Medical Electronic Systems	Title: QwikCheck DFI Kit Production File			
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Appendix 2 COA and Batch Release Form

Batch Details					
Product Name	QwikCheck™ DFI Kit	Batch Number	070425		
Product Number	A-CA-01873-00 / EU-A-CA-01940-00	Expiration date	APR-2026		
Storage Conditions	2°C-8°C (36°F-46°F)	Number of Kits	78		

Visual and pH QC of Bulk materials					
Kit Component	Test	Pass Criteria (test specifications)	Results Pass/Fail		
Lys 1 Solution	Turbidity	Clear	Pass		
	Color	Colorless	Pass		
	рН	7.5 +/- 0.5	Result: 7.51		
			Pass		
Lys 2 Solution	Turbidity	Clear	Pass		
	Color	Colorless	Pass		
	рН	10.0 +/- 0.5	Result: 10.00		
			Pass		
Lys 2 Powder	Color	White	Pass		
Diluent Solution Washing Solution	Turbidity	Clear	Pass		
	Color	Colorless	Pass		
	рН	7.0-7.5	Result: 7.19		
			Pass		
Fixative	Turbidity	Clear	Pass		
	Color	Colorless	Pass		
Giemsa A	Homogeneity	Homogenous, no precipitation	Pass		
	Color	Dark Blue	Pass		
Ciaraa D	Turbidity	Clear	Pass		
Giemsa B	Color	Colorless	Pass		
	Perfo	ormance Testing			
Test	Definition		Results Pass/Fail		
Functional Performance	Ability to complete a test run using the DFI kit components of the specified batch (Appendix 3)		Pass		

This document confirms that these parameters have been tested in a QC laboratory and have been satisfactorily completed.

D.K

Laboratory Technician

SZ

Production Laboratory Manager

15-Apr-25

Date

15-Apr-25 Date