

HAEMOGLOBINS | POINT OF CARE | INFECTIOUS DISEASE | CLINICAL CHEMISTRY

Premier Hb9210™

The Premier Choice for HbA1c Testing



Difficult Demands

1. Diabetes, the Global Challenge

425 million people are estimated to have diabetes, with its treatment & management costing at least 727 billion USD in 2017. The worldwide prevalence is expected to rise by 48% to 629 million by 2045¹.

Requirement: Cope with ever increasing workloads.

2. Increasing Laboratory Demands

With pressure to consolidate workloads & reduce costs, the speed, performance and ease of analysis becomes ever more important.

Requirement: Provide fast HbA1c results with minimal user intervention.

3. HbA1c as a Diabetic Marker

The use of an HbA1c result, increasingly in two decimal places, for diabetes diagnosis, monitoring & identification of high risk patients demands an extremely high level of precision.

Requirement: Accurately & precisely report HbA1c in IFCC & NGSP units.

4. Abnormal Haemoglobins

Abnormal hemoglobins are the most prevalent monogenic disorder, with HbS present in up to 788,000 newborns annually.² The importance of minimizing interference with the HbA1c result, common with ion-exchange HPLC, has risen with increased global migration.

Requirement: Report a precise and accurate HbA1c result in the presence of abnormal hemoglobins.

1. IDF Diabetes Atlas, 8th Edition, 2017

2. Global epidemiology of sickle haemoglobin in neonates. Lancet. 2013 January 12; 381(9861): 142–151.



A Clear Solution

With a range of methodologies available & increasing demands from clinicians for a fast, accurate HbA1c result, it does not need to be difficult to choose the best instrument for your laboratory.

Insist on boronate affinity HPLC to meet all of your essential requirements:

	Boronate Affinity HPLC	Immunoassay	Capillary Electrophoresis	Ion-Exchange HPLC
1. Speed	✓	✓	✓	✓
2. Capacity	✓	✓	x	x
3. Precision	✓	x	✓	✓
4. Accuracy	✓	?	✓	✓
5. Lack of Interference	✓	?	✓	x
6. Operator Friendly	✓	✓	x	x
7. Cost Effective	✓	✓	?	?

Real World Performance

When instruments are used in a clinical environment accuracy claims need to be reflected in EQA and evaluation performance. The clean separation of boronate affinity and the reliability of HPLC is a standard other platforms strive to match.

“HbA1c% values measured using the Premier Hb9210 are accurate and precise as demonstrated by the excellent correlation between assays and the imprecision studies performed. The TAT and cost per reportable test showed a significant decrease.”

Arias-Stella et al. - Henry Ford Hospital, Detroit. AACC 2013 Poster Presentation

“For GH2-06, values were assigned by only two NGSP SRLs (boronate affinity HPLC only) due to presence of HbS trait. Three methods showed a clear positive bias due to HbS.”

Dr. R. Little, NGSP Steering Committee. CAP 2012 GH2-B Report.

Introducing the Premier Hb9210™

Our patented boronate affinity methodology offers you accurate & precise results, virtually free from interference, in a rapid & highly scalable package.

Delivering substantial workflow benefits, the platform is ideal for the most demanding laboratory & clinical environments.



Accurate & Precise

The consistency of HPLC with the clean separation of boronate affinity gives you repeatable, accurate results every time. The Premier Hb9210™ is certified to report in the following units:

- IFCC (mmol HbA1c/mol Hb)
- NGSP (% HbA1c)

You can also rely on best in class precision, linearity & specificity:

