Trinity Biotech

# Affinity Analytical Column

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

LOT 7742
2020-09-30
REF 03-02-0079
CONT 1 Each
EC REP

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IVD

TRANSPORT 30 DAYS MAX 2°C – 28°C

LONG TERM STORAGE 2°C – 8°C

## Certificate of Analysis

| Production Date | 2017-09-25 |
|---|---|
| Intended Use | This analytical column is intended for use with the Ultra2 Affinity HbA1c Analyzer, PDQ Plus, and PDQ Analyzer only. No substitutions are permitted, registered, cleared or authorized. No other uses are intended, registered, cleared or authorized.<br><br>The Ultra2 Affinity HbA1c Analyzer, PDQ Plus, and PDQ Analyzer are 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 0.40 and 0.59 Minutes. |
| Result | **The recovery of peak 1 is between 0.40 and 0.59 minutes** |
| **RETENTION TIME – PEAK 2** | |
| Standard | Peak 2 recovery between 0.90 and 1.20 Minutes. |
| Result | **The recovery of peak 2 is between 0.90 and 1.20 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 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: 10/31/2017

### 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.

| | | |
|---|---|---|
| | **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 of a few weeks and will be gradually consumed once opened, including when removed from the system.

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. | Item | Quantity |
|---|---|---|
| 03-02-0079 | Affinity Analytical Column | 1 each |

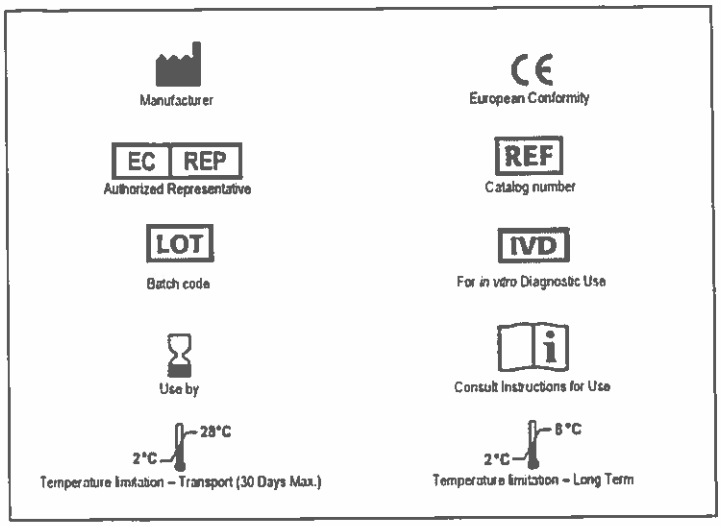
### COLUMN LIFE

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 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.**

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.

PM 10/31/2017

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