



# Trinity Biotech

## Certificate of Analysis

Lot Number: 6860      Manufacture Date: 2016-12-06      Shelf-Life/Expiration Date: 2017-12-31

Product Name: HbA1c (GHb) Controls Kit, 400 $\mu$ l (Levels I & II)

**REF:** 01-04-0015

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

**Intended Use:** Hemoglobin A1c (HbA1c) Controls are intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation. For *in vitro* use only.

**Method of Analysis:** Performance Testing in Comparison to Reference Materials

Standard: HPLC performance validation in comparison to reference standards.

Result:

| Trinity Biotech HbA1c (GHb) Control Kit Lot # 6860       |       |                                     |     |   |     |                                     |      |   |      |
|----------------------------------------------------------|-------|-------------------------------------|-----|---|-----|-------------------------------------|------|---|------|
| Units                                                    |       | Control Level I Lot # 6861          |     |   |     | Control Level II Lot # 6862         |      |   |      |
|                                                          |       | <input checked="" type="checkbox"/> | RNG |   |     | <input checked="" type="checkbox"/> | RNG  |   |      |
| Premier Hb9210                                           |       |                                     |     |   |     |                                     |      |   |      |
| HbA1c (NGSP)                                             | %     | 5.9                                 | 5.6 | - | 6.2 | 10.4                                | 9.8  | - | 11.0 |
| HbA1c (IFCC)                                             | S.I.* | 41                                  | 38  | - | 44  | 90                                  | 83   | - | 97   |
| PDQ                                                      |       |                                     |     |   |     |                                     |      |   |      |
| HbA1c (NGSP)                                             | %     | 5.9                                 | 5.6 | - | 6.2 | 10.4                                | 9.8  | - | 11.0 |
| HbA1c (IFCC)                                             | S.I.* | 41                                  | 38  | - | 44  | 90                                  | 83   | - | 97   |
| Ultra2                                                   |       |                                     |     |   |     |                                     |      |   |      |
| HbA1c (NGSP)                                             | %     | 6.1                                 | 5.8 | - | 6.4 | 10.6                                | 10.0 | - | 11.2 |
| HbA1c (IFCC)                                             | S.I.* | 43                                  | 40  | - | 46  | 92                                  | 85   | - | 99   |
| S.I.* units (Système Internationale) = mmol HbA1c/mol Hb |       |                                     |     |   |     |                                     |      |   |      |

### Traceability to International Reference Standards

Standard: Value assignment to NGSP and IFCC reference materials.

Results: Value assignment to NGSP and IFCC reference materials. Meets specification

### Testing to Confirm Non-Reactivity for Common Pathogens

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HIV-1, HIV-2, and HCV.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

### Approval

Quality Manager:

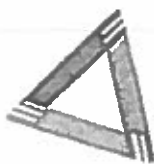
Date:

12-01-2016

4231 E. 75<sup>th</sup> Terrace • Kansas City, MO 64132 • 816-523-7491 • 800-377-4752 • FAX: 816-214-4410

Rev 4, 2015-08-24

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12/1/16



# Trinity Biotech

## Certificate of Analysis

Lot Number: 6850      Manufacture Date: 2016-12-06      Shelf-Life/Expiration Date: 2017-12-31

Product Name: HbA1c (GHb) Calibrator Kit, 400µl (Levels 1 & 2)

REF: 01-04-0018

Manufactured/Distributed By: Trinity Biotech

**Storage Requirements:** Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

**Intended Use:** Hemoglobin A1c (HbA1c) Calibrators are intended for the calibration of quantitative HbA1c affinity assays. For *in vitro* use only.

**Method of Analysis:** Performance Testing in Comparison to Reference Materials

Standard: HPLC performance validation in comparison to reference standards.

Result:

| Trinity Biotech HbA1c (GHb) Calibrator Kit Lot # 6850 |                   |                            |                            |
|-------------------------------------------------------|-------------------|----------------------------|----------------------------|
|                                                       | Units             | Calibrator 1<br>Lot # 6851 | Calibrator 2<br>Lot # 6852 |
| <b>Premier Hb9210</b>                                 |                   |                            |                            |
| HbA1c (NGSP)                                          | %                 | 5.2                        | 12.1                       |
| HbA1c (IFCC)                                          | mMol HbA1c/Mol Hb | 33                         | 109                        |
| <b>PDQ</b>                                            |                   |                            |                            |
| HbA1c (NGSP)                                          | %                 | 5.2                        | 12.1                       |
| HbA1c (IFCC)                                          | mMol HbA1c/Mol Hb | 33                         | 109                        |
| <b>Ultra2</b>                                         |                   |                            |                            |
| HbA1c (NGSP)                                          | %                 | 5.4                        | 12.2                       |
| HbA1c (IFCC)                                          | mMol HbA1c/Mol Hb | 36                         | 110                        |

### Traceability to International Reference Standards

Standard: Value assignment to NGSP and IFCC reference materials.

