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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.: 20240520	
Product Catalog No.: A-CA-01873-00	Expiry Date: 30 <sup>th</sup> APR 2025	
Storage Condition: 2-25°C (36-77°F)	Test Date: 20 <sup>th</sup> MAY 2024	

Kit Components:	Critical Attributes	Pass Results	Results Pass / Fail
Los A Caladan	Turbidity	Clear	Pass
Lys A Solution	Color	Colorless	Pass
Lys A Powder	Color	White	Pass
D.1	Turbidity	Clear	Pass
Diluent Solution	Color	Colorless	Pass
Fixative Solution	Turbidity	Clear	Pass
	Color	Colorless	Pass
Giemsa A	Turbidity	Clear, no precipitation	Pass
	Color	Dark Blue	Pass
	Turbidity	Clear, no precipitation	Pass
Giemsa B	Color	Colorless	Pass
Functional Assay (performed with Normozoospermia sample)	Differential Halos	Clear differences in Fragmented and Non-fragmented sperms seen	Pass

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	DFI Kit Batch Release Form					
Batch #: 20240520				Expiration Date: 30 <sup>th</sup> APR 2025		
Item #	Component		Quantity	Description		Status
1	Diluent (fo	or 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	10 Coverslips 40mm x 22mm		1	10-Coverslip Holder box		V
	QC Tests					Pass/Fail
APPROVALS						
Na	ame	Position		Date	Signature	
С	O.K	Laboratory Technician		23 <sup>rd</sup> MAY 2024	の.犬	
S.Z		Production Lab Manager		23 <sup>rd</sup> MAY 2024	5.3	

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