HPLC TECHNOLOGY

High Performance Liquid Chromatography, or HPLC, is the gold standard method for hemoglobin A1c testing. Using Tosoh's proprietary, non-porous column, our ion-exchange methodology provides chromatographic results in high resolution chromatograms without loss of precision.

Not all HbA1c testing methods are the same. Using the right method gives you confidence in the results you deliver. **Choose wisely. Choose Tosoh.**

TOSOH BIOSCIENCE
www.tosohbioscience.us

TOSOH

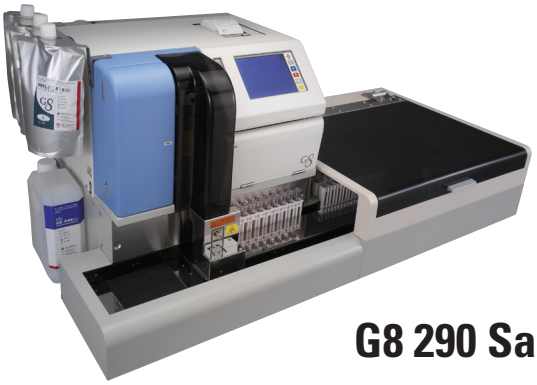
CHOOSE WISELY. CHOOSE TOSOH.

The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (G8) analyzer offers the laboratory all the features and benefits you need for Hemoglobin A1c testing.

The G8 is an ideal solution for rapid and reliable diabetic monitoring and diagnosis.

G8 90 Sample Loader Model*

**Available in Lab Automation Model*



G8 290 Sample Loader Model

Simplified Operation

Simple and intuitive user interface requires minimal interaction and maintenance.

Automated start-up and daily maintenance, only requires the push of a button to begin processing samples.

Precision & Reliability

With less than 2% CVs, provides confidence in the results you deliver.

Precise engineering and a proven record of high meantime between failure of over 300 days translates to constant, reliable performance.

Efficiency & Speed

Equipped with direct primary tube sampling and cap piercing capabilities enables the user to load different sample types and test tube sizes in any order and any rack.

Continuous sample loading enables high throughput and fast results with analysis time of 1.6 minutes.

Compact & Flexible

Small, benchtop footprint that fits into any location.

Flexible platform options are available to meet the increasing demands of every laboratory:

- G8 90 Sample Loader Model
- G8 290 Sample Loader Model
- G8 LA (Line Automation) Model

DIABETES

Diabetes is a condition called continuous hyperglycemia where the blood glucose, or blood sugar, levels are too high. The underlying cause is due to the inability of insulin, a hormone produced by the pancreas, to be produced or function effectively in order to regulate blood glucose levels.

