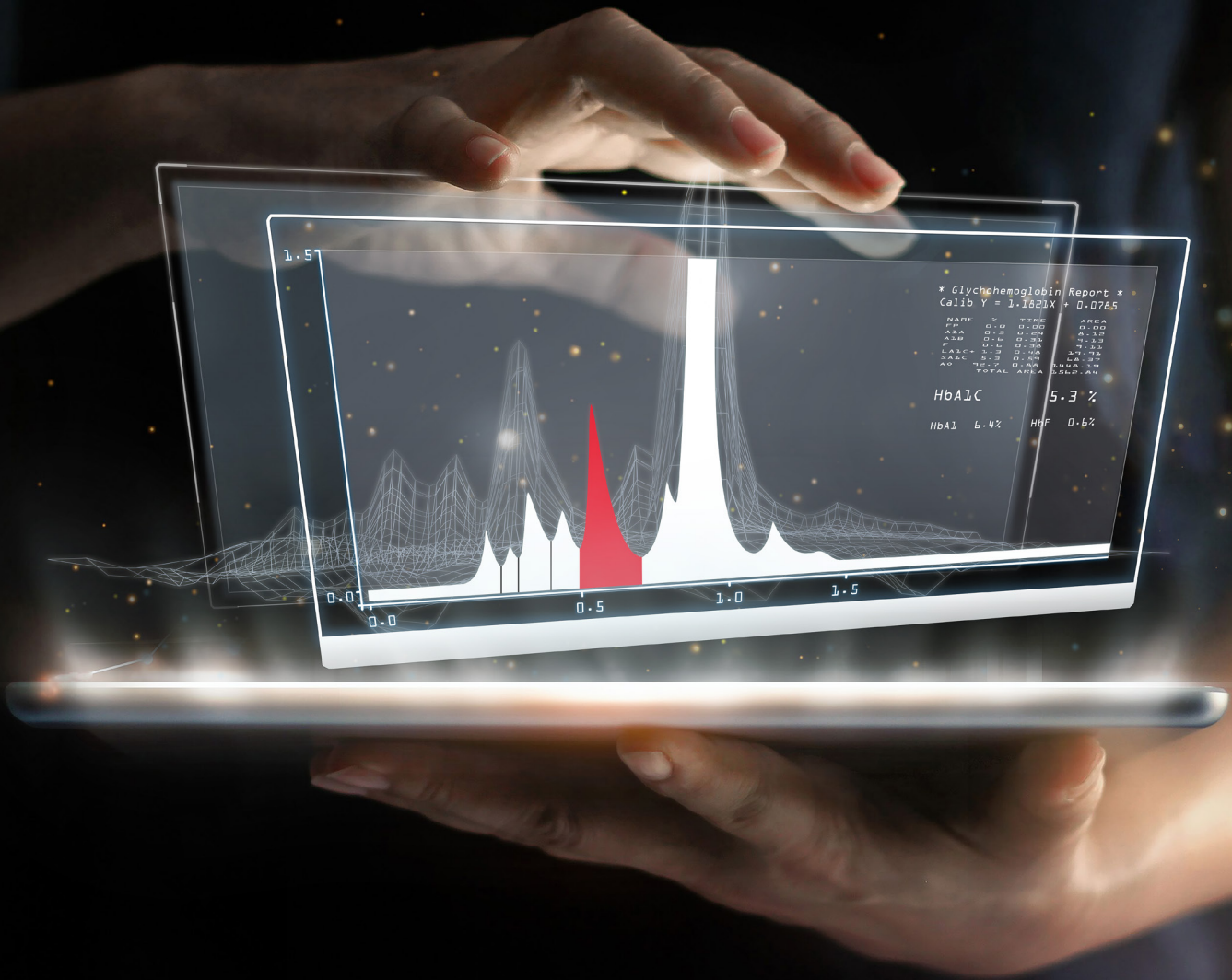


# HPLC TECHNOLOGY



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](http://www.tosohbioscience.us)



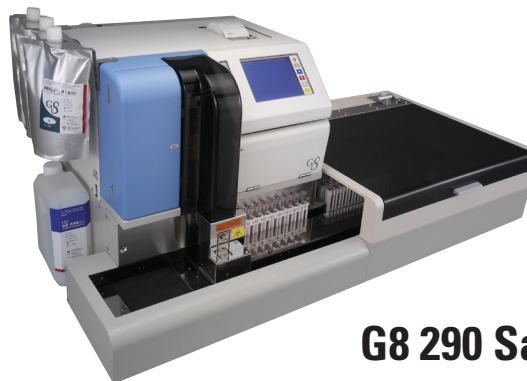
# CHOOSE WISELY. CHOOSE TOSOH.

