GX

AUTOMATED GLYCOHEMOGLOBIN ANALYZER

PRIMECARE DIAGNOSTICS
& Medical Equipment Co.Ltd

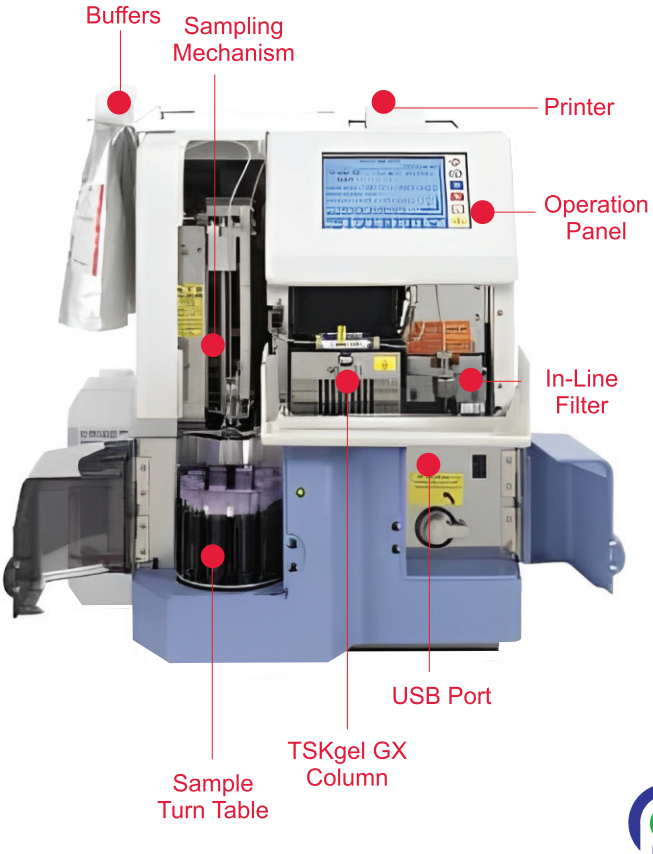
AUTOMATED GLYCOHEMOGLOBIN ANALYZER

Stable HbA1c result with variant detection in 2.2 minutes,

The GX will deliver:

- **Precision**
  Direct determination of stable HbA1c with less than 1 % CV.
- **Speed**
  Stable HbA1c result with variant detection in 2.2 minutes.
  Time to first result is 6.6 minutes.
- **Operational Simplicity**
  With cap piercing, positive sample identification, automated maintenance, the GX is simplicity itself.
- **Absence of Interference**
  In the presence of the most common haemoglobin variants, HbF or haemoglobin derivatives such as labile and carbamylated haemoglobin, HbA1c results are unaffected.

System Overview



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The Diabetes Epidemic and the role of HbA_{1c}

Diabetes is recognised worldwide as a disease that is reaching epidemic proportions. [1]

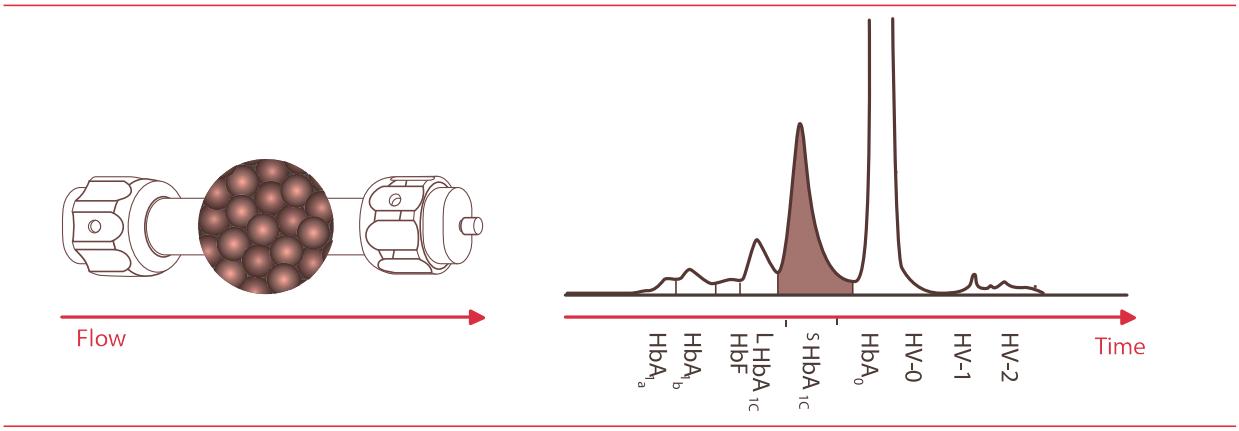
IDF region	Adult Population (20-79) in 1000s	Diabetes cases (20-79) in 1000s	Diabetes national prevalence (%)	Undiagnosed Diabetics in 1000s	Undiagnosed Diabetics %	Diabetes related deaths (20-79)	Mean diabetes-related expenditure per person with diabetes (EURO)
WORLD	4,479,259	371,329	8.29 %	187,087	4.18 %	4,802,747	1,027
EUR	655,983	54,942	8.38 %	21,204	3.23 %	622,114	2,043
MENA	366,249	34,163	9.33 %	18,114	4.95 %	356,586	285
AFR	398,113	14,920	3.75 %	12,148	3.05 %	401,276	135

