



Trinity Biotech

Certificate of Analysis

Lot Number: 7389

Expiration Date: 2019-05-31

Production Date: 2017-05-11

Product Name: Mobile Phase 1 Reagent

REF: 01-03-0042 (940mL), 01-03-0040 (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 Trinity Biotech Hemoglobin Variants 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.

Performance

Standard: No F, A, S, or C Hb peak outside of the RT acceptance range in Quick Scan.

Result:	Hb Peak	Acceptance Criteria	
		Low Range	High Range
	F	1.350	1.649
	A	2.150	2.649
	S	2.750	3.249
	C	3.250	3.649

Meets specification.

Performance - Controls

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

Result: Meets specification.

Performance - Chromatography

Standard: A1c peak separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control.

Result: A1c peak is separated from HbF peak in the FASC control.

Peaks occurring earlier than 0.2 minutes are less than 20mm.

A2 peak has baseline separation from HbA and HbS in the FASC control. Meets specification.

Approval

Quality Manager:

Date:

5/18/2017