

Certificate of Analysis				
Production Date		2021-12-27		
Intended Use	This analytical column is intended for use with the Premier Hb9210 HbA1c An only. No substitutions are permitted, registered, cleared or authorized. No uses are intended, registered, cleared or authorized. The Premier Hb9210 system is intended for the quantitative measurem.			
	hereoglobin A1c (HbA1c) in human capillary and venous whole blood. HbA1c is used for the monitoring of long-term glycemic control in individuals with diabetes mellitus. For <i>in vitro</i> diagnostic use only.			
09-06-0046 Lot 13002				

## Performance Analysis

	Fenomiance An	aiysis	
	-	CCEPTABILITY	
Standard	Baseline flat and quiet with no deflection higher than 5 mm above normal.		
Result		ith no deflection on the printed	
	chromatogram greater th	han 5mm above the normal.	
	CHROMATOGRAF	PHY ACCEPTABILITY	
Standard		hape, resolution and separation good	
Result		ted peak shape, resolution and	
	separation are good.		
	ACCURACY	AND LINEARITY	
Standard	Pool linearity set (with traceability to IFCC standards) recovery wit		
o tantati a	limits.		
Result	The pool linearity set recovery is within acceptable limits.		
	RETENTION	TIME – PEAK 1	
Standard		en 0.20 and 0.30 Minutes.	
Result	The recovery of peak 1 is between 0.20 and 0.30 minutes .		
	DETENTION		
Standard	RETENTION TIME – PEAK 2		
Result	Peak 2 recovery between 0.58 and 0.68 Minutes. The recovery of peak 2 is between 0.58 and 0.68 minutes		
Result		setween 0.00 and 0.00 minutes	
	DRIFT - %HbA1c V	WITH CALIBRATOR 1	
Standard		drift 0.0 to 0.2	
Result	The standard drift i	s between 0.0 and 0.2.	
	DRIFT - %HbA1c V	WITH CALIBRATOR 2	
Standard	Standard Drift 0.0 to 0.3		
Result	The standard drift is between 0.0 and 0.3		
	BORONATE AFFINITY A		
Standard		BORONATE AFFINITY ACTIVITY ACCEPTABILITY Acceptable total peak area count for C-trait and normal patient sample.	
Result		The total peak area count for C-trait and normal patient sample.	
	acceptable.		
	AUTHORIZED REPRESENTAT	IVE APPROVAL	
<u> </u>	0	Date:	
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Quality Cont		A COMPANY AND	

09-06-0046 Lot 13002

## SUMMARY AND EXPLANATION OF TEST

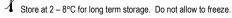
HbA1c - Assessment of hemoglobin A1c has proven useful in the control of diabetes.

Analytical column is performance validated to assure accuracy and precision with the Trinity Biotech assay and system for the measurement of hemoglobin A1c.

Column is ready for use.

ĹÌ	Important Information	Immediately following each column change, please verify that the baseline is smooth and quiet prior to running calibration. Do not proceed if excessive noise is present. Please refer to the system Operator's Manual chapter for "Chromatography" for additional information regarding column change verification and baseline verification checks.
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## STORAGE AND STABILITY



Columns that are refrigerated at 2-8°C are stable until the noted expiry when kept tightly closed. Columns that are placed into service have a limited shelf life and will be gradually consumed once opened, including when removed from the system. Refer to the Column Life section below for details.

EXP See the column label for the expiration date. DO NOT USE after the expiration date.

For in vitro diagnostic use only. Avoid skin contact. Consult the product MSDS for safety information. This
column is used in conjunction with blood testing equipment and warrants handling under universal precaution
procedures for safety.

PRECAUTIONS

ORDERING INFORMATION		
Reference No.	Item	Quantity
09-06-0046	Premier Hb9210 HbA1c Analytical Column	1 each

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	COLUMN LIFE	

Column life will vary depending on diligence in:

- System maintenance (regular and preventative maintenance, as scheduled and using manufacturer-specified items).
- Column maintenance (frit changes, proper shutdowns (nightly/weekends) with WASH reagent to preserve the column).
- Reagent management (closed containers, no topping-off, and replacement of fouled check-valves if reagent is allowed to run dry), and/or
- Calibrator and control management (careful preparation according to PI reconstitution instructions, careful preservation according to PI instructions). \*Note: Use of alternate control materials, not supplied by Trinity Biotech, may result in control drift and reduced column life and thereby voids any implied or written column performance or column life warranty.

Additionally, column life will vary depending on weekly test throughput (low throughput and infrequentlyused systems may not achieve the average number injections).

Any series of columns experiencing reduced life on the same instrument is indication of a system or operation issue (or very low weekly test throughput). Systems in need of routine or preventive maintenance will experience reduced column life. For these systems, although changing the column provides improvement, it is not the cause, and short column life will continue until the issue is properly addressed.

NOTE: Column warranty claims must include the following supporting information: maintenance schedule (date of last PM), column change report (or cycle count) report, chromatography (including cover page and header information), the number of injections, and any follow-up information requests made. Any claim with missing information, as specified above, cannot be processed.

Pour d'autres langues Für andere Sprachen Para otras lenguas Per le altre lingue Dla innych języków

Para outras línguas Για τις άλλες λώσσες För andra språk For andre språk



For other languages, please contact your local distributor



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