



Trinity Biotech

Certificate of Analysis

Lot Number: 7448

Expiration Date: 2019-06-30

Production Date: 2017-06-05

Product Name: PDQ 1 Reagent

REF: 01-03-0064 (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_{1c} 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.

pH Conformance

Standard: 9.35 to 9.45

Result: Meets specification.

PDQ Control Performance

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

Result: Meets specification.

PDQ Calibration

Standard: %A_{1c} raw recovery within +/-0.3% for level 1 and +/-0.5% for level 2.

Result: Meets specification.

Approval

Quality Manager: _____

Date: _____

6/21/2017