The significance of HbA_{1c} for the diagnosis and follow-up of diabetes has increased with the continuing rise in the number of patients. This represents a significant workload challenge to many laboratories.

How to measure HbA_{1c}?

One of the reference methods for HbA_{1c} measurement is “High Performance Liquid Chromatography”, better known as “HPLC” (this method was also used in the DCCT and UKPDS trials). With this technique the different haemoglobin fractions are separated based on charge.

When using the Tosoh Automated Glycohemoglobin Analyzer HLC-723GX (GX) separation of the haemoglobin fractions is obtained by use of a negatively charged column and positively charged buffers that compete with the different haemoglobins to bind to the column (= cation exchange). Tosoh offers you over 35 years of world leading HPLC experience.



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Why use HPLC?

Besides being the method used during the DCCT and UKPDS trials different arguments are raised in literature.

"The method of choice should measure HbA_{1c} highly precisely; should be economical, automatable and simple to perform; and should yield results that are comparable between different laboratories, …one should use a method that meets the following conditions: The Hb variant should be recognised; and HbA_{1c}, HbA_0 and Hb variants should be separated and quantified reliably." [2]

"The advantage of HPLC lies in its ability to separate variant haemoglobins and, in doing so, allowing better interpretation of the result!" [3]

The Importance of low CV%

HbA_{1c} can be used for three specific applications*:

1. For identifying risk.

HbA_{1c} could be used as a tool, among other parameters, to identify individuals at risk for developing diabetes. The American Diabetes Association (ADA) suggested 5.7 – 6.4 % (39 – 47 mmol/mol) as the high risk range. [4,5]

2. For Diagnosis.

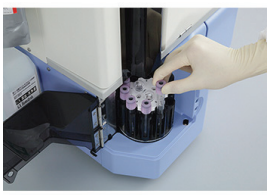
An international expert committee assembled by the American Diabetes Association (ADA), International Diabetes Federation (IDF), and European Association for the Study of Diabetes (EASD) has recommended the HbA_{1c} assay as the new test for the diagnosis of diabetes. An HbA_{1c} value greater than or equal to 6.5 %, or 48 mmol/mol, is used as cut-off for the diagnosis of diabetes. Diagnosis should be confirmed with a repeat HbA_{1c} test. [4,5]

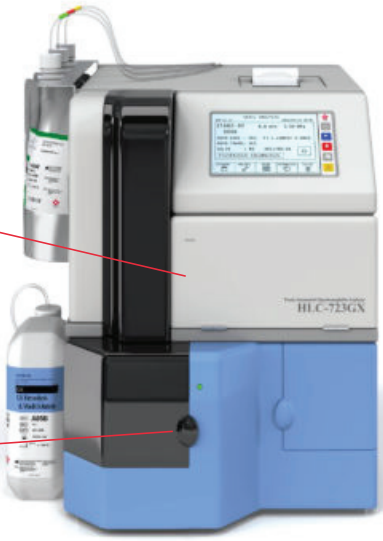
3. For treatment follow-up.

Lowering HbA_{1c} to below or around 7 %, or 53 mmol/mol, has been shown to reduce micro-vascular and neuropathic complications of type 1 and type 2 diabetes. HbA_{1c} of ≥ 7 %, or 53 mmol/mol, should initiate or change therapy to reach an HbA1c level of < 7 %, or 53 mmol/mol. Relevant changes in serial measurements of HbA_{1c} testing serve as the guide to changes in therapeutic regimes. [6,7]

The Coefficient of Variation (CV) determines the difference between two serial HbA_{1c} measurements.
At a medical decision point of 7 %, or 53 mmol/mol, a healthcare provider should be able to conclude that a significant difference of 0.5 %, or 5 mmol/mol, is caused by a change in glycaemic control of a patient and not by the analytical imprecision. For that reason the CV% of the method should be ≤ 2.4 %. [8]

"…95 % of the laboratories using a method from Tosoh were able to meet the criteria of having an analytical CV% of ≤ 2.4 %!" [8]





Stable HbA1c result with variant detection in 2.2 minutes,

The GX provides you exceptional Operational Simplicity...