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\***



**G8 290 Sample  
Loader Model**

*\*Available in Lab Automation 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

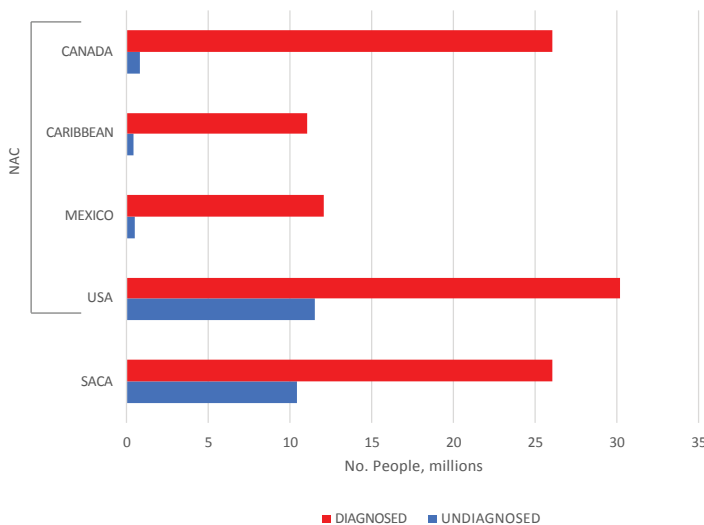


**TYPE 2 DIABETES**  
Body produces insulin but cannot use it properly

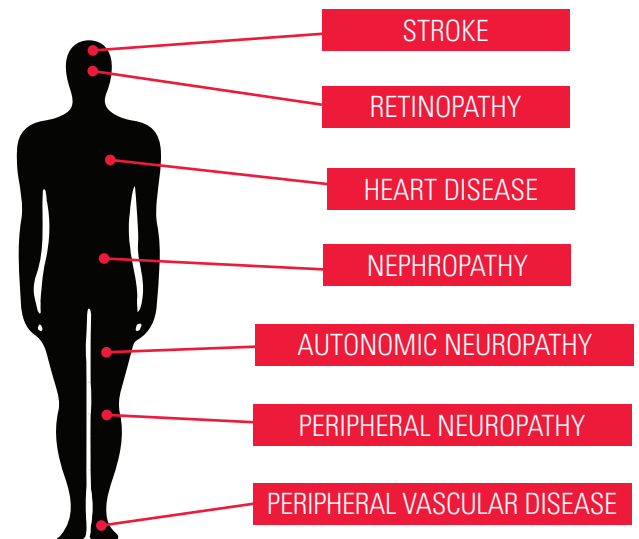


**GESTATIONAL DIABETES**  
Temporary condition during pregnancy

## National Prevalence of Diabetes<sup>1</sup>



## Consequences of Diabetes



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

## Considerations for an A1c Method<sup>2</sup>

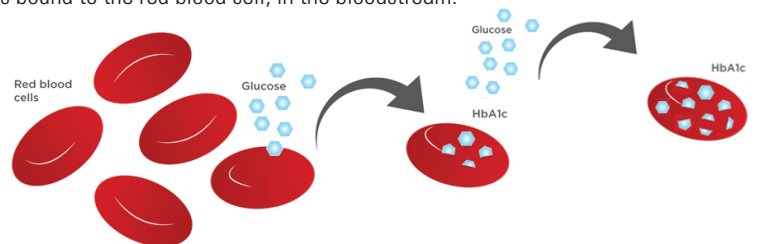
- Specific measurement of A1c
- Precision
- NGSP certified method
- Hemoglobin variant detection when present
- Reduction of interferences

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:

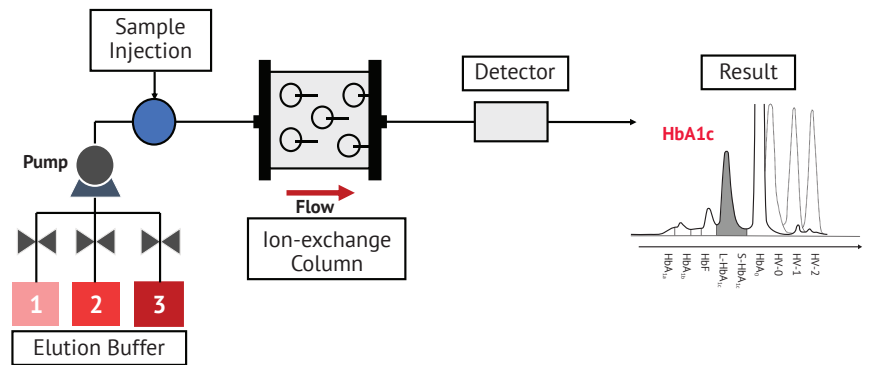
- For identifying individuals at risk for developing diabetes
- For aid in diagnosis of diabetes
- For monitoring, management, and follow-up treatment of diabetes

