

## **Certificate of Analysis**

Lot Number: 7788

Expiration Date: 2019-09-30 Production Date: 2017-09-27

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: 10/6/2017