Results: Value assignment to NGSP and IFCC reference materials. Meets specification

### Testing to Confirm Non-Reactivity for Common Pathogens

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HIV-1, HIV-2, and HCV.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

### Approval

Quality Manager:

Date: 12/21/2016



# Trinity Biotech

## Certificate of Analysis

Lot Number: 6110      Manufacture Date: 2015-10-20      Shelf-Life/Expiration Date: 2017-10-31

Product Name: FASC Position Marker Kit

**REF** 01-04-0042

Manufactured/Distributed By: Trinity Biotech

**Storage Requirements:** Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

**Intended Use:** FASC Position Marker is intended for *in vitro* diagnostic use in laboratory quality control program for the qualitative identification of FASC hemoglobin fractions.

**Method of Analysis:** Performance Testing

Standard: HPLC performance validation.

Result:

| <u>Hemoglobin</u> |           | <u>Retention Time</u>              |           | <u>Retention Time</u>           |
|-------------------|-----------|------------------------------------|-----------|---------------------------------|
| <u>Fraction</u>   | <u>RT</u> | <u>Resolution™ High Resolution</u> | <u>RT</u> | <u>GeneSys™ High Resolution</u> |
| F                 | 1.802     | At least 1.2 minutes               | 2.023     | At least 1.2 minutes            |
| A                 | 4.174     | At least 1.3 minutes after F       | 3.788     | At least 1.3 minutes after F    |
| S                 | 5.786     | At least 1.3 minutes after A       | 5.300     | At least 1.3 minutes after A    |
| C                 | 7.755     | At least 7.0 minutes               | 6.997     | At least 6.8 minutes            |

### Testing to Confirm Non-Reactivity for Common Pathogens

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HBc, HIV-1&2, HCV, HTLV 1&2, HIV 1&2-RNA, Syphilis, HBV-DNA.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

### Approval

Quality Manager:

Date:

10/20/2015



# Trinity Biotech

## Certificate of Analysis

Lot Number: 7140      Manufacture Date: 2017-01-31      Shelf-Life/Expiration Date: 2019-01-31

Product Name: A2+F Control Material Kit

**REF** 01-04-0043

Manufactured/Distributed By: Trinity Biotech

**Storage Requirements:** Store lyophilized material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on storage of reconstituted, aliquot, and diluted materials.

**Intended Use:** A2+F Control Material is intended for *in vitro* diagnostic use in laboratory quality control program for the quantitation of HbA2 and HbF.

**Method of Analysis:** Performance Testing  
Standard: HPLC performance validation.  
Result:

**Resolution™ Quick Scan Assay**

|                     |           |                  |           |
|---------------------|-----------|------------------|-----------|
| Level 1 Control: %F | Mean: 1.9 | Range: 1.5 – 2.3 | Lot# 7141 |
| %A2                 | Mean: 2.2 | Range: 1.8 – 2.6 |           |

|                     |            |                    |           |
|---------------------|------------|--------------------|-----------|
| Level 2 Control: %F | Mean: 7.8  | Range: 6.2 – 9.4   | Lot# 7142 |
| %A2                 | Mean: 5.9  | Range: 4.7 – 7.1   |           |
| %S                  | Mean: 31.5 | Range: 25.2 – 37.8 |           |

**Resolution™ High Resolution Assay**

|                     |           |                  |           |
|---------------------|-----------|------------------|-----------|
| Level 1 Control: %F | Mean: 2.1 | Range: 1.7 – 2.5 | Lot# 7141 |
| %A2                 | Mean: 2.4 | Range: 1.9 – 2.9 |           |

|                     |            |                    |           |
|---------------------|------------|--------------------|-----------|
| Level 2 Control: %F | Mean: 7.7  | Range: 6.2 – 9.2   | Lot# 7142 |
| %A2                 | Mean: 6.2  | Range: 5.0 – 7.4   |           |
| %S                  | Mean: 31.3 | Range: 25.0 – 37.6 |           |

