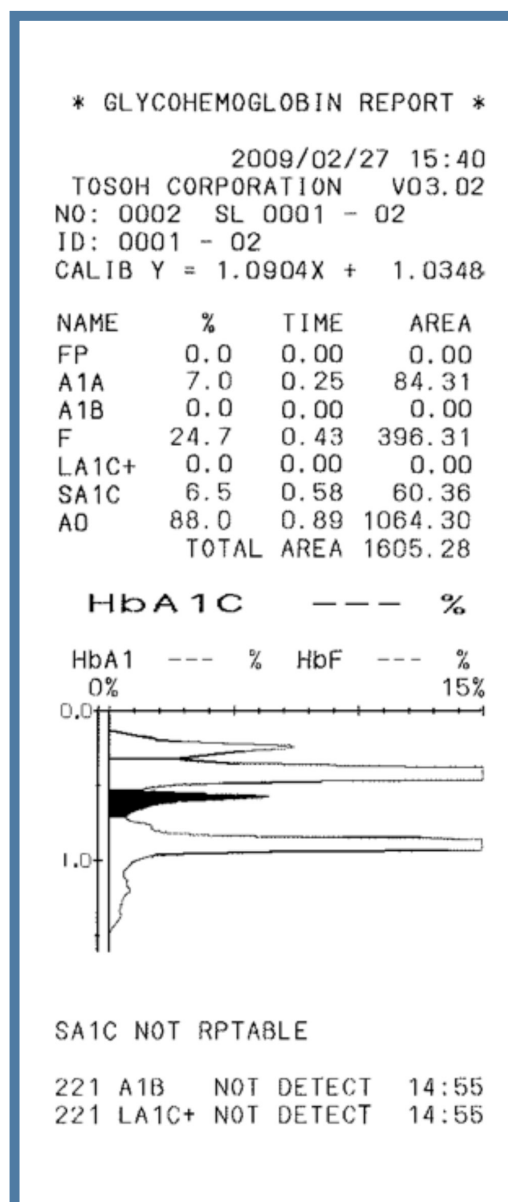
The Tosoh G8 directly measures HbA1c along with each individual hemoglobin fragment. Elevated fetal hemoglobin (HbF), which may cause erroneous measurement, occurs in approximately 7.5% of the diabetic population. The G8 separates and identifies HbA1c even in the presence of elevated HbF. As you can see from the chromatogram on the right, the user will be alerted if the HbF concentration is too high to report the HbA1c.

In contrast, other methods such as boronate affinity and immunoassay measure only total hemoglobin. A calculation is used to differentiate the HbA1c from the glycated hemoglobin variants and HbF rather than directly measure HbA1c.

The ability of the G8 to directly measure HbA1c and to identify HbF and other hemoglobin fragments is what truly gives confidence in the quality of the reported result.