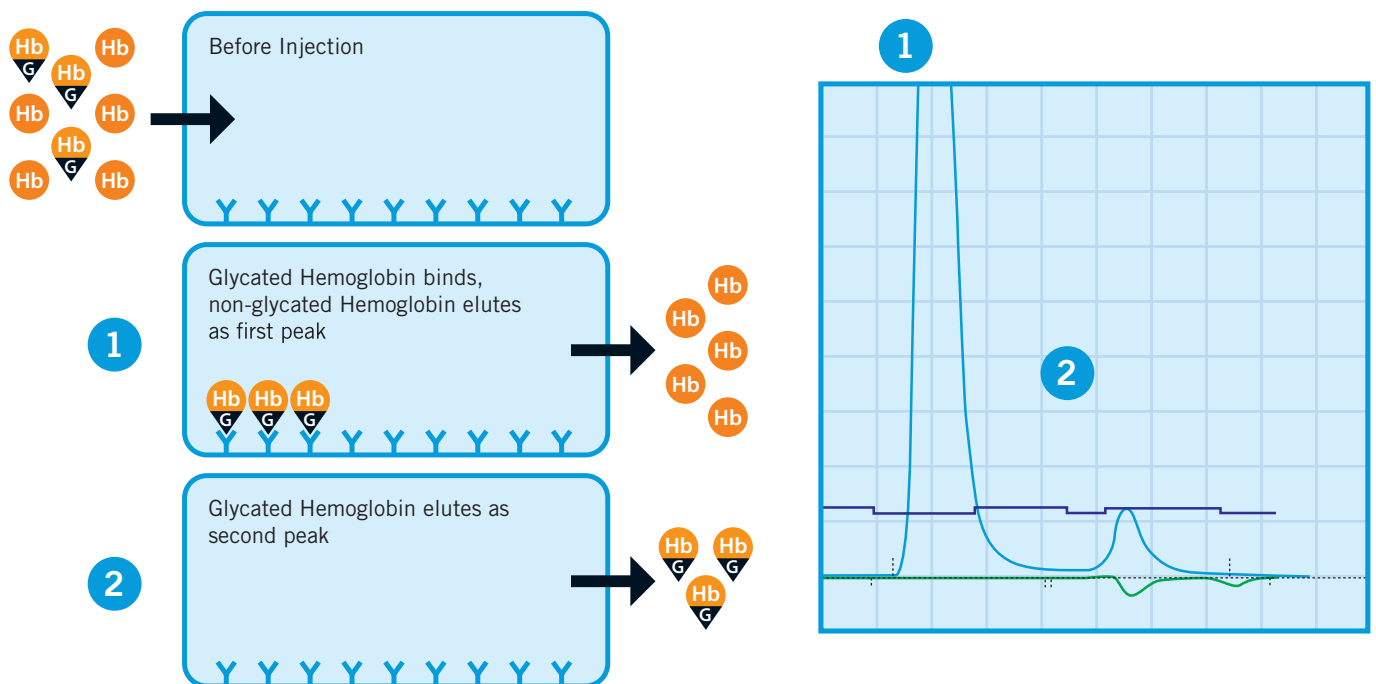
- Precision: Intra-run CVs below 2% (NGSP) / 3% (IFCC) guarantee a reliable, repeatable result.
- From 18-179 mmol/mol, 3.8-18.5% HbA1c ensures accuracy for the whole diabetic population
- Specificity: minimal interference from variants, interferents, matrix effects & sample freezing.

The Boronate Affinity Advantage

The Premier Hb9210™ uses patented boronate affinity HPLC to detect all of the glycated Hb species present.

The final HbA1c result is determined from a simple peak area fraction, making result interpretation extremely straightforward as there are only two peaks on the chromatogram:

- 1 one non-glycated (all other hemoglobin types)
- 2 one glycated (directly correlated to the HbA1c result)



