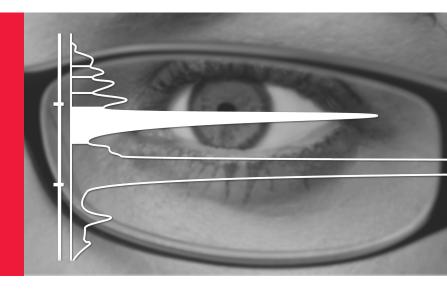


See More than an A1c Number

Tosoh G8 delivers HbA1c results with a detailed graphic representation of the patient, allowing you to see all that is behind the number.







- Gold Standard HPLC Methodology
- Time tested Coefficient of Variation (CV) of less than 2%
- Proven track record of instrument reliability
- Method of choice for accurate A1c results without common hemoglobin variant interference
- The G8 grows with your needs and is an ideal partner for laboratories with Track Line Automation needs







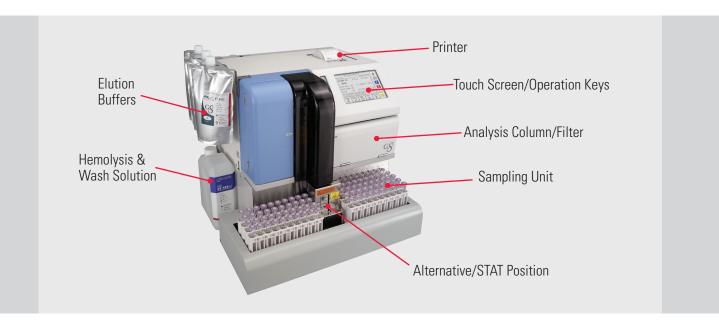
Accurate, Reliable and Efficient

Compact and Flexible

- Small benchtop footprint that fits into any laboratory – 21"w x 20"d x 19"h
- Weighs only 75 lbs
- Scalable in volume with compatibility with third party track lines

Minimal Maintenance

- High Mean Time Between Failure (MTBF)
- Proven record of over 300 days MTBF
- ≤1 service calls per year
- Minimal instrument downtime
- Cost savings

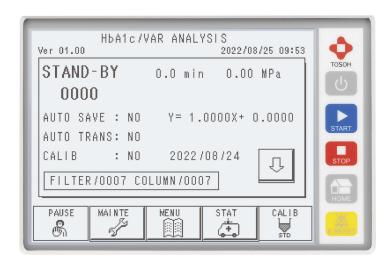


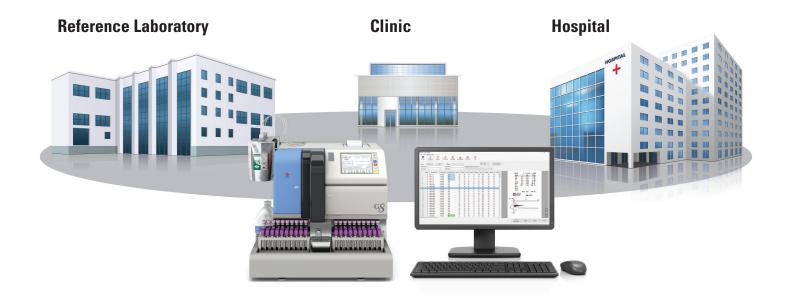
Streamlined Workflow

- No manual cap piercing/sample pre-treatment
- Continuous sample loading
- Positive sample identification
- Result validated autoverification
- Minimum hands-on time

Simplified Operation

- Touch screen
- User-friendly interface
- Automated start-up and daily maintenance
- Automated primary tube sampling



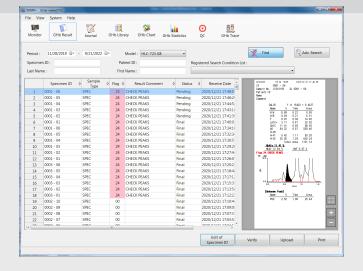


Adaptable to All Workload Volumes

With an increase in diabetics, laboratories are experiencing an increase in the volume of A1c testing. The Tosoh G8 is a perfect solution for outpatient clinics, hospitals and large laboratory consolidated set-ups.

The Tosoh G8 fits seamlessly on third-party track lines for a complete laboratory automation experience.





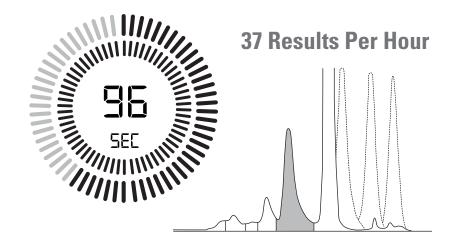
Powerful Middleware

With the power of the 501RP+ middleware solution, the efficiencies in your laboratory, from sample processing to result reporting, have just gotten even better.

