



Trinity Biotech

30143

Certificate of Analysis

Lot Number: 6871

Expiration Date: 2018-11-30

Production Date: 2016-11-11

Product Name: Premier Buffer A Reagent

REF: 01-03-0095 (940mL), 01-03-0080 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

pH Conformance

Standard: 9.27 – 9.43

Result: Meets specification.

Control Performance

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

Result: Meets specification.

Approval

Quality Manager:

Date:

11/11/2016



Trinity Biotech

Certificate of Analysis

Lot Number: 6478

Expiration Date: 2018-06-30

Production Date: 2016-06-24

Product Name: Premier Buffer B Reagent

REF: 01-03-0096 (940ml), 01-03-0081 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

Control Performance

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

Result: Meets specification.

pH Conformance

Standard: 8.00 - 9.00

Result: Meets specification.

Approval

Quality Manager: *Melanie Rombin* **Date:** *6-30-16*



Trinity Biotech

Certificate of Analysis

Lot Number: 6722

Expiration Date: 2018-09-30

Production Date: 2016-09-09

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: *Melanie Rankin* **Date:** 9-16-16



Trinity Biotech

Certificate of Analysis

Lot Number: 6489

Expiration Date: 2018-07-31

Production Date: 2016-07-01

Product Name: Premier Wash Reagent

REF: 01-03-0098

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

Manufactured 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: 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:

8/5/2016



Trinity Biotech

Certificate of Analysis

31384

Lot Number: 6938

Expiration Date: 2018-11-30

Production Date: 2016-12-01

Product Name: Premier Buffer A Reagent

REF: 01-03-0095 (940mL), 01-03-0080 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

pH Conformance

Standard: 9.27 – 9.43

Result: Meets specification.

Control Performance

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

Result: Meets specification.

Approval

Quality Manager:

Date:

12/7/2016



Trinity Biotech

Certificate of Analysis

Lot Number: 6856

Expiration Date: 2018-10-31

Production Date: 2016-10-27

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:

10/31/2016



Trinity Biotech

Certificate of Analysis

Lot Number: 6671

Expiration Date: 2018-08-31

Production Date: 2016-08-26

Product Name: Premier Wash Reagent

REF: 01-03-0098

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

Manufactured 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: 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:

9/2/2016



Trinity Biotech

Certificate of Analysis

Lot Number: 6928

Expiration Date: 2018-11-30

Production Date: 2016-11-29

Product Name: Premier Buffer B Reagent

REF: 01-03-0096 (940ml), 01-03-0081 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

Control Performance

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

Result: Meets specification.

pH Conformance

Standard: 8.00 - 9.00

Result: Meets specification.

Approval

Quality Manager:

Date:

11/29/2014



Trinity Biotech

30900

Certificate of Analysis

Lot Number: 6854

Expiration Date: 2018-10-31

Production Date: 2016-10-27

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:

10/31/2024



Trinity Biotech

Certificate of Analysis

Lot Number: 6928

Expiration Date: 2018-11-30

Production Date: 2016-11-29

Product Name: Premier Buffer B Reagent

REF: 01-03-0096 (940ml), 01-03-0081 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

Control Performance

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

Result: Meets specification.

pH Conformance

Standard: 8.00 - 9.00

Result: Meets specification.

Approval

Quality Manager:

Date:

11/29/2014



Trinity Biotech

Certificate of Analysis

Lot Number: 6679

Expiration Date: 2018-10-31

Production Date: 2016-10-18

Product Name: Premier Buffer A Reagent

REF: 01-03-0095 (940mL), 01-03-0080 (3.8L)

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.

Use: For use with the Trinity Biotech 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.

pH Conformance

Standard: 9.27 – 9.43

Result: Meets specification.

Control Performance

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

Result: Meets specification.

Approval

Quality Manager:

Melanie Hankin

Date: *10-20-16*



Trinity Biotech

Certificate of Analysis

Lot Number: 6671

Expiration Date: 2018-08-31

Production Date: 2016-08-26

Product Name: Premier Wash Reagent

REF: 01-03-0098

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

Manufactured 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: 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:

9/2/2016