



**Appendix 2**  
**COA and Batch Release Form**

Batch Details			
<b>Product Name</b>	<b>QwikCheck™ DFI Kit</b>	<b>Batch Number</b>	140126
<b>Product Number</b>	A-CA-01873-00 / EU-A-CA-01940-00	<b>Expiration date</b>	JAN 2027
<b>Storage Conditions</b>	2°C-8°C (36°F-46°F)	<b>Number of Kits</b>	35

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: 7.50 Pass
Lys 2 Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
	pH	10.0 +/- 0.5	Result: 10.01 Pass
Lys 2 Powder	Color	White	Pass
Diluent Solution Washing Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
	pH	7.0-7.5	Result: 7.22 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)		<b>Pass</b>

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

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**Laboratory Technician**\_\_\_\_\_  
26-Jan-2026**Date**\_\_\_\_\_  
**Clinical Director**\_\_\_\_\_  
27-Jan-2026**Date**