# 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 HbA<sub>1c</sub> measurement yields direct determination of stable HbA<sub>1c</sub> through clear separation between labile HbA<sub>1c</sub> and stable HbA<sub>1c</sub> 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.

## HbA<sub>1c</sub> Method Comparison<sup>3</sup>

METHOD	ADVANTAGES	DISADVANTAGES	TOSOH SOLUTIONS
<b>ENZYMATIC</b>	High throughput	<ul style="list-style-type: none"> <li>A1c is only reported as a number</li> <li>Unable to detect variants</li> </ul>	<ul style="list-style-type: none"> <li>Direct determination of stable HbA<sub>1c</sub></li> </ul>
<b>IMMUNOASSAY</b>	Multiple assays on one platform	<ul style="list-style-type: none"> <li>Extra maintenance needed when running whole blood</li> <li>A1c is just a number</li> <li>Unable to detect variants</li> <li>Low tolerance for high levels of HbF (~10-15%)*</li> </ul>	<ul style="list-style-type: none"> <li>Detection of hemoglobin variants D, S, C, and E</li> <li>Presumptive identification of variants D, S, C and E</li> <li>Reportability of HbA<sub>1c</sub> in the presence of HbAS, HbAC, HbAD and HbAE</li> </ul>
<b>BORONATE AFFINITY</b>	Chromatography with only 2 peaks: Glycated and non-glycated	<ul style="list-style-type: none"> <li>Not suited for high-throughput labs</li> <li>Unable to detect variants</li> <li>Low tolerance for high levels of HbF (~10-15%)*</li> </ul>	<ul style="list-style-type: none"> <li>No interference with A1c results from HbF (up to 25%)</li> </ul>
<b>CAPILLARY ELECTROPHORESIS</b>	<ul style="list-style-type: none"> <li>Multiple capillaries provide multiple results at the same time</li> <li>Variant detection</li> </ul>	<ul style="list-style-type: none"> <li>Increased operational steps and maintenance</li> <li>Compromised workflow</li> <li>Results available only in batches</li> <li>Low tolerance for high levels of HbF (~10-15%)*</li> </ul>	<ul style="list-style-type: none"> <li>Low maintenance</li> <li>Less number of operational steps for streamlined workflow</li> <li>Line automation friendly</li> <li>No interference with A1c results from HbF (up to 25%)</li> </ul>
<b>TOSOH ION-EXCHANGE HPLC</b>	Tosoh's patented non-porous resin ensures no loss of efficiency in separation of hemoglobin fractions		
	<ul style="list-style-type: none"> <li>Tosoh offers consistently low CV's of less than 2% year over year</li> <li>Low maintenance and easy to use</li> <li>Direct determination of stable HbA<sub>1c</sub> and detection of variants</li> <li>Reportability of HbA<sub>1c</sub> in the presence of HbAS, HbAC, HbAD, HbAE and HbF (up to 25%)</li> <li>Line automation friendly</li> </ul>		

