

Gold Standard Accuracy by Ion-Exchange HbA1c



Precise Chromatographic Detail

FDA Cleared to Diagnose Diabetes

TOSOH BIOSCIENCE



GS 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.



<pre>* GLYCOHEMOGLOBIN REPORT *</pre>					
2009/02/27 15:40 TOSOH CORPORATION V03.02 NO: 0002 SL 0001 - 02 ID: 0001 - 02 CALIB Y = 1.0904X + 1.0348					
NAME % TIME AREA FP 0.0 0.00 0.00 A1A 7.0 0.25 84.31 A1B 0.0 0.00 0.00 F 24.7 0.43 396.31 LA1C+ 0.0 0.00 0.00 SA1C 6.5 0.58 60.36 A0 88.0 0.89 1064.30 TOTAL AREA 1605.28					
HbA1C %					
HbA1 % HbF % 0% 15% 0.0 1.0					
SA1C NOT RPTABLE					
221 A1B NOT DETECT 14:55 221 LA1C+ NOT DETECT 14:55					

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.



"...we can be quite confident (93% probability) that the patient is actually meeting the ADA goal if his or her A1C is 6.8% when the assay CV is 2%. We are less confident (72% probability) when the assay CV is 5% and not nearly confident enough (64% probability) when the assay precision is as high as 8%."

Little & Rohlfing, DT&T, 2003, 5(6): 979-981





Levey-Jennings



Trend

Result Report	t					
Print 🔍 🔍	75 % 💌	承 ⊉ 1/1	🛛 🖨 Back	Forward T	op End <u>C</u> lose	
Result Report						
Training la	ab	TOSOF	University		A1c report	
	PatientID:					
	Entitle comment: Comment1: Comment2: Record Date: 2007 Barcode: 0007 SampleNo: 1127	/11/27 12:30:42 - 02 0012	Unknow	n		
	NAME	%	TIME	AREA		
	A1A	0.7	0.24	9.45		
	A1B	0.7	0.32	9.93		
	F	1.4	0.39	19.75		
	LA1C+	1.4	0.49	19.60		
	SAIC	10.4	0.89	1260.80		
	AV	00.4	TOTAL AREA	1446.72		
		HbA1C 10.4 % HbA1 11.8 %	, HbF	1.4 %		
	1		(Me) 1.00	1.50		
South San Fri 11/27/2007 12	ancisco, CA 94080 2:30 root	6000	Sharaline Court		Hgb A1c REPORT Page: 1 / 1	

Result Report - 1 Chromatogram

On-Point and On-Time

Reporting Software - Sophisticated Simplicity The G8 Reporting Software highlights flagged results 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.

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.



Result Report - 6 Chromatogram

Specifications

Analytes Principle Sample requirement Sampling volume Throughput Data storage	HbA1c (SA1c), HbF, HbA1 (Total A1) lon-exchange high performance liquid chromatography Visible two-wavelength absorption Whole blood or diluted blood (Preserved with EDTA) Whole blood: 4 μL Diluted blood: 80 μL 1.6 minutes per sample On-board memory: up to 800 samples Unlimited storage with Reporting Software	* GLYCOHEMOGLOBIN REPORT * 2006/12/19 11:15 TOSOH CORPORATION VO1.05 NO: 0001 SL 0001 - 03 ID: 0001 - 03 CALIB Y = 1.2283X + 0.0726
Main unit Sampling Whole blood Column oven Colulmn connection Detector unit	Cap-piercing of primary sample tubes Automatic dilution by Hemolysis and Wash solution in the dilution port Thermomodule in aluminum block Finger-tight type LED colorimetric detector	NAME % TIME AREA FP 0.0 0.00 0.00 A1A 0.5 0.23 7.84 A1B 0.7 0.31 10.57 F 0.8 0.38 12.31 LA1C+ 1.5 0.48 23.69 SA1C 5.3 0.59 66.41 A0 92.3 0.89 1454.68 TOTAL AREA 1575.49
Sample loading units Sample loading capacity	G8-90SL: 90 samples plus one STAT sample G8-290SL: 290 samples plus one STAT sample	H6A1C 5.3%
Sample holding	10 samples/rack	HbA1 6.4 % HbF 0.8 % 0% 15% 0.0 11 + + + + + + + + + + + + + + + + + +
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	1.0
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	Chromatogram for non-diab
Power requirement	AC 100 - 240 V, 50/60 Hz, 180 VA	patient sample
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)	

betic



G8 90 Sample Loader

90SL Line Automation model available.

Please contact your local Tosoh representative for further information.



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

