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.
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.

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

**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**

<table>
<thead>
<tr>
<th>Region</th>
<th>No. People, millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>0.5</td>
</tr>
<tr>
<td>Caribbean</td>
<td>0.3</td>
</tr>
<tr>
<td>Mexico</td>
<td>1.0</td>
</tr>
<tr>
<td>USA</td>
<td>2.8</td>
</tr>
<tr>
<td>SACA</td>
<td>5.0</td>
</tr>
</tbody>
</table>

**Consequences of Diabetes**

- Stroke
- Retinopathy
- Heart Disease
- Nephropathy
- Autonomic Neuropathy
- Peripheral Neuropathy
- Peripheral Vascular Disease

**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.

**Considerations for an A1c Method**

- 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

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, or HPLC, is an analytical chemistry technique to separate, identify, and quantify each component in a mixture. In ion-exchange chromatography, the glyated 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

<table>
<thead>
<tr>
<th>METHOD</th>
<th>ADVANTAGES</th>
<th>DISADVANTAGES</th>
<th>TOSOH SOLUTIONS</th>
</tr>
</thead>
</table>
| 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            | • 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                         | Low volume through-put                | • 90-290 sample loader for automatic processing  
                              | • Hb variant detection                   |                                        | • High walk-away time                
                              |                                           |                                        | • Quick TAT for result               |
| ION-EXCHANGE HPLC       | • High precision                          | Risk of co-elution of variants and interference | NON-POROUS  
                              | • High efficiency                        |                                        | • Equally efficient for proteins spanning a wide range of molecular weights  
                              | • Clear separation                       |                                        | • No size exclusion                  
                              | • High resolution chromatograms          |                                        | • No loss of efficiency              
                              | • Direct determination of s-HbA1c        |                                        | • No interference with HbS, HbC, HbD and HbE  
                              | • Detection of D, S, C, and E            |                                        |                                        |
                              | • Rapid, automatic processing             |                                        |                                        |
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 %
### TECHNICAL SPECIFICATIONS

<table>
<thead>
<tr>
<th>Analytes</th>
<th>HbA1c (Sa1c), HbF, HbA1 (Total A1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principle</td>
<td>Ion-exchange high performance liquid chromatography</td>
</tr>
<tr>
<td>Sample Requirement</td>
<td>Whole blood or diluted blood (Preserved with EDTA)</td>
</tr>
<tr>
<td>Sampling Volume</td>
<td>Whole blood: 4 μL Diluted blood: 80 μL</td>
</tr>
<tr>
<td>Throughput</td>
<td>1.6 minutes per sample</td>
</tr>
<tr>
<td>Data storage</td>
<td>On-board memory up to 800 samples</td>
</tr>
</tbody>
</table>

### 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 °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

For more information, call 1.800.248.6764

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

**TOSOH BIOSCIENCE**

www.tosohbioscience.us