**GeneSys™ High Resolution Assay**

|                     |           |                  |           |
|---------------------|-----------|------------------|-----------|
| Level 1 Control: %F | Mean: 2.1 | Range: 1.7 – 2.5 | Lot# 7141 |
| %A2                 | Mean: 2.4 | Range: 1.9 – 2.9 |           |

|                     |           |                  |           |
|---------------------|-----------|------------------|-----------|
| Level 2 Control: %F | Mean: 7.7 | Range: 6.2 – 9.2 | Lot# 7142 |
| %A2                 | Mean: 6.2 | Range: 5.0 – 7.4 |           |

**Testing to Confirm Non-Reactivity for Common Pathogens**

Standard: Verify test results or confirm certification that source material have been tested and found non-reactive for common pathogens, including HBsAG, HBc, HIV-1&2, HCV, HTLV 1&2, HIV 1&2-RNA, Syphilis, HBV-DNA.

Results: Testing certification confirmed to be negative/non-reactive for common pathogens.

**Approval**

Quality Manager:

Date:

4/6/2017



Trinity Biotech

## Certificate of Analysis

**Product Name:** TRI-stat Liquid Controls Kit

**REF:** 03-06-0011

**Lot Number:** 7220

**Production Date:** 2017-02-02

**Expiration Date:** 2018-03-31

**Manufactured/Distributed By:** Trinity Biotech, Kansas City, Missouri, USA

**Storage Requirements:** Store liquid material in original container at 2-8°C up to the expiration date. See Package Insert for instructions on usage and stability.

**Intended Use:** Tri-stat Liquid Controls are intended for the control of the quantitative HbA1c affinity assay on the Tri-stat Analyzer only. No other control materials may be used with the Tri-stat and will not perform correctly. This control may not be used with other systems. For *in vitro* use only.

**Method of Analysis:** Performance Testing in Comparison to Reference Materials

Standard: HPLC performance validation in comparison to reference standards.

Result:

| Trinity Biotech Tri-stat Liquid Control Kit Lot # 7220   |       |                            |        |     |     |                             |             |
|----------------------------------------------------------|-------|----------------------------|--------|-----|-----|-----------------------------|-------------|
|                                                          |       | Control Level I Lot # 7221 |        |     |     | Control Level II Lot # 7222 |             |
|                                                          |       | Units                      | Target | RNG |     | Target                      | RNG         |
| HbA1c(NGSP)                                              | %     | 7.1                        | 6.3    | -   | 7.9 | 11.8                        | 10.6 - 13.0 |
| HbA1c(IFCC)                                              | S.I.* | 54                         | 45     | -   | 63  | 105                         | 92 - 119    |
| S.I.* units (Système Internationale) = mmol HbA1c/mol Hb |       |                            |        |     |     |                             |             |

### Traceability to International Reference Standards

Standard: Value assignment to NGSP and IFCC reference materials.

Results: Value assignment to NGSP and IFCC reference materials. Meets specification

### Testing to Confirm Non-Reactive for Common Pathogens

Standard: Verify test results or confirm certification that source materials have been tested and found non-reactive for common pathogens, including HBsAg, HBc, HIV 1&2, HCV, HTLV I/II, HIV 1&2-RNA, Syphilis, HBV-DNA.

Result: Verified with testing confirmed to be negative/non-reactive for pathogens.

### Approval

Quality Manager:

Date:

2/24/2017



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 6999

**Expiration Date:** 2018-12-31

**Production Date:** 2016-12-15

**Product Name:** Genesys Diluent Reagent

**REF:** 01-03-0019 (3.8L)

**Shelf-Life:** Two Years (Unopened)

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

**Intended Use:** For Trinity Biotech Hemoglobin Variants IVD Assay Use

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter.  
Meets specification.

#### Identity

**Standard:** Reagent foaming should occur when solution is vigorously shaken.

**Result:** The reagent foams when solution is vigorously shaken. Meets specification.

#### Conductivity

**Standard:** 320-500  $\mu\text{S}/\text{cm}$  @ 25°C

**Result:** Meets specification.

### Approval

Quality Manager.