HPLC Column

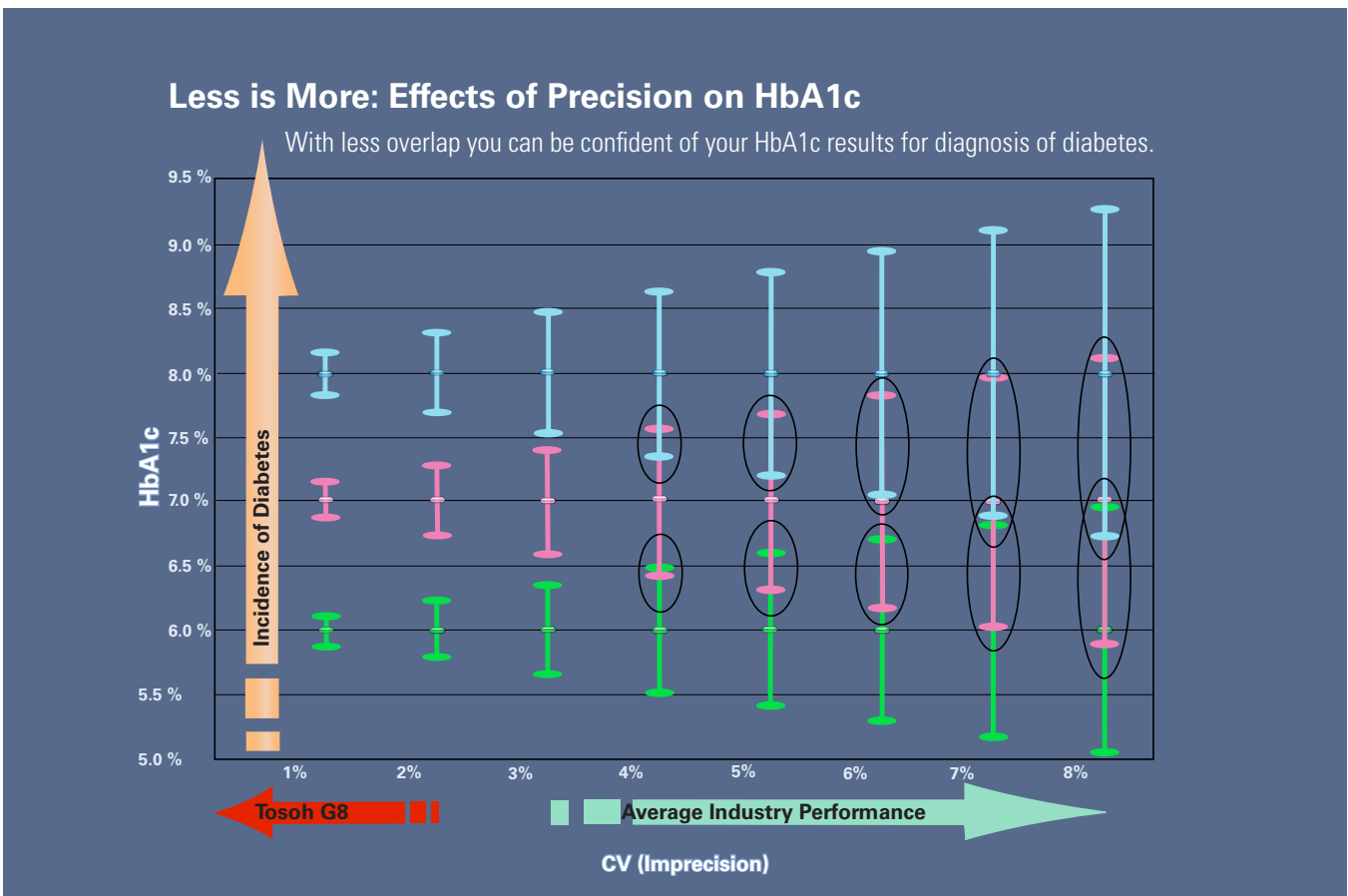
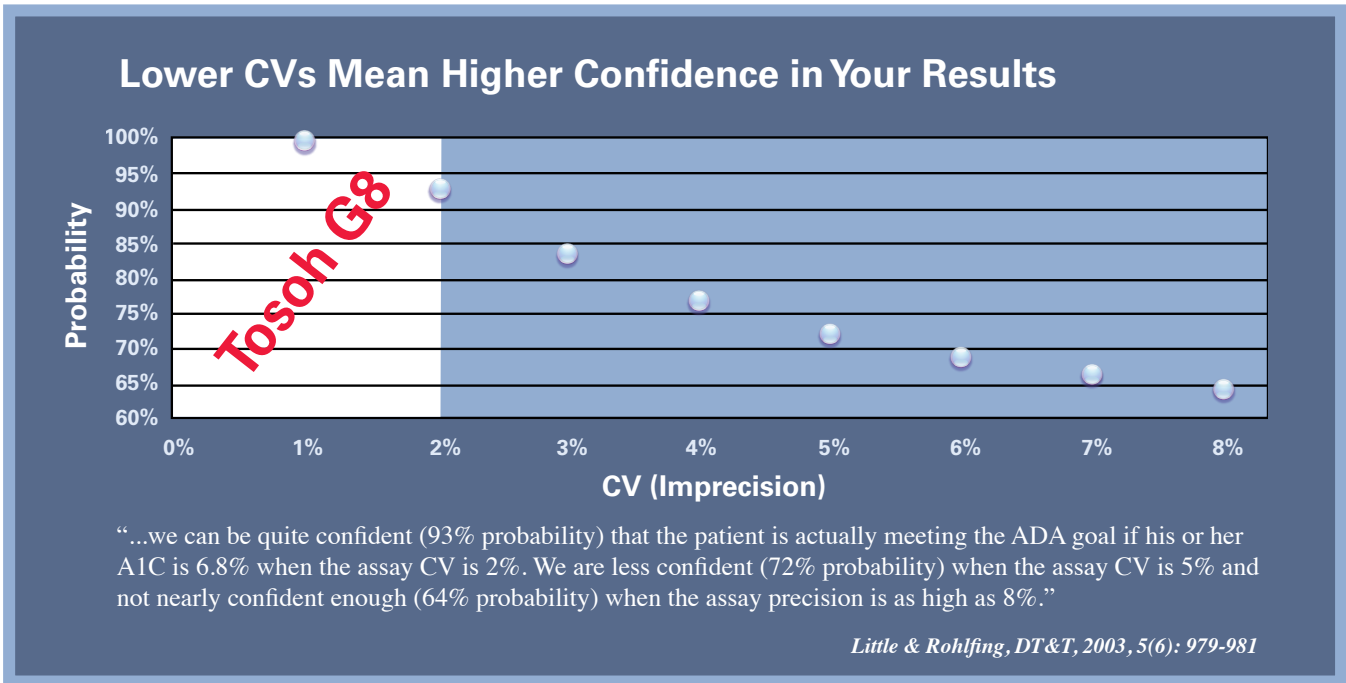


