



Trinity Biotech

Certificate of Analysis

Lot Number: 8688

Expiration Date: 2020-06-30

Production Date: 2018-06-12

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:

6/15/2018