



Trinity Biotech

Certificate of Analysis

Lot Number: 8377

Expiration Date: 2020-03-31

Production Date: 2018-03-12

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 15-28°C, 59-82°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: 8.47 to 8.53

Result: Meets specification.

Control Performance

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

Result: Meets specification.

Approval

Quality Manager:

Date:

3/19/2018

PH 10/16/17