Date:

12/27/2020



## Certificate of Analysis

**Lot Number:** 7099

**Expiration Date:** 2019-01-31

**Production Date:** 2017-01-26

**Product Name:** System Wash Reagent

**REF:** 01-03-0035 (940mL)

**Shelf-Life:** Two Years (Unopened), 30 Days (Opened)

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

**Intended Use:** For Trinity Biotech A<sub>1c</sub> and Hemoglobin Variants IVD Assay Use

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** A clear, colorless solution is free from observable particulate matter.  
Meets specification.

#### Specific Gravity

**Standard:** 0.985 – 0.995 Nominal

**Result:** Meets specification

### Approval

**Quality Manager:**

**Date:**

1/27/2017



# Trinity Biotech

## Certificate of Analysis

Lot Number: 6305

Expiration Date: 2018-03-31

Production Date: 2016-03-16

Product Name: Mobile Phase 1 Reagent

REF: 01-03-0042 (940mL), 01-03-0040 (3.8L)

Shelf-Life: Two Years (Unopened)

Manufactured/Distributed By: Trinity Biotech

Storage Requirements: Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

Intended Use: For Trinity Biotech Hemoglobin Variants IVD Assay Use

### Method of Analysis:

#### Visual Examination

Standard: A clear, colorless solution free from observable particulate matter

Result: The solution is clear, colorless and free from observable particulate matter. Meets specification.

#### Performance

Standard: No F, A, S, or C Hb peak outside of the RT acceptance range in Quick Scan.

| Result: | Hb Peak | Acceptance Criteria |            |
|---------|---------|---------------------|------------|
|         |         | Low Range           | High Range |
|         | F       | 1.350               | 1.649      |
|         | A       | 2.150               | 2.649      |
|         | S       | 2.750               | 3.249      |
|         | C       | 3.250               | 3.649      |

Meets specification.

#### Performance - Controls

Standard: No test value outside of controls upper and lower limit on HPLC.

Result: Meets specification.

#### Performance - Chromatography

Standard: A1c peak separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control.

Result: A1c peak is separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control. Meets specification.

### Approval

Quality Manager:

Date:

3/16/2016



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 7117

**Expiration Date:** 2019-01-31

**Production Date:** 2017-01-30

**Product Name:** Mobile Phase 2 Reagent

**REF:** 01-03-0044 (940mL), 01-03-0041 (3.8L)

**Shelf-Life:** Two Years (Unopened)

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

**Intended Use:** For Trinity Biotech Hemoglobin Variants IVD Assay Use

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter. Meets specification.

#### Performance

**Standard:** No F, A, S, or C Hb peak outside of the RT acceptance range in Quick Scan.

| Result: | <u>Hb Peak</u> | <u>Acceptance Criteria</u> |                   |
|---------|----------------|----------------------------|-------------------|
|         |                | <u>Low Range</u>           | <u>High Range</u> |
|         | F              | 1.350                      | 1.649             |
|         | A              | 2.150                      | 2.649             |
|         | S              | 2.750                      | 3.249             |
|         | C              | 3.250                      | 3.649             |

Meets specification

#### Performance - Controls

**Standard:** No test value outside of controls upper and lower limit on HPLC.

**Result:** Meets specification.

#### Performance - Chromatography

**Standard:** A1c peak separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control.

**Result:** A1c peak is separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control. Meets specification.

### Approval

**Quality Manager:**

**Date:**

2/7/2017



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 7021

**Expiration Date:** 2018-12-31

**Production Date:** 2016-12-22

**Product Name:** 2 Diluent Reagent

**REF:** 01-03-0059 (940mL), 01-03-0056 (3.8L)

**Shelf-Life:** Two Years (Unopened)

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

**Intended Use:** For use on Trinity Biotech Ultra2 Affinity HbA1c and the Ultra2 Resolution Variants Analyzers.

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter. Meets specification.

#### Baseline Flatness

**Standard:** Flat baseline with no deflection.

**Result:** The baseline is flat with no deflection. Meets specification.

#### Identity

**Standard:** Reagent foaming should occur when solution is vigorously shaken.

**Result:** The reagent foams when solution is vigorously shaken. Meets specification.

#### Lysis

**Standard:** A clear red solution is produced with no turbidity on standing.

**Result:** A clear red solution is produced with no turbidity on standing. Meets specification.

#### Performance

**Standard:** No test value outside of controls upper and lower limit on HPLC.

**Result:** Meets specification.

### Approval

Quality Manager:

Date:

12/29/2016



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 6632

**Expiration Date:** 2018-08-31

**Production Date:** 2016-08-16

**Product Name:** PDQ 2 Reagent

**REF:** 01-03-0065 (940mL)

**Shelf-Life:** 2-Years (*Unopened with seal intact*), 30-Days (*After opening, if installed and capped.*)

**Manufactured and Distributed By:** Trinity Biotech, Kansas City, Missouri, USA

**Storage Reqs:** Keep tightly closed and store in a cool, dry location at 2-28°C, 36-82°F.

**Intended Use:** For Trinity Biotech A<sub>1c</sub> IVD Assay Use

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter.  
Meets specification.

