



Trinity Biotech

Certificate of Analysis

Lot Number: 8028

Expiration Date: 2019-12-31

Production Date: 2017-12-11

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 Kunkin* **Date:** 12-14-17