

Premier
Hb9210

HbA1c Analytical Column (1000)

TRINITY BIOTECH
KANSAS CITY, MO 64132 USA
www.trinitybiotech.comTRANSPORT
30 DAYS MAX
28°CLONG TERM
STORAGE
8°C

LOT

12702

2024-10-31

REF

09-06-0046

CONT

1 Each

EC REP

Trinity Biotech plc
Bray, Co. Wicklow, Ireland
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Fax: +353 1 276 9888

05-02-0010

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.Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych językówPara outras línguas
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For andre språkwww.trinitybiotech.com

For other languages, please contact your local distributor.

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EC REP

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Certificate of Analysis

Production Date 2021-10-25

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**

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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

Quality Control

Date:

2021-10-29