

Biotherapeutics Section, TGA - Biotherapeutics

Displayed in Version: 6.0.2

Report Generated: 22/10/2021 3:24:42PM (UTC+11)

SpectraMax M5 reader

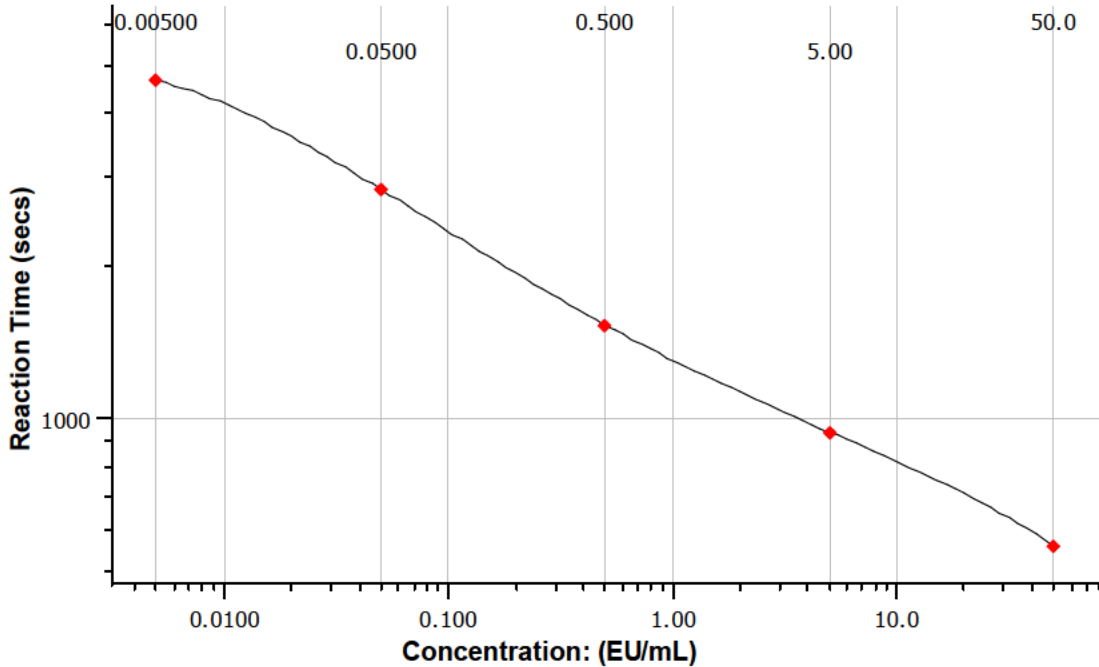
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Lonza - WinKQCL Version 6.0.2

Page 1 of 5

Performed By [REDACTED] (VA)	LAL Lot No.: VL136G9FFR	Exp: 30/06/2022	Time: 1:37:17PM (UTC+11)
KQCL - Routine Test	Water Lot No.: 0000830072	Exp: 1/03/2022	Date: 22/10/2021
Template: 2021 Oct 22 s 22 Pfizer & Covid Vaccine	Endotoxin Lot No.: 0000837915	Exp: 30/09/2023	SPECTRAMax M5
Temperature: 36.8°C - 37.1°C			S/N mv05705
Linear Regression:	Correlation Coefficient = -0.999	Slope = -0.232	Y-Intercept = 3.136
PowerCurve:	A = 3.1155	B = -0.2222	C = 0.0340
		D = -0.0056	E = -0.0074



**Standards Results**

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4866	4886	< 0.00500
		A 2	4906		
Std. 1	0.00500	B 1	4659	4663	0.00500
		B 2	4667		
Std. 2	0.0500	C 1	2824	2840	0.0500
		C 2	2856		
Std. 3	0.500	D 1	1529	1533	0.500
		D 2	1537		
Std. 4	5.00	E 1	929	940	5.00
		E 2	951		
Std. 5	50.0	F 1	552	559	50.0
		F 2	566		

**Product Results**

Redacted under section 22 of the FOI Act

Signed By: [REDACTED] (et1-sig) Date/Time: 22/10/2021 3:24:36PM(UTC+11)

Reviewed By: [REDACTED] e-signature not applied Date/Time: [REDACTED]