- Paperless chromatography
- Auto verification by filtering results
- Reagent and data traceability
- Centralized QC and Levy-Jennings graphs

Fast Turnaround Time

Results in 96 Seconds



Confidence to the Core

The core of the G8 is Tosoh's proprietary cation exchange HPLC column packed with non-porous resin. With over 30 years of HPLC experience, the G8 analyzer continues to use its in-house developed ion-exchange HPLC column to provide clear and true separation chromatography. The HPLC technology is considered gold standard technology and has been used in pioneer studies like the DCCT*.

*Diabetes Control and Complications Trial



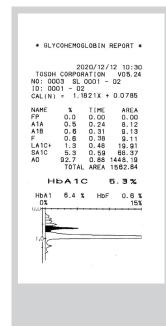
Get the Complete Picture with Tosoh HPLC

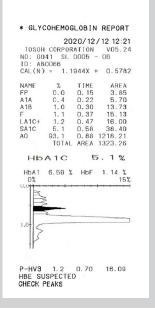
Reliable A1c Results

- Clear separation between labile A1c (LA1C or LA1c) and stable A1c (SA1C or sA1c)
- 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

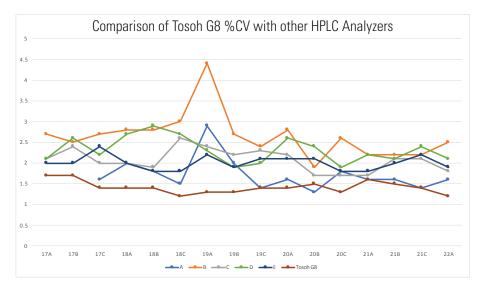
- Renowned precision, efficiency, and separation
- High resolution chromatograms
- Detailed report showing current calibration and characteristics (retention, percentage, and retention time of each fraction)
- Value of HbA1c %





Tosoh HPLC-Your Key to a Reliable A1c Result

Historically Consistent CVs Year after Year of less than 2%



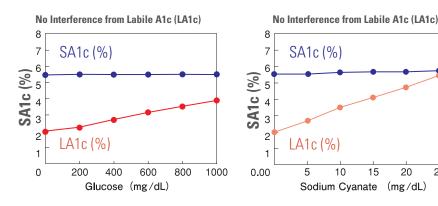
In-house Precision Data

| Mean HbA1c | %CV (Total) |
|---------------|-------------|
| 5% | 0.97 |
| 6.5% | 1.04 |
| 8% | 1.28 |
| 12% | 0.87 |

Summary of between Lot, Day, Run and Analyzer.

Reference: CAP Survey data: 2017 to 2022

No Interference from Labile A1c



The G8 provides direct determination of stable HbA1c (SA1c) with less than 2% CVs. The HbA1c results are not clinically affected by the presence of most hemoglobin variants or hemoglobin derivatives.

Tosoh HPLC-Brings Valuable Information to the Forefront

| Method | Ability to detect common hemoglobin variants and HbF | Interference from elevated HbF |
|-------------------------|--|-----------------------------------|
| Tosoh Ion-Exchange HPLC | Yes | >25% |
| Immunoassay* | No | >10-15% |
| Enzymatic* | No | >10-15% |
| Boronate Affinity* | No | >15% |

^{*} Manufacturers' package inserts have variable claims for tolerance limits to HbF

TECHNICAL SPECIFICATIONS

| Analytes | HbA1c (SA1c), HbF, HbA1 (Total A1) | 021560 | HLC-723G8 (Main Unit) |
|--------------------|---|----------|-------------------------------------|
| | Ion-exchange high performance liquid chromatography | 021674 | G8-LA (Lab Automation) |
| Principle | Visible two-wavelength absorption | 021561 | G8-90SL (90 Sample Loader) |
| Sample Requirement | Whole blood or diluted blood (K2/K3 EDTA) | 021562 | G8-290SL (290 Sample Loader) |
| Sampling Volume | Whole blood: 4 µL | 021955 | TSKgel G8 Variant HSi (Column) |
| | Diluted blood: 80 μL | 021956 | G8 Variant Elution Buffer HSi No. 1 |
| Throughput | 1.6 minutes per sample | 021957 | G8 Variant Elution Buffer HSi No. 2 |
| Data storage | On-board memory up to 800 samples | 021858 | G8 Variant Elution Buffer HSi No. 3 |
| | | 018431US | HSi Hemolysis & Wash Solution |
| Main Unit | | 018767 | Hemoglobin A1c Calibrator Set |
| Sampling | Cap-piercing of primary sample tubes | 220232 | Hemoglobin A1c Control |

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

Thermal paper (roll paper), USB, LIS or 501RP+ Output

RS-232C serial standard (bi-directional) Communication

 $15 - 30^{\circ}$ C Operating temperature

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)

For more information, call 1.800,248,6764

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

TOSOH BIOSCIENCE

www.tosohbioscience.us

HbA1c Calibrator Set

HbA1c Control

PART NUMBER & DESCRIPTION



Analysis Column



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



