

**Biotherapeutics Section, TGA - Biotherapeutics**

Displayed in Version: 6.0.2

Report Generated: 19/10/2021 4:08:05PM (UTC+11)

**SpectraMax M5 reader**

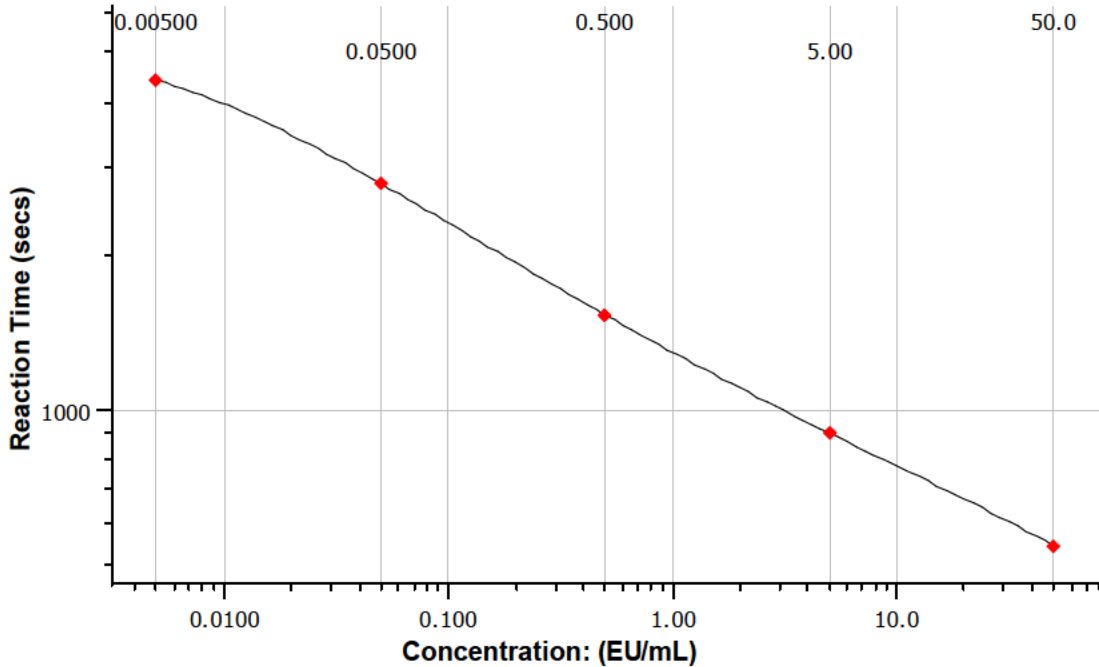
Calculated in Version: 6.0.2

Results Generated: 19/10/2021 3:24:04PM (UTC+11)

**Lonza - WinKQCL Version 6.0.2**

Page 1 of 3

Performed By : ██████ (VA)	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 1:45:23PM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000830072	Exp : 1/03/2022	Date : 19/10/2021
Template : 2021 Oct 19 - Pfizer Covid Vaccine	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAmax M5
Temperature : 36.7°C - 37.1°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.231	Y-Intercept = 3.123	
PowerCurve :	A = 3.1124	B = -0.2386	C = 0.0194	D = 0.0008
				E = -0.0039



<b>Standards Results</b>					
Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	5045	4902	< 0.00500
		A 2	4758		
Std. 1	0.00500	B 1	4423	4405	0.00500
		B 2	4387		
Std. 2	0.0500	C 1	2793	2771	0.0500
		C 2	2749		
Std. 3	0.500	D 1	1541	1535	0.500
		D 2	1528		
Std. 4	5.00	E 1	899	901	5.00
		E 2	902		
Std. 5	50.0	F 1	540	542	50.0
		F 2	544		

<b>Product Results</b>							
Unique Id: 000335-001351		Pfizer Covid vaccine - Comirnaty		Lot No. FL3560	ID. 2110003744-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	G 1	5306	5217	< 0.00500	< 5.00	██████
		G 2	5127				

Signed By : ██████ (et1-sig) Date/Time : 19/10/2021 4:08:02PM(UTC+11)

Reviewed By : ██████ e-signature not applied Date/Time : ██████

**R REVIEW ONLY**

( !! = Masked, \*\*\*\* = reaction time > 5850, ???? = atypical, # = Modified, >>>> = High OD, See Comment Page)  
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**Product Results**

Unique Id: 000335-001351		Pfizer Covid vaccine - Comirnaty		Lot No. FL3560	ID. 2110003744-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
PPC	1000	H 1	1385	1382	0.765		
		H 2	1379				
PPC Value: 0.5		% PPC Recovery :	153%	(PPC - SAMPLE 1) Endotoxin Recovered : 0.765			

**Curve Parameters**

Parameter	Value	Specification	Status
Correlation Coefficient	-0.999	-1.000 to -0.980	PASS
Slope	-0.231	-0.400 to -0.100	PASS
Y Intercept	3.123	2.500 to 3.500	PASS

**Standards AER**

Concentration	CV	Specification	Status	Notes
0.00500	0.58%	<10.00%	PASS	
0.0500	1.12%	<10.00%	PASS	
0.500	0.60%	<10.00%	PASS	
5.00	0.24%	<10.00%	PASS	
50.0	0.52%	<10.00%	PASS	

Blank/lowest standard alert based on average replicates.

**Product AER**

Concentration/ Dilution	Parameter	Results (Power Curve)	Specification	Status	Notes
		Pfizer Covid vaccine - Comirnaty		Lot No. FL3560 ID. 2110003744-R1	
1000	%CV	2.43%	██████████	PASS	
	Endotoxin	< 5.00 EU/mL	██████████	PASS	
PPC	%CV	0.31%	██████████	PASS	
PPC	% PPC Recovery	153%	██████████	PASS	

**Reader Parameters:**

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

Signed By : ██████ (et1-sig) Date/Time : 19/10/2021 4:08:02PM(UTC+11)

Reviewed By : ██████ e-signature not applied Date/Time : ██████

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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
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 RunDateTime: 19/10/2021 1:45:24 PM (AUS Eastern Daylight Time) Serial # : mv05705		██████	19/10/2021 1:45:23PM
Analyst E-sig applied - ██████ Run Date/Time - Oct 19 2021 01:45:23 PM (AUS Eastern Daylight Time) Number - 0		██████	19/10/2021 4:08:02PM

Signed By : ██████ (et1-sig) Date/Time : 19/10/2021 4:08:02PM(UTC+11)

Reviewed By : ██████ e-signature not applied Date/Time : ██████

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