- Cap piercing capability minimises manual handling.
- Positive sample identification via barcode reader (optional).
- Up to 10 samples per batch.
- Automated daily maintenance.
- A user friendly touch screen enables easy instrument operation.
- Simple finger tight connectors permit quick, convenient and easy replacement of columns and pre-filters.
- Constant visual monitoring of buffer consumption with customisable alarm.
- Integration to Tosoh's data management software (optional) for full data management capabilities including:
- Patient linked result validation
- Chromatogram review with overlay and library facility
- Full QC-package including Levey-Jennings charts
- Reagent logging and audit trail
- Data storage and full result archiving

- Unique TSKgel column and optimal column temperature control guarantee stable results.

The GX: the perfect solution for reliable diabetic patient monitoring!

- H bA_{1c} results directly determined with less than 1 % CV and reportable to 2 decimal places.
- R esults unaffected by the presence of the most common haemoglobin variants or haemoglobin derivatives such as labile HbA_{1c} and carbamylated - or acetylated haemoglobin.
- H bA_{1c} results traceable to the NGSP / DCCT and IFCC.

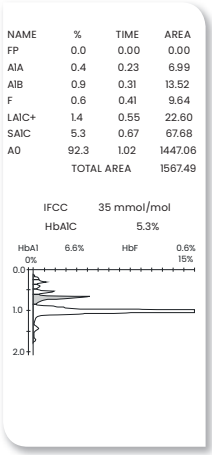
	Intra-Assay precision			Inter-Assay precision	
N = 30	Mean HbA_{1c} (%)	CV (%)	N = 91	Mean HbA_{1c} (%)	CV (%)
Normal value	4.97	0.41	Normal value	5.28	0.89
Elevated value	9.25	0.29	Elevated value	10.11	0.28

Source: Evaluation de l'automate HLC-723GX Tosoh Bioscience pour le dosage de l'hémoglobine A1c. Protocole EH12-08. Fonfrède et. al. Laboratoire de biochimie métabolique, Groupe Hospitalier Pitié-Salpêtrière, APHP, Paris, France.

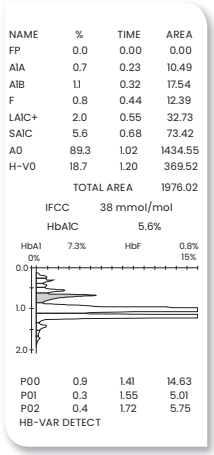
Best-in-class chromatographic separation!

- Separation of labile A_{1c} from stable A_{1c} is achieved without loss of precision or resolution and without manipulating the sample or using mathematical algorithms.

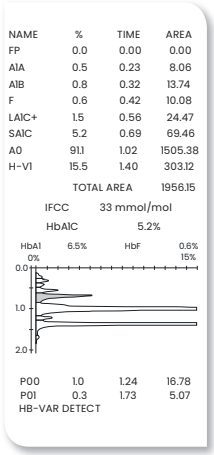
Non-diabetic Patient*



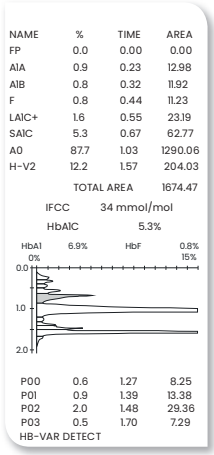
HbD Patient*



HbS Patient*



HbC Patient*



* HbA_{1c} is reportable and in the presence of the most common variants the result is flagged.

Technical Specifications

Principle	Cation Exchange HPLC
Parameter	HbA1c (s-mc)
Analysis Tlme	2.2 Minutes / Sample
Samples	Whole Blood And Diluted Samples
Sample Volumes	3 PL (Whole Blood) 120 PL (Diluted Samples)
Sampling Method	Cap-piercing For Primary Tubes
Sample Capacity	10 + 2 (CAL Port) Built-in Type
Sample Tubes	Primary Tubes (Diameter x Length mm): 12X75. 15X75, 100, 15X 100 Sample Cup
Barcode Reader	Optional
Column	TSKgel HSi Non-porous column
Column Connection	Finger-tight type
Detection Method	2 Wave Absorption / LED Absorption Photometer (415 nm)
Display & Input	Touch Screen Panel
Output	Thermal Printer, USB
Data Storage	up To 800 samples on Board,

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