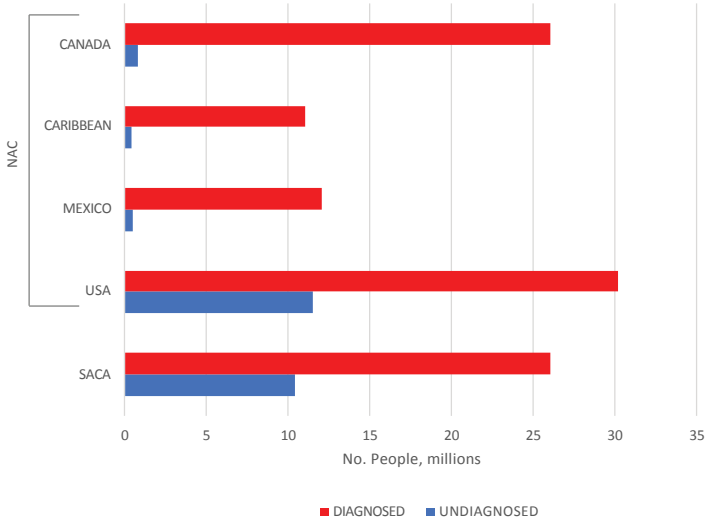
Types of Diabetes

TYPE 1 DIABETES
Body does not produce enough insulin

TYPE 2 DIABETES
Body produces insulin but cannot use it properly

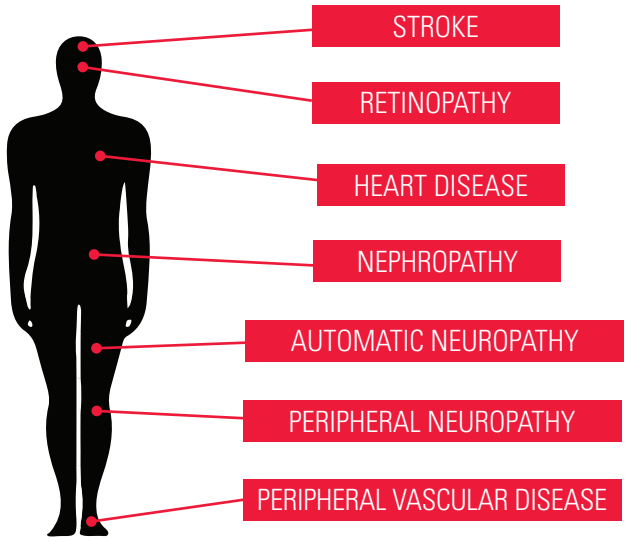
GESTATIONAL DIABETES
Temporary condition during pregnancy

National Prevalence of Diabetes[1]



- By 2045, diabetes in North America and Caribbean (NAC) and South and Central America (SACA) are expected to increase by 35% and 62% respectively.
- Globally, NAC and SACA is responsible for 52% of diabetes-related healthcare expenditure.

Consequences of Diabetes



Considerations for an A1c Method[2]

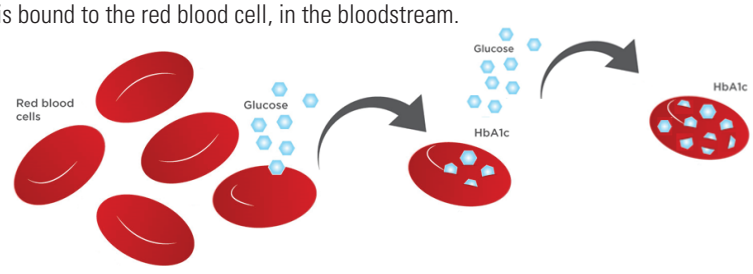
- Specific measurement of A1c
- Precision
- NGSP certified method
- Hemoglobin variant detection when present
- Removal of interferences

Tosoh's ion-exchange HPLC methodology for HbA1c testing meets performance characteristics by offering:

- ✔ Direct determination of stable HbA1c
- ✔ Precision of <2% CV
- ✔ Analyzers that are NGSP certified
- ✔ Detection of hemoglobin variants

Importance of HbA1c Testing

Hemoglobin A1c, also known as HbA1c or A1c, is a blood test that measures a person's average blood glucose levels over a period of 1 to 3 months. HbA1c test measures the percentage of a person's glycated hemoglobin, glucose that is bound to the red blood cell, in the bloodstream.