#### Baseline Flatness

**Standard:** Flat baseline with no deflection.

**Result:** The baseline is flat with no deflection. Meets specification.

#### pH Conformance

**Standard:** 8.00 to 9.00

**Result:** Meets specification.

#### Control Performance

**Standard:** No test value outside of controls upper and lower limit on HPLC.

**Result:** Meets specification.

#### PDQ Calibration

**Standard:** %A<sub>1c</sub> raw recovery within +/-0.3% for level 1 and +/-0.5% for level 2.

**Result:** Meets specification.

### Approval

**Quality Manager:**

**Date:**

8/22/2017



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 7105

**Expiration Date:** 2019-01-31

**Production Date:** 2017-01-24

**Product Name:** PDQ Wash Reagent

**REF:** 01-03-0067 (940mL)

**Shelf-Life:** Two Years (Unopened)

**Manufactured/Distributed By:** Trinity Biotech

**Storage Requirements:** Tightly Closed. Cool, Dry Location. (2-28°C, 36-82°F)

**Intended Use:** For Trinity Biotech A<sub>1c</sub> IVD Assay Use

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** A clear, colorless solution is free from observable particulate matter.  
Meets specification.

#### Specific Gravity

**Standard:** 0.985 – 0.995 Nominal

**Result:** Meets specification

### Approval

**Quality Manager:**

**Date:**

1/31/2017



# Trinity Biotech

## Certificate of Analysis

**Product Name:** TRI-stat Reagent Kit

**REF:** 03-06-0010

**Lot Number:** 6969 (11)

**Production Date:** 2017-03-21

**Expiration Date:** 2018-06-30

**Manufactured/Distributed By:** Trinity Biotech, Kansas City, Missouri, USA

**Storage Requirements:** Store refrigerated in an upright position at 2-8°C. **DO NOT FREEZE.**  
See Package Insert for instructions on usage and stability.

**Intended Use:** The Tri-stat Reagent Kit for use with Trinity Biotech Tri-stat Analyzer, is a rapid *in vitro* test for measuring the level of glycated haemoglobin (HbA1c) in human blood from finger stick or venous samples.

### Method of Analysis:

#### Control Performance

**Standard:** No test value outside of controls upper and lower limit on Tri-stat analyzer

**Result:** Meets specification.

#### Whole Blood Performance

**Standard:** No test value outside of controls upper and lower limit on Tri-stat analyzer

**Result:** Meets specification

#### Correlation

**Standard:** No correlation value outside of the lower limit on Tri-stat analyzer ( $r^2 > 0.980$ )

**Result:** Meets specification

#### Key Card Conformance

**Standard:** Tri-stat analyzer accurately displays the reagent calibration information

**Result:** Key card is scanned accurately by the Tri-stat analyzer.

### Approval

**Quality Manager:**

**Date:**

4/5/2017



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 6606

**Expiration Date:** 2018-08-31

**Production Date:** 2016-08-02

**Product Name:** Premier Diluent Reagent

**REF:** 01-03-0097

**Shelf-Life:** 2-Years (*Unopened*)

**Manufactured and Distributed By:** Trinity Biotech, Kansas City, Missouri, USA

**Storage Reqs:** Keep tightly closed and store in a cool, dry location at 2-28°C, 36-82°F.

**Use:** For use with the Premier Hb9210 HbA1c Analyzer No substitutions or other uses are permitted.

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter.  
Meets specification.

