

	Title: DFI Kit Production File		Page 16 of 20
	Work / Test Instruction No: WI1-125	Revision: 02	Effective Date: 01_MAY_2024

APPENDIX 5: DFI KIT FINAL QC and LOT RELEASE FORM # 5

Certificate Of Analysis	
Product Name: QwikCheck™ DFI Kit	Batch No.: 20240701
Product Catalog No.: A-CA-01873-00	Expiry Date: 31 st JUL 2025
Storage Condition: 2-25°C (36-77°F)	Test Date: 01 st JUL 2024

Kit Components:	Critical Attributes	Pass Results	Results Pass / Fail
Lys A Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
Lys A Powder	Color	White	Pass
Diluent Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
Fixative Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
Giemsa A	Turbidity	Clear, no precipitation	Pass
	Color	Dark Blue	Pass
Giemsa B	Turbidity	Clear, no precipitation	Pass
	Color	Colorless	Pass
Functional Assay (performed with Normozoospermia sample)	Differential Halos	Clear differences in Fragmented and Non-fragmented sperms seen	Pass

**DFI Kit Batch Release Form**

Batch #: 20240701

Expiration Date: 31st JUL 2025

Item #	Component	Quantity	Description	Status
1	Diluent (for sample see chart)	1	15 mL dropper bottle	V
2	Low Gelling Agarose (LMA) tubes	10	0.5 ml tubes	V
3	Agarose coated Slides	1	10 -Slide Holder Boxes	V
4	Lys A Powder	10	2 mL amber vials	V
5	Lys A Solution	1	15 mL wide mouth bottle	V
7	Fixative	1	15 mL Dropper bottle	V
8	Giemsa A	1	15 mL Dropper bottle	V
9	Giemsa B	1	15 mL Dropper bottle	V
10	Coverslips 40mm x 22mm	1	10-Coverslip Holder box	V
QC Tests				Pass/Fail
APPROVALS				
Name	Position	Date	Signature	
D.K	Laboratory Technician	04 th JUL 2024	D.K	
S.Z	Production Lab Manager	04 th JUL 2024	S.Z	