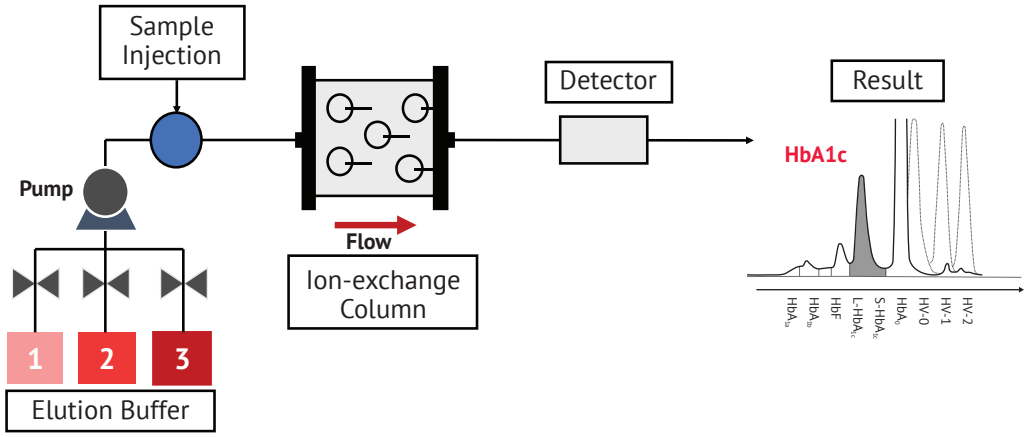


Tosoh's HbA1c test is used in three applications:

- For identifying individuals at risk for developing diabetes
- For aid in diagnosis of diabetes
- For monitoring, management, and follow-up treatment of diabetes

HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

High performance liquid chromatography, or HPLC, is an analytical chemistry technique to separate, identify, and quantify each component in a mixture. In ion-exchange chromatography, the glycated hemoglobin components are separated according to their different electrical charge. As fractions elute, the time it takes to separate that fraction is called the retention time. The retention times for each fraction determines the identity of the component.



Tosoh's ion-exchange methodology utilizes a proprietary, in-house developed, non-porous polymer resin column that provides high resolution chromatograms and high efficiency separation without loss of precision. The HbA1c measurement yields direct determination of stable HbA1c through clear separation between labile HbA1c and stable HbA1c by generating a chromatogram that contains key valuable information about the patient including the presence of a hemoglobin variant or hereditary persistence of fetal Hb- a feature unique to the HPLC ion-exchange methodology.

HbA1C Method Comparison[3]

METHOD	ADVANTAGES	DISADVANTAGES	TOSOH SOLUTIONS
ENZYMATIC	No Hb variant interference	Unable to detect variants	• Detection of hemoglobin variant D, S, C, and E • Removal of interference
IMMUNOASSAY	No Hb variant interference	Unable to detect variants	• Detection of hemoglobin variant D, S, C, and E • Removal of interference
BORONATE AFFINITY	No/Minimal Hb variant interference	• Unable to detect variants • Measures glycated Hb and not just HbA1c	• Direct determination of stable HbA1c • Detection of hemoglobin variant D, S, C, and E • Clear separation between labile HbA1c and stable HbA1c
CAPILLARY ELECTROPHORESIS	• High resolution • Hb variant detection	Low volume through-put	• 90-290 sample loader for automatic processing • High walk-away time • Quick TAT for result
ION-EXCHANGE HPLC	• High precision • High efficiency • Clear separation • High resolution chromatograms • Direct determination of s-HbA1c • Detection of D, S, C, and E • Rapid, automatic processing	Risk of co-elution of variants and interference POROUS • Decrease or loss of efficiency for larger proteins • Size exclusion	NON-POROUS • Equally efficient for proteins spanning a wide range of molecular weights • No size exclusion • No loss of efficiency • No interference with HbS, HbC, HbD and HbE

