



**Appendix 2
COA and Batch Release Form**

Batch Details			
Product Name	QwikCheck™ DFI Kit	Batch Number	010426
Product Number	A-CA-01873-00 / EU-A-CA-01940-00	Expiration date	APR 2027
Storage Conditions	2°C-8°C (36°F-46°F)	Number of Kits	100

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
	pH	7.5 +/- 0.5	Result: 7.56 Pass
Lys 2 Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
	pH	10.0 +/- 0.5	Result: 10.03 Pass
Lys 2 Powder	Color	White	Pass
Diluent Solution Washing Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
	pH	7.0-7.5	Result: 7.18 Pass
Fixative	Turbidity	Clear	Pass
	Color	Colorless	Pass
Giemsa A	Homogeneity	Homogenous, no precipitation	Pass
	Color	Dark Blue	Pass
Giemsa B	Turbidity	Clear	Pass
	Color	Colorless	Pass
Performance 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.



Laboratory Technician


Clinical Director

 23-APR-2026
Date

 26-APR-2026
Date