

Genesys Analytical Column

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

LOT

15-090-3



2018-10-28

REF

01-05-0017

CONT

1 Each

EC REP

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TRANSPORT
30 DAYS MAX

2°C — 28°C

LONG TERM STORAGE

2°C — 8°C

Certificate of Analysis

Intended Use

The Trinity Biotech Genesys Analytical Column is intended for use with the Ultra2 Genesys Variants Analyzer. No substitutions are permitted, registered, cleared or authorized. No other uses are intended, registered, cleared or authorized.

The Ultra2 Genesys Variants Analyzer is intended for the qualitative detection of hemoglobin variants and quantitative measurement of hemoglobin HbF and HbA2 in human capillary, venous whole blood and dried blood spots. HbF and HbA2 are used for evaluating samples for thalassemia and other hemoglobinopathies.

For *in vitro* diagnostic use only. **IVD**

Performance Analysis

BASELINE ACCEPTABILITY

Standard	Initial baseline flat with no deflection higher than 20 mm above starting base.
Result	The initial baseline is flat with no deflection on the printed chromatogram greater than 20mm.

HbA2 INTEGRATION ACCEPTABILITY

Standard	Baseline separation of A2 from HbA and HbS with symmetrical peak shape.
Result	HbA2 is symmetrical and has baseline separation from HbA and HbS.

PATIENT SAMPLE RESULTS

Standard	Normal and HbC patients integrate A2 and HbC returns to baseline.
Result	HbA2 is integrated and HbC returns to baseline.

FASC RETENTION TIME (QUICK SCAN) – HbF PEAK

Standard	HbF elutes between 0.81 and 0.91 minutes.
Result	The retention time of HbF is between 0.81 and 0.91 minutes.

FASC RETENTION TIME (QUICK SCAN) – HbA PEAK

Standard	HbA elutes between 1.19 and 1.29 minutes.
Result	The retention time of HbA is between 1.19 and 1.29 minutes.

FASC RETENTION TIME (QUICK SCAN) – HbS PEAK

Standard	HbS elutes between 1.50 and 1.60 minutes.
Result	The retention time of HbS is between 1.50 and 1.60 minutes.

FASC RETENTION TIME (QUICK SCAN) – HbC PEAK

Standard	HbC elutes between 1.75 and 1.85 minutes and returns to baseline.
Result	The retention time of HbC is between 1.75 and 1.85 minutes.

CROSS COLUMN PRESSURE

Standard	The cross-column pressure is less than 75bar at 1.5mL/minute.
Result	At 1.5mL/min the cross-column pressure is less than 75bar.

AUTHORIZED REPRESENTATIVE APPROVAL

Quality Control

Date:

11/17/2016

Genesys Analytical Column

REF 01-05-0017

1 each

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

Para outras línguas
Για τις άλλεςλώσσες
Für andra språk
For andre språk



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SUMMARY AND EXPLANATION OF TEST

Utilizing a High Performance Liquid Chromatography (HPLC) system hemoglobins are separated, quantified and presumptively identified by comparison to reference peaks of Hb F, A, S and C. The ion-exchange column that has been equilibrated with respect to pH and ionic strength is used to separate the hemoglobin species.

*ultra*² GeneSys Analytical Columns are performance validated to assure accuracy and precision with our assays and systems for the measurement of hemoglobin species.

The Column is ready for use.

STORAGE AND STABILITY

Store at 2 – 8°C for long term storage.

Columns that are refrigerated at 2-8°C are stable for two years 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 placed into service.

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

	Important Information	Allow the column to warm to room temperature before installing on the instrument. Equilibrate the column at 1.5mL/min at the Standby conditions for 15 minutes before use.
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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

REF	Item	Quantity
01-05-0017	Genesys 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** (frit changes, reversing column direction (flipping), proper shutdowns (nightly/weekends) 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 **control management** (careful preparation according to PI reconstitution instructions, careful preservation according to PI instructions).

Any series of columns experiencing reduced life on the same instrument is an 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 underlying 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 monthly inventory) 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.

USED COLUMN RETURN

Please return used columns each month. Columns are tracked by serial number. Return columns may be tested and reviewed for the purposes of product improvement.

Manufacturer

European Conformity

Authorized Representative

Catalog number

Batch code

For *in vitro* Diagnostic Use

Use by

Consult Instructions for Use

TRANSPORT
30 DAYS MAX
2°C – 28°C
Temperature Limitation

LONG TERM
STORAGE
2°C – 8°C
Temperature Limitation

Rev E
10/15

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W 11/17/16
MSK 11-17-16