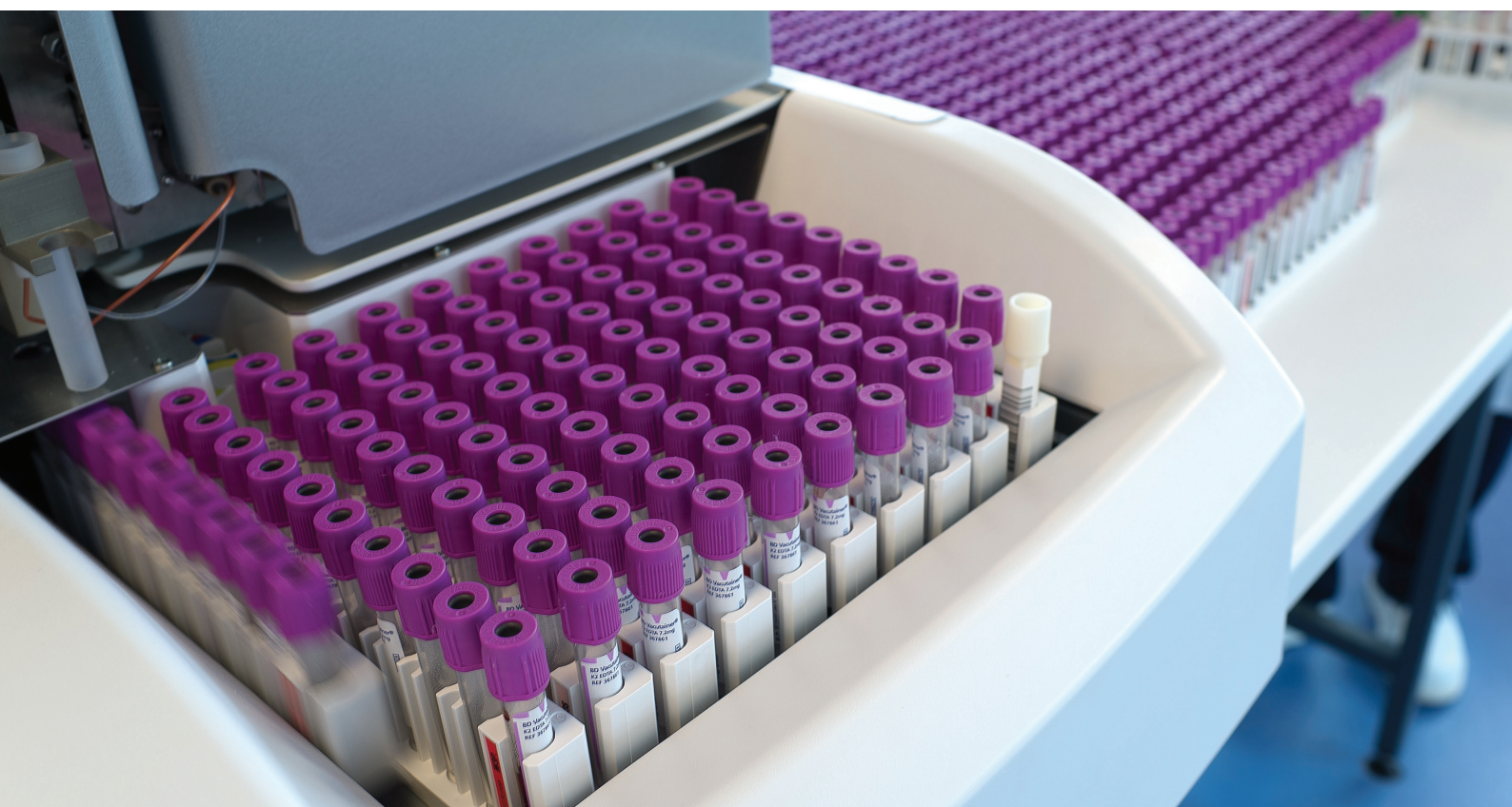
Uniquely this offers:

- No interference from common – and virtually all other hemoglobin variants
 - » No issue with reporting an unrequested genetic parameter
 - » Report HbA1c results with confidence
- Automated validation of the chromatography
 - » Eliminates operator intervention
 - » Removes subjective interpretation
 - » Allows automatic release to the LIS

Fast & High Capacity

Sample analysis in just 75 seconds delivers a throughput of 48 tests per hour.

Capacity of 210 patient samples gives flexibility & capacity to all medium & high throughput laboratories.



