Gold Standard Accuracy by Ion-Exchange HbA1c

Precise Chromatographic Detail

FDA Cleared to Diagnose Diabetes

TOSOH BIOSCIENCE
G8 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.
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%.”

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, Levey-Jennings and Westgard rules, inventory management and much more.
## 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>
</tbody>
</table>
| 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  
|                   | Unlimited storage with Reporting Software |

### Main unit

- **Sampling**: Cap-piercing of primary sample tubes
- **Whole blood**: Automatic dilution by Hemolysis and Wash solution in the 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 plus one STAT sample  
  G8-290SL: 290 samples plus one STAT sample
- **Sample holding**: 10 samples/rack
- **Sample specifications**: 12-15 mm x 75-100 mm primary tubes and Tosoh sample cups
- **Barcode specifications**: NW-7, CODE9, ITF, CODE128, JAN, COOP 2 of 5, Industrial 2 of 5

### 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
- **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)

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90SL Line Automation model available.

Please contact your local Tosoh representative for further information.