



Trinity Biotech

Certificate of Analysis

Lot Number: 6632

Expiration Date: 2018-08-31

Production Date: 2016-08-16

Product Name: PDQ 2 Reagent

REF: 01-03-0065 (940mL)

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.

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.

Baseline Flatness

Standard: Flat baseline with no deflection.

Result: The baseline is flat with no deflection. Meets specification.

pH Conformance

Standard: 8.00 to 9.00

Result: Meets specification.

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:

8/22/2012

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Rev 4, 2015-12-14