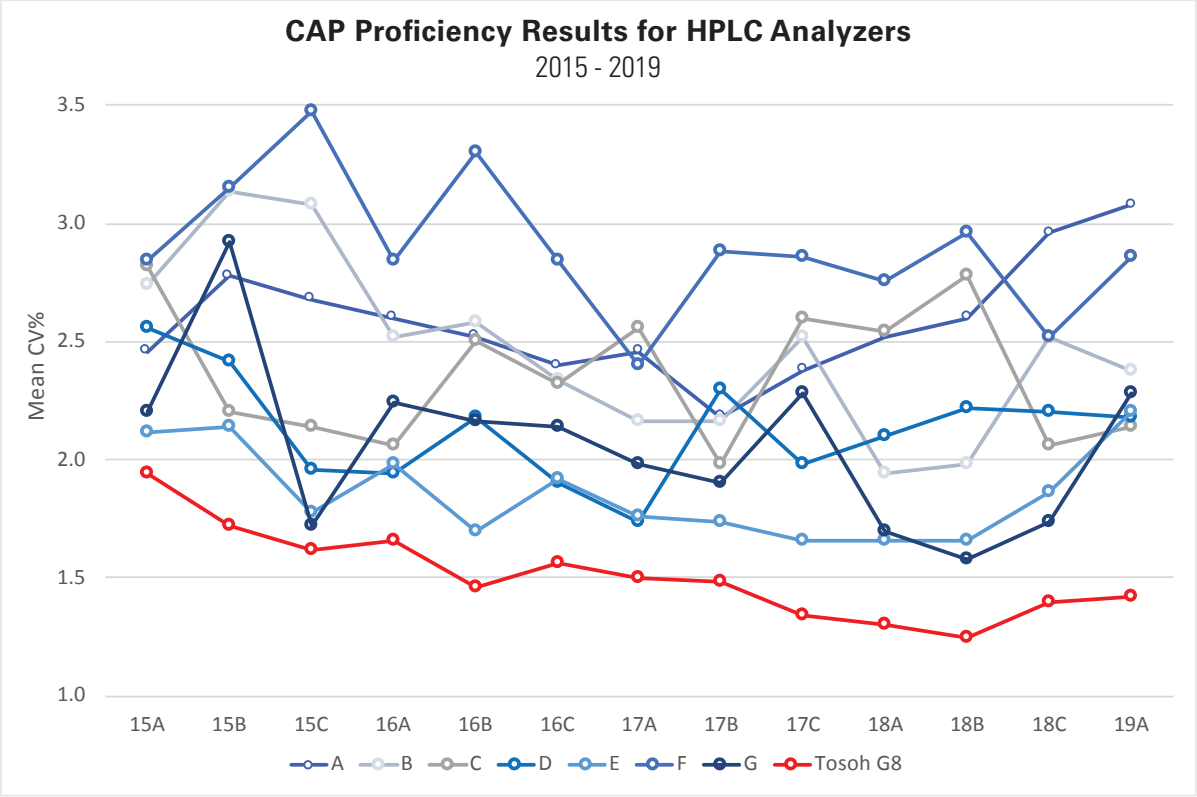
FEATURES & BENEFITS

Gold Standard Technology

- Ion-exchange HPLC is the gold standard for HbA1c measurement
- Ion-exchange HPLC was used in the Diabetes Control and Complications Trial, or DCCT, study undertaken in the United States

Accuracy and Precision

- Less than 2% CV

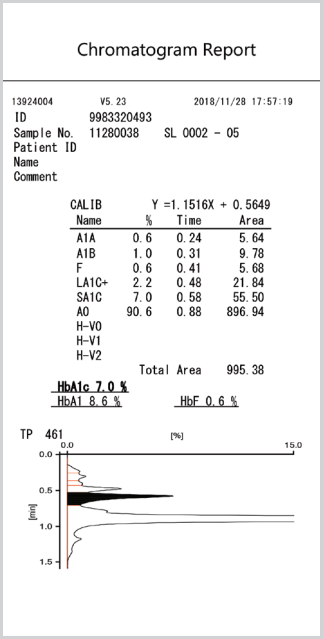


No Clinical Interference

- Clear separation between L-HbA1c and s-HbA1c
- HbAD, HbAS, and HbAC separated from A0 peak
- No clinical interference with HbAD, HbAS, HbAC, and HbAE
- No clinical interference with labile A1c, acetylated Hb, aldehyde Hb, and carbamylated Hb

Detailed Chromatographic Result

- Renowned precision, efficiency, and separation
- High resolution chromatograms
- Detailed report showing current calibration and characteristics (retention, percentage, and retention time of each fraction.
- Value of HbA1c %



