



HbA1c Analytical Column (1000)





TRINITY BIOTECH KANSAS CITY, MO 64132 USA www.trinitybiotech.com



TRANSPORT

30 DAYS MAX

- 28°C







7335 2020-04-30 09-06-0046

1 Each

CONT

Trinity Blotech plc Bray, Co. Wicklow, Ireland Tet: +353 1 276 9800 Ear: +353 1 278 9880

Certificate of Analysis

Production Date

2017-04-19

Intended Use

This analytical column is intended for use with the Premier Hb9210TM HbA1c Analyzer only. No substitutions are permitted, registered, cleared or authorized. No other uses are intended, registered, cleared or authorized.

The Premier Hb9210™ system is intended for the quantitative measurement of hemoglobin 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 *in vitro* diagnostic use only. IVD

	Performance Analysis
	BASELINE ACCEPTABILITY
Standard	Baseline flat and quiet with no deflection higher than 5 mm above normal.
Result	The initial baseline is flat with no deflection on the printed chromatogram greater than 5mm about the normal.
	CHROMATOGRAPHY ACCEPTABILITY
Standard	Non-glycated and glycated peak shape, resolution and separation good.
Result	The non-glycated and glycated peak shape, resolution and separation are good.
	ACCURACY AND LINEARITY
Standard	Pool linearity set (with traceability to IFCC standards) recovery within limits.
Result	The pool linearity set recovery is within acceptable limits.
	RETENTION TIME - PEAK 1
Standard	Peak 1 recovery between 0.20 and 0.30 Minutes.
Result	The recovery of peak 1 is between 0.20 and 0.30 minutes .
	RETENTION TIME - PEAK 2
Standard	Peak 2 recovery between 0.58 and 0.68 Minutes.
Result	The recovery of peak 2 is between 0.58 and 0.68 minutes
	DRIFT - %HbA1c WITH CALIBRATOR 1
Standard	Standard drift 0.1 to 0.2
Result	The standard drift is between 0.1 and 0.2.
	DRIFT - %HbA1c WITH CALIBRATOR 2
Standard	Standard Drift 0.1 to 0.3
Result	The standard drift is between 0.1 and 0.3
	BORONATE AFFINITY ACCEPTABILITY
Standard	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 is acceptable.

AUTHORIZED REPRESENTATIVE APPROVAL

Quality Control

Date:

5/1/2017

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.

STORAGE AND STABILITY

A Store at 2 – 8°C for long term storage. Do not allow to freeze.

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 shell life of a few weeks and will be gradually consumed once opened, including when removed from the system.

7

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

PRECAUTIONS

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.

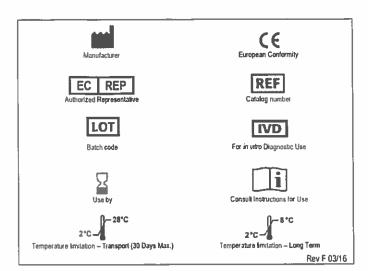
ORDERING INFORMATION			
Catalogue No.	ltem	Quantity	
09-06-0046	Premier Hb9210™ HbA1c Analytical Column	1 each	

COLUMN LIFE

Column life will vary depending on diligence in system maIntenance (regular and preventative maintenance, as scheduled and using manufacturer specified items). Column life will vary depending on weekly test throughput (low throughput and infrequently used systems may not achieve the average number injections.) Column life will vary depending on diligence in column maintenance (enzyme treatments, frit changes, reversing column direction (flipping), proper shutdowns (nightly/weekends) with wash reagent to preserve the column. Column life will vary depending on diligence in reagent management (closed containers, no topping-off, replacement of fouled check-valves if reagent is allowed to run dry). Column life will vary depending on diligence in calibrator and control management (careful preparation according to PI reconstitution instructions, careful preservation according to PI instructions). *Note: Use of atternate control materials, not supplied by Trinity Blotech, may result in control drift and reduced column life and thereby voids any implied or written column performance or column life warrants.

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.





EC REP

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