Premier™ Hb9210

C

HbA1c Analytical Column (1000)

Trinity Biotech

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

LOT 12802
2024-11-30
REF 09-06-0046
CONT 1 Each

IVD

EC REP
Trinity Biotech plc
Bray, Co. Wicklow, Ireland
Tel: +353 1 276 9800
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TRANSPORT 30 DAYS MAX 2°C – 28°C

LONG TERM STORAGE 2°C – 8°C

05-02-0010

Certificate of Analysis

Production Date	2021-11-30
Intended Use	This analytical column is intended for use with the Premier Hb9210 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

09-06-0046 Lot 12802

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 above 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 0.0 to 0.2
Result	**The standard drift is between 0.0 and 0.2.**
DRIFT - %HbA1c WITH CALIBRATOR 2	
Standard	Standard Drift 0.0 to 0.3
Result	**The standard drift is between 0.0 and 0.3**
BORONATE AFFINITY ACTIVITY 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

Melanie Rankin
Quality Control

Date: 2021-12-06

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.

	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.

STORAGE AND STABILITY

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 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.

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

Reference No.	Item	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 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 infrequently-used 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.

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www.trinitybiotech.com

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