Chromatogram for patient with elevated HbF

Be Proud of Your Performance

Trust Tosoh

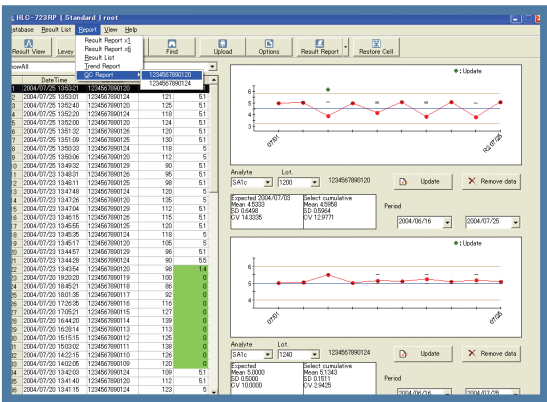
The G8 provides direct determination of stable HbA1c with less than 2% CVs. The G8's low CVs inspire confidence in the reliable quality of HbA1c results. As seen below, a small difference in CV can create a large gap in quality. With Tosoh you can trust your results.



On-Point and On-Time

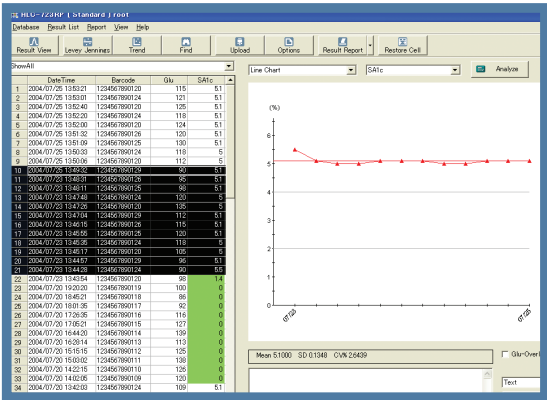
Reporting Software - Sophisticated Simplicity

The G8 Reporting Software highlights results flagged based upon the 20 user-defined parameters which are set-up in the G8 analyzer. This allows the user to quickly identify and accept all non-flagged results to assist with auto-verification.