**R REVIEW ONLY**

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Performed By : ██████████ (VA)	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 1:37:17PM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000830072	Exp : 1/03/2022	Date : 22/10/2021
Template : 2021 Oct 22 <sup>s22</sup> Pfizer &	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAmax M5
<sup>section 22</sup> Covid Vaccine				S/N mv05705
Temperature : 36.8°C - 37.1°C				
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.232	Y-Intercept = 3.136	
PowerCurve :	A = 3.1155	B = -0.2222	C = 0.0340	D = -0.0056
				E = -0.0074

**Product Results**

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Unique Id: 000336-001354		Pfizer Covid vaccine - Comirnaty		Lot No. FH3221	ID. 2110003737-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	C 3	5321	5268	< 0.00500	< 5.00	██████████
		C 4	5214				
PPC	1000	D 3	1452	1445	0.641		
		D 4	1437				
	PPC Value: 0.5	% PPC Recovery :	128%	(PPC - SAMPLE 1) Endotoxin Recovered : 0.641			

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Template : 2021 Oct 22 <sup>s22</sup> Pfizer & [REDACTED]	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAmax M5
<sup>section 22</sup> Covid Vaccine				S/N mv05705
Temperature : 36.8°C - 37.1°C				
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.232	Y-Intercept = 3.136	
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**Product Results**

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**Curve Parameters**

Parameter	Value	Specification	Status
Correlation Coefficient	-0.999	-1.000 to -0.980	PASS
Slope	-0.232	-0.400 to -0.100	PASS
Y Intercept	3.136	2.500 to 3.500	PASS

**Standards AER**

Concentration	CV	Specification	Status	Notes
0.00500	0.12%	<10.00%	PASS	
0.0500	0.80%	<10.00%	PASS	
0.500	0.37%	<10.00%	PASS	
5.00	1.65%	<10.00%	PASS	
50.0	1.77%	<10.00%	PASS	

Blank/lowest standard alert based on average replicates.

**Product AER**

Concentration/ Dilution	Parameter	Results (Power Curve)	Specification	Status	Notes
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**Product AER**

Concentration/ Dilution	Parameter	Results (Power Curve)	Specification	Status	Notes
		<b>Pfizer Covid vaccine - Comirnaty — Lot No. FH3221 ID. 2110003737-R1</b>			
1000	%CV	1.44%	[REDACTED]	PASS	
	Endotoxin	< 5.00 EU/mL	[REDACTED]	PASS	
PPC	%CV	0.73%	[REDACTED]	PASS	
PPC	% PPC Recovery	128%	[REDACTED]	PASS	

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**Reader Parameters:**

Delta t (s) = 150	Measurement Filter (nm) = 405	Delta mOD = 200
Shake (s) = 30	Actua /Max Reads = 37/40	

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**Accessories Summary**

Name	Comment	Lot No.	Manufacturer	Cal. Due Date	Exp
Biopur Blue Tips		G171028G - 2603	Eppendorf		31/01/2022
Biopur Yellow Tips		J193082Q-3245	Eppendorf		28/11/2025
LAL reagent water		0000837899	Lonza		18/03/2022
Multichannel Pipette		32199	Eppendorf	21/12/2021	
Cal: 13Sep2021					
Pipette (100-1000)		5707	Eppendorf	19/11/2021	
Cal: 04Aug2021					
Pipette (20-100)		5846	Gilson	22/12/2021	
Cal LAL epp tip on: 06Oct2021					
Pipette (20-200)		32832	eppendorf	14/01/2022	
Cal 18Oct2021					
Pipette (2-20)		32704	eppendorf	30/10/2021	
Cal: 20July2021					
Plate (3596)		0000991045	LONZA		12/02/2024
Pyrogen free tubes		0000953458	Lpnza		31/10/2024
Reagent reservoir		4665026	Lonza		14/12/2023

**Log Summary**

Description	Comment	User ID	Date
Routine Test RunDate/Time: 22/10/2021 1:37:17 PM (AUS Eastern Daylight Time) Serial # : mv05705		██████	22/10/2021 1:37:17PM
Analyst E-sig applied - ██████ Run Date/Time - Oct 22 2021 01:37:17 PM (AUS Eastern Daylight Time) Number - 0		██████	22/10/2021 3:24:36PM

Signed By : ██████ (et1-sig) Date/Time : 22/10/2021 3:24:36PM(UTC+11)

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