



## High Performance Liquid Chromatography



**TOSOH BIOSCIENCE** 

# Choose wisely. Choose Tosoh.

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

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

GS

without loss of precision.

### The Tosoh Automated Glycohemoglobin Analyzer HLC-723G8 (G8) analyzer

HbA1C

6.59 %

HbA1

0%

5.1%

1.14 % 15%

HbF

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.

**Diabetes** is a condition characterized by persistent hyperglycemia, where blood glucose (or blood sugar) levels remain too high. This occurs due to the body's inability to produce insulin-a hormone made by the pancreas—or because the insulin produced is not effective in regulating blood glucose levels.

A1c

during pregnancy

### **Types of Diabetes**



**TYPE 2 DIABETES** 

cannot use it properly

#### **TYPE 1 DIABETES** Body does not produce

enough insulin

#### **Consequences of Diabetes**



**GESTATIONAL DIABETES** Temporary condition

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

North America and Caribbean (NAC)				South and Central America (SACA)		
2050	68.1 Million		21% increase	2050	51.5 Million	<b>45</b> %
2024	56.2 Million	i		2024	35.4 Million	increase

IDF Region	Proportion undiagnosed (%)	Number of people with undiagnosed diabetes (millions)
SACA (South and Central America)	30.4	10.7
NAC (North America and Caribbean)	29.1	16.3

- By 2050, diabetes in North America and Caribbean (NAC) and South and Central America (SACA) is expected to increase by 22% and 46% respectively.
- Globally NAC and SACA are responsible for 43% and 8% of global diabetes-related expenditures respectively.

#### Importance of HbA1c Testing

The A1c test, also known as the Hemoglobin A1c or HbA1c test, is used to assess a person's average blood glucose levels over the previous 8 to 12 weeks. It works by measuring the percentage of glycated hemoglobin—hemoglobin in red blood cells that has glucose molecules attached to it.



### 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

### **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

# **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<sup>3</sup>

METHOD	ADVANTAGES	DISADVANTAGES	TOSOH SOLUTIONS			
ENZYMATIC	<ul> <li>High throughput</li> </ul>	<ul><li>A1c is only reported as a number</li><li>Unable to detect variants</li></ul>	<ul> <li>Direct determination of stable HbA1c</li> <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 HbA1c in the presence of HbAS. HbAC, HbAD and HbAE</li> </ul>			
IMMUNOASSAY	<ul> <li>Multiple assays on one platform</li> </ul>	<ul> <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>				
BORONATE AFFINITYENZYMATIC	<ul> <li>Chromatography with only 2 peaks: Glycated and non-glycated</li> </ul>	<ul> <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> <li>No interference with A1c results from HbF (up to 25%)</li> </ul>			
CAPILLARY ELECTROPHORESIS	CAPILLARY CAPILLARY CTROPHORESIS • Multiple capillaries provide multiple results at the same time • Variant detection • Low tolerance for the formation of the		<ul> <li>Low maintenance</li> <li>Less number of operational steps for streamlined workflow</li> <li>Line automation friendly</li> </ul>			
TOSOH ION-EXCHANGE HPLC	<ul> <li>Tosoh's patented non-porous resin ensures no loss of efficiency in separation of hemoglobin fractions</li> <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 HbA1c and detection of variants</li> <li>Reportability of HbA1c in the presence of HbAS, HbAC, HbAD, HbAE and HbF (up to 25%)</li> <li>Line automation friendly</li> </ul>					

# **Choose wisely. Choose Tosoh.**



#### 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.



#### **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.



#### **PRECISION & RELIABILITY**

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

Precise engineering and high mean time between failure translates to constant, reliable performance with ≤1 service calls per year.



### **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 on Sysmex Automation System
- G8 LA (Line Automation) Model

#### 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.

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

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