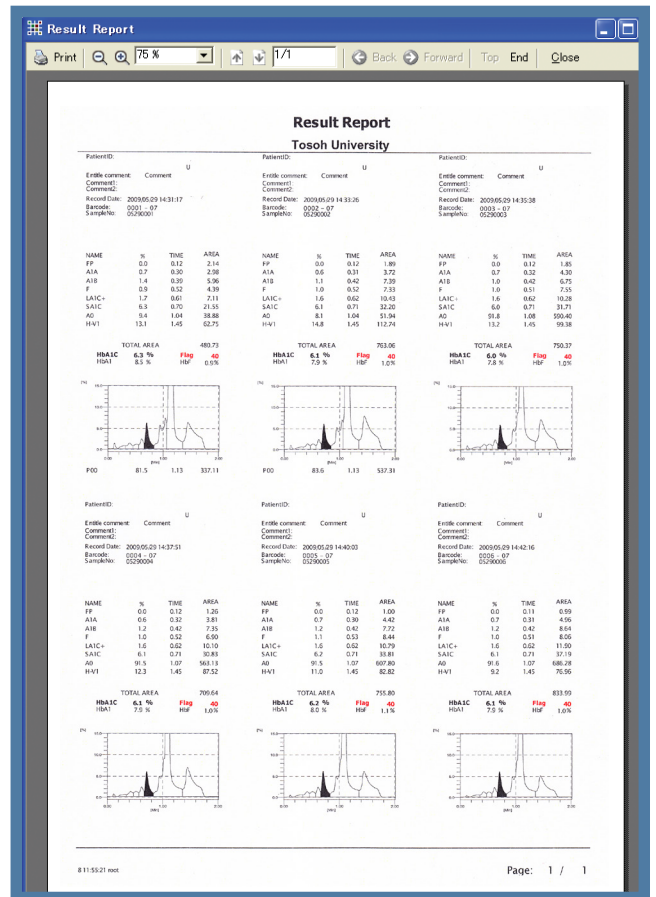
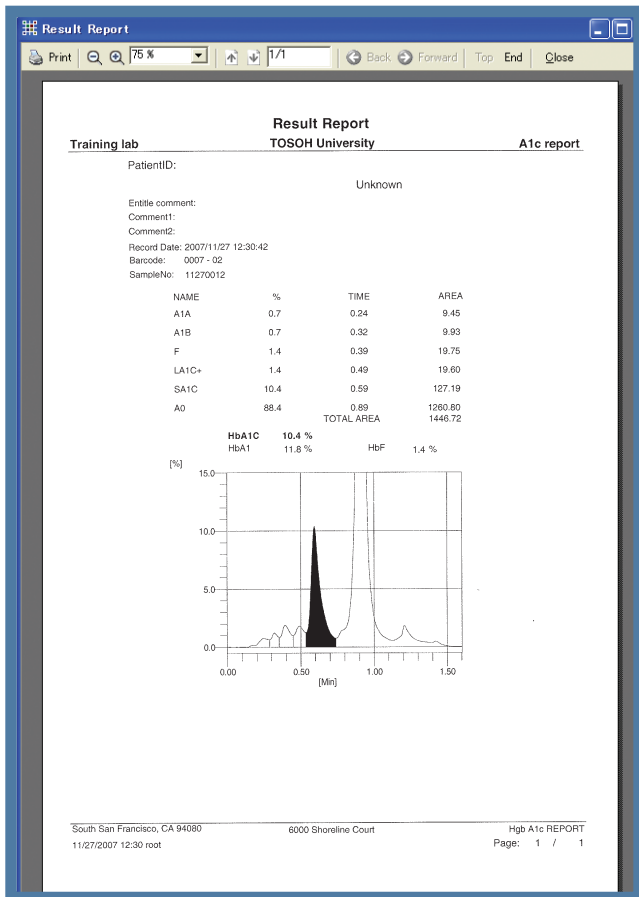
Levey-Jennings

Flagged results will be highlighted and these "abnormal" results can be investigated in real time via detailed chromatograms and patient-specific trend analysis.