Chromatogram Report

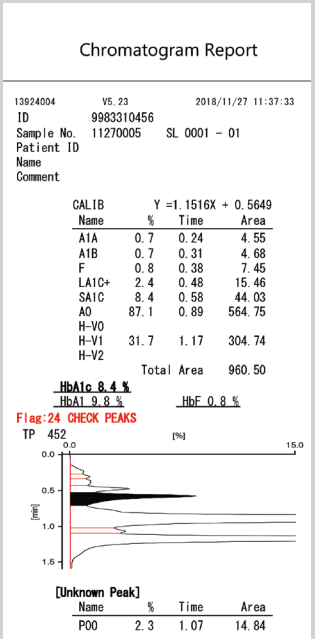
13924004 V5.23 2018/11/28 17:57:19
ID 9983320493
Sample No. 11280038 SL 0002 - 05
Patient ID
Name
Comment

CALIB Y =1.1516X + 0.5649

Name	%	Time	Area
A1A	0.6	0.24	5.64
A1B	1.0	0.31	9.78
F	0.6	0.41	5.68
LA1C+	2.2	0.48	21.84
SA1C	7.0	0.58	55.50
A0	90.6	0.88	896.94
H-V0			
H-V1			
H-V2			
	Total Area		995.38

HbA1c 7.0 %
HbA1 8.6 %
HbF 0.6 %

TP 461 [%]



Chromatogram Report

13924004 V5.23 2018/11/27 11:37:33
ID 9983310456
Sample No. 11270005 SL 0001 - 01
Patient ID
Name
Comment

CALIB Y =1.1516X + 0.5649

Name	%	Time	Area
A1A	0.7	0.24	4.55
A1B	0.7	0.31	4.68
F	0.8	0.38	7.45
LA1C+	2.4	0.48	15.46
SA1C	8.4	0.58	44.03
A0	87.1	0.89	564.75
H-V0			
H-V1	31.7	1.17	304.74
H-V2			
	Total Area		960.50

HbA1c 8.4 %
HbA1 9.8 %
HbF 0.8 %
Flag:24 CHECK PEAKS

TP 452 [%]

[Unknown Peak]

Name	%	Time	Area
P00	2.3	1.07	14.84

TECHNICAL SPECIFICATIONS

Analytes	HbA1c (Sa1c), HbF, HbA1 (Total A1)
	Ion-exchange high performance liquid chromatography
Principle	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

Main Unit

Sampling	Cap-piercing of primary sample tubes
Whole Blood	Automatic dilution by Hemolysis and Wash solution in 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 and one STAT position
	G8-290SL: 290 sample and one STAT position
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
Output	Thermal paper (roll paper), Smart Media, LIS or 501RP+
Communication	RS-232C serial standard (bi-directional)
Operating temperature	15 – 30 ^{0} 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)
LA Model	W 21" (530 mm) x D 29" (723 mm) x H 19" (482 mm)
	79.4 lbs (36.0 kg)

PART NUMBER & DESCRIPTION

021560	HLC-723G8 (Main Unit)
021674	G8-LA (Lab Automation)
021561	G8-90SL (90 Sample Loader)
021562	G8-290SL (290 Sample Loader)
021955	TSKgel G8 Variant HSi (Column)
021956	G8 Variant Elution Buffer HSi No. 1
021957	G8 Variant Elution Buffer HSi No. 2
021858	G8 Variant Elution Buffer HSi No. 3
018431US	HSi Hemolysis & Wash Solution
018767	Hemoglobin A1c Calibrator Set
992133	Hemoglobin A1c Control

HbA1c Calibrator Set

HbA1c Control

Analysis Column

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

References:
1. IDF Diabetes Atlas Eighth Edition 2017
2. Hanley T, Signorelli H. Considerations in Choosing Hemoglobin A1c Methods. CLinical Laboratory News. April 1, 2015.
3. Yedla N, Kuchay MS, Mithal A. Hemoglobin E disease and glycosylated hemoglobin. Indian J Endocr Metab 2015;19:683-5.

For more information, call 1.800.248.6764

Tosoh products are for Prescription use only as In-Vitro Diagnostics

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