#### Baseline Flatness

**Standard:** Flat baseline with no deflection.

**Result:** The baseline is flat with no deflection. Meets specification.

#### Identity

**Standard:** Reagent foaming should occur when solution is vigorously shaken.

**Result:** The reagent foams when solution is vigorously shaken. Meets specification.

#### Lysis

**Standard:** A clear red solution is produced with no turbidity on standing.

**Result:** A clear red solution is produced with no turbidity on standing. Meets specification.

#### Control Performance

**Standard:** No test value outside of controls upper and lower limit on HPLC.

**Result:** Meets specification.

### Approval

**Quality Manager:**

**Date:**

8/2/2016



# Trinity Biotech

## Certificate of Analysis

**Lot Number:** 6685

**Expiration Date:** 2018-09-30

**Production Date:** 2016-09-02

**Product Name:** Premier Diluent Reagent

**REF:** 01-03-0097

**Shelf-Life:** 2-Years (*Unopened*)

**Manufactured and Distributed By:** Trinity Biotech, Kansas City, Missouri, USA

**Storage Reqs:** Keep tightly closed and store in a cool, dry location at 2-28°C, 36-82°F.

**Use:** For use with the Premier Hb9210 HbA1c Analyzer No substitutions or other uses are permitted.

### Method of Analysis:

#### Visual Examination

**Standard:** A clear, colorless solution free from observable particulate matter

**Result:** The solution is clear, colorless and free from observable particulate matter. Meets specification.

#### Baseline Flatness

**Standard:** Flat baseline with no deflection.

**Result:** The baseline is flat with no deflection. Meets specification.

#### Identity

**Standard:** Reagent foaming should occur when solution is vigorously shaken.

**Result:** The reagent foams when solution is vigorously shaken. Meets specification.

#### Lysis

**Standard:** A clear red solution is produced with no turbidity on standing.

**Result:** A clear red solution is produced with no turbidity on standing. Meets specification.

#### Control Performance

**Standard:** No test value outside of controls upper and lower limit on HPLC.

**Result:** Meets specification.

### Approval

**Quality Manager:**

**Date:**

9/12/2016

Premier  
Hb9210

C

## HbA1c Analytical Column (1000)

Trinity Biotech

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



TRANSPORT  
30 DAYS MAX  
2°C



LONG TERM  
STORAGE  
2°C

LOT 6622  
2019-08-31  
REF 09-06-0046  
CONT 1 Each  
EC REP  
Trinity Biotech plc  
Bray, Co. Wicklow, Ireland  
Tel: +353 1 276 9800  
Fax: +353 1 276 9886

### Certificate of Analysis

Production Date 2016-08-31

#### 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**

### 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 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

Date:

9/19/2020

Quality Control

### 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.

|  |                              |                                                                                                                                                                                                                                                                                                                                                       |
|--|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>Important Information</b> | 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 |
|---------------|-----------------------------------------|----------|
| 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 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.



Manufacturer



European Conformity



Authorized Representative



Catalog number



Batch code



For *in vitro* Diagnostic Use



Use by



Consult Instructions for Use



Temperature limitation – Transport (30 Days Max.)



Temperature limitation – Long Term

Rev F 03/16



Trinity Biotech  
Kansas City, MO 64132



Trinity Biotech plc  
Bray Co. Wicklow, Ireland  
Tel. 353 1 2769800  
Fax 353 1 2769888  
[www.trinitybiotech.com](http://www.trinitybiotech.com)



*Handwritten signature/initials*

Premier  
Hb9210

C

## HbA1c Analytical Column (500)



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



TRANSPORT  
30 DAYS MAX  
2°C



LONG TERM  
STORAGE  
2°C

LOT 6621  
2019-08-31  
REF 09-06-0050  
CONT 1 Each  
EC REP  
Trinity Biotech plc  
Bray, Co. Wicklow, Ireland  
Tel: +353 1 278 9800  
Fax: +353 1 278 9888

### Certificate of Analysis

Production Date 2016-08-31

#### 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

### 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 pool linearity set recovery is within acceptable limits. |

#### 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 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

Date:

9/19/2016

Quality Control

#### 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.

|  |                              |                                                                                                                                                                                                                                                                                                                                                       |
|--|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <b>Important Information</b> | 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 |
|---------------|-----------------------------------------|----------|
| 09-06-0050    | 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 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.

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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.



Manufacturer

CE  
European Conformity

EC REP

Authorized Representative

REF

Catalog number

LOT

Batch code

IVD

For in vitro Diagnostic Use



Use by



Consult Instructions for Use

2°C - 28°C

Temperature limitation - Transport (30 Days Max.)

2°C - 8°C

Temperature limitation - Long Term

Rev F 03/16



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Kansas City, MO 64132

EC REP

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CE

*for results  
PH 9/19/2006*