Total Laboratory Automation

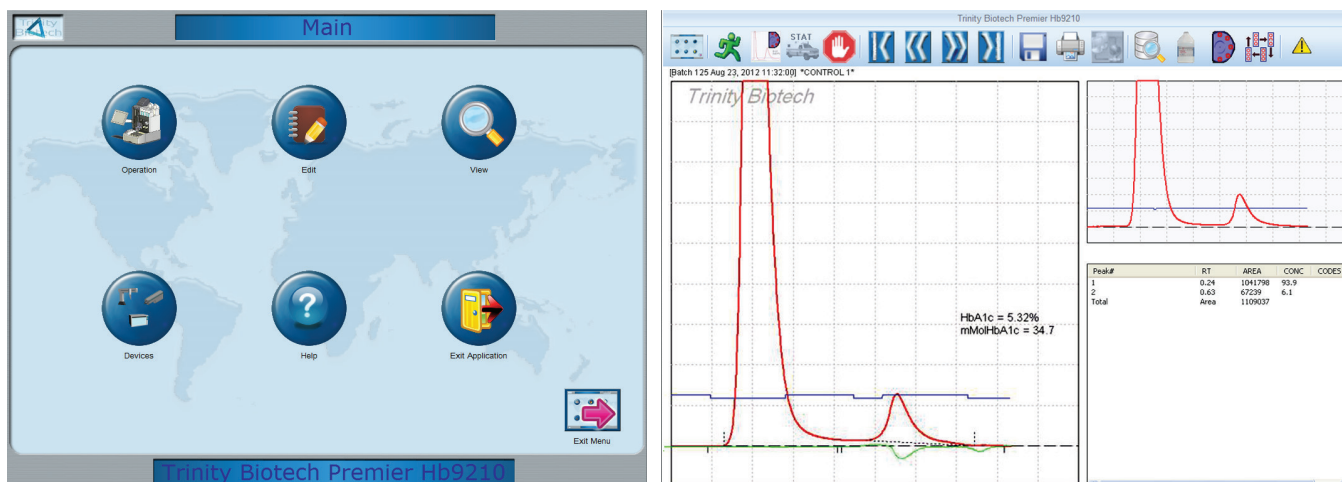


The Premier Hb9210™ is fully compatible with the Inpeco® FlexLab® Total Laboratory Automation solution. The FlexLab® automatically feeds the analyzer with tubes through a dedicated connection. Patient samples are directly presented to the analyzer without the need for operator intervention; optimizing turnaround time, ensuring full traceability and improving overall laboratory efficiency. The new Total Laboratory Automation feature allows the Premier Hb9210™ to be competitive in any high throughput laboratory with a FlexLab®.

The Premier Hb9210™ connection with the Inpeco® FlexLab® is the first of many future Total Laboratory Automation solutions projects to come; both with our partner Inpeco® and with other Total Laboratory Automation solutions providers.

Inpeco Group is the global leader in Total Laboratory Automation solutions and has manufacturing agreements with both Abbott and Siemens.

Software & Connectivity



The Premier Hb9210 software combines operator ease-of-use with advanced data management facilities & LIS integration.

The icon based touch-screen interface enables instant access to instrument operation, options, results & reagent options.

Barcode entry of reagent, QC & sample data eliminates transcription errors and speed of data entry. A full audit trail allows for maximum quality assurance and regulatory compliance.

Reagents & Consumables



Reagents for the Premier Hb9210™ are provided in a pack format, with a different pack available for low, medium & high workloads.

Each pack contains all of the reagents and analytical columns required to perform the requisite number of patient tests, with sufficient reagents for your calibration & quality control program. Calibrator & control materials are available separately.

Together this allows for simplified inventory management & transparent pricing based on a guaranteed number of patient samples.

Specifications

Operation:	Intended Use	For in vitro diagnostic quantitative determination of hemoglobin A1c (HbA1c) in whole blood from venous draw and finger stick. For in vitro diagnostic use only.
	Elements of Analysis	Quantification of glycated hemoglobins
	Principle	Patented Boronate Affinity HPLC
	Automation	Completely Automated
	Operation	Continuous
	Test Time	75 seconds
	Instrumentation Control	Windows Operating System with Proprietary Assay Software
	Results Output	Display and Print
	Printout	Automatic, User Select
Sampling:	Sample capacity	210 samples, with continuous sample loading capabilities
	Sample Types	Whole blood, hemolysates made from whole blood or packed red blood cells. Blood can be fresh or thawed from frozen state. Venous EDTA, Heparin or Sodium Fluoride or Finger Stick
	Minimum readable division	IFCC: One decimal place. NGSP Two decimal places.
	Minimum sample requirement	10 µL (whole blood to make 1:150 hemolysate dilution) 0.5mL (whole blood to make direct injection)
	Sample ID	Operator Input or Bar Code Reader
Performance:	Standards / Traceability	IFCC, NGSP
	Reporting Units	mmol/mol (IFCC) & % HbA1c (NGSP / DCCT)
	Equation Used for Final HbA1c Value	$\text{mmol/mol} = (\% \text{HbA1c} - 2.15) / 0.0915$ $\% \text{HbA1c} = 0.588 * \% \text{GHb} + 1.706$
	Calibration	Previous IFCC/NGSP calibration used for each sample
	Controls	With each run per clinical laboratory policies
	C.V.	<2.0% NGSP / <3% IFCC
Methodology:	Column	Boronate Affinity Matrix
	Column Matrix	Replenished, Re-Used
	Reagents	Boronate Affinity Chemistry
	Column temperature	55.0°C
	Detector	LED single wavelength detector 413 ± 2nm
	Solution Phases	2
	Optical Phases	1
	Chromatography Integration	Peak Separation and Area Determination
	Detector UV Wavelength	413 nM
	Detector UV Light	LED
	Environmental:	Safety Standards for Electrical Equipment for Lab and IVD Use
Electromagnetic Compatibility		EMC Certified
Dimensions		74cm (H) x 54cm (W) x 66cm (D)
Weight		62kgs
Laboratory Interface		ASTM

To explore the Trinity Biotech solution that is right for your laboratory, please contact us now or visit our website at www.trinitybiotech.com