\* <http://www.ngsp.org/interf.asp>

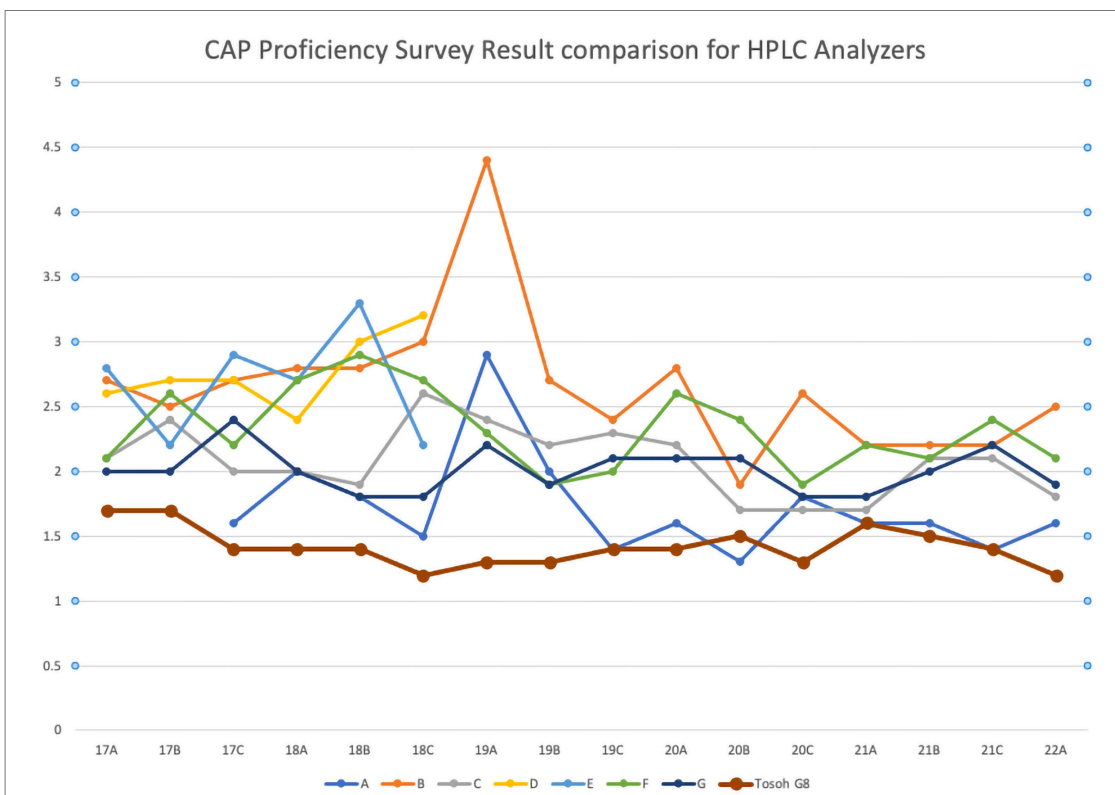
# FEATURES & BENEFITS

## 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

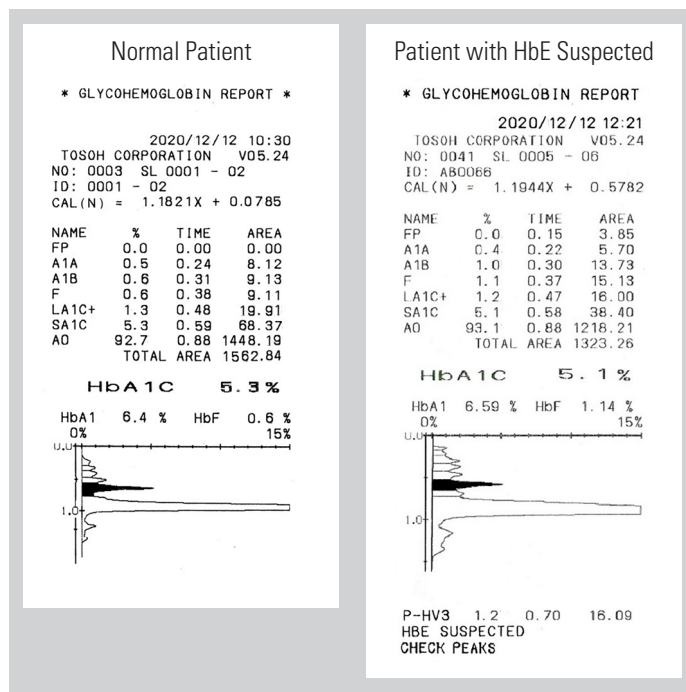


## Reliable A1c Results

- Clear separation between labile HbA1c and stable HbA1c
- HbAD, HbAS, and HbAC separated from A0 peak
- Reportability of HbA1c in the presence of HbAS, HbAC, HbAD, HbAE and HbF (up to 25%)
- Reportability of HbA1c in the presence of labile Hb, 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 %



## TECHNICAL SPECIFICATIONS

Analytes	HbA1c (Sa1c), HbF, HbA1 (Total A1)
Principle	Ion-exchange high performance liquid chromatography
Sample Requirement	Whole blood or diluted blood (K2/K3 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), USB, LIS or 501RP+
Communication	RS-232C serial standard (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)
LA Model	W 21" (530 mm) x D 29" (723 mm) x H 19" (482 mm) 79.4 lbs (36.0 kg)

#### 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*

# TOSOH BIOSCIENCE

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LBL-00122

## 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
220232	Hemoglobin A1c Control

### HbA1c Calibrator Set



### HbA1c Control



### Analysis Column



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