Added features include customizable database management, flexible chartable reporting, result tracking by lot, Levy-Jennings and Westgard rules, inventory management and much more.

Trend



Result Report - 1 Chromatogram

Result Report - 6 Chromatogram

Specifications

Analytes	HbA1c (SA1c), HbF, HbA1 (Total A1)
Principle	Ion-exchange high performance liquid chromatography Visible two-wavelength absorption
Sample requirement	Whole blood or diluted blood (Preserved with EDTA)
Sampling volume	Whole blood: 4 µL Diluted blood: 80 µL
Throughput	1.6 minutes per sample
Data storage	On-board memory: up to 800 samples Unlimited storage with Reporting Software

Main unit

Sampling	Cap-piercing of primary sample tubes
Whole blood	Automatic dilution by Hemolysis and Wash solution in the dilution port
Column oven	Thermomodule in aluminum block
Column connection	Finger-tight type
Detector unit	LED colorimetric detector

Sample loading units

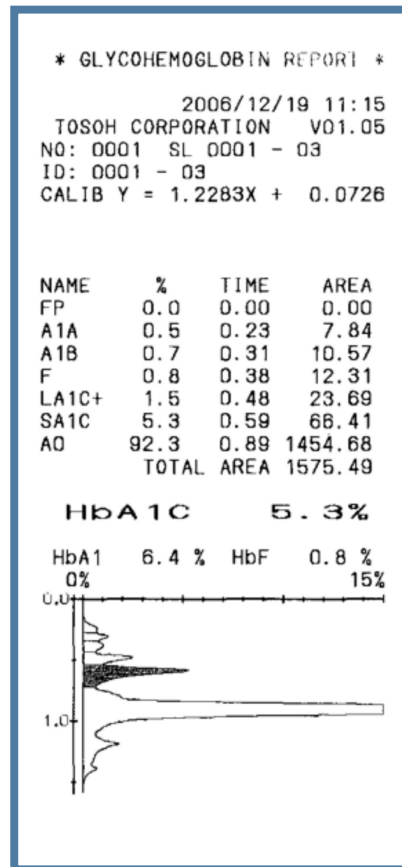
Sample loading capacity	G8-90SL: 90 samples plus one STAT sample G8-290SL: 290 samples plus one STAT sample
Sample holding	10 samples/rack
Sample specifications	12-15 mm x 75-100 mm primary tubes and Tosoh sample cups
Barcode specifications	NW-7, CODE39, ITF, CODE128, JAN, COOP 2 of 5, Industrial 2 of 5

System control/Data processing

Display & Input	Liquid crystal display touch panel
Output	Thermal printer (roll paper), SmartMedia or LIS
Communication	RS-232C standard serial (bi-directional)
Operating temperature	15 - 30 °C
Power requirement	AC 100 - 240 V, 50/60 Hz, 180 VA
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)

90SL Line Automation model available.

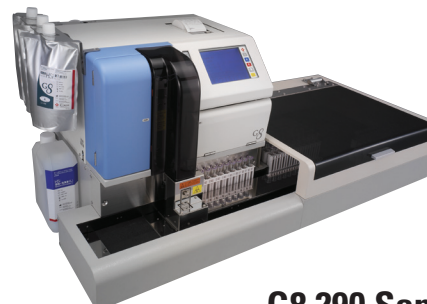
Please contact your local Tosoh representative for further information.



Chromatogram for non-diabetic patient sample



G8 90 Sample Loader



G8 290 Sample Loader



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