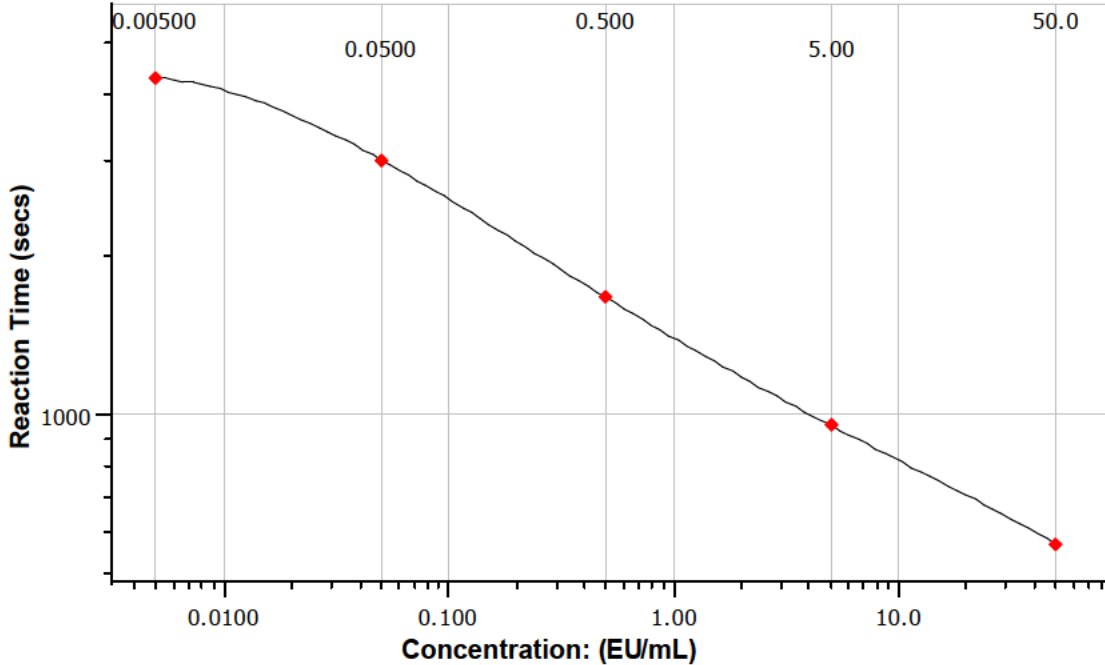


**Biotherapeutics Section, TGA - Biotherapeutics**  
**SpectraMax M5 reader**  
**Lonza - WinKQCL Version 6.0.2**

Displayed in Version: 6.0.2  
 Calculated in Version: 6.0.2  
 Page 1 of 3

Report Generated: 20/07/2021 8:32:49AM (UTC+10)  
 Results Generated: 19/07/2021 6:19:32PM (UTC+10)

Performed By : ██████ (VA)	LAL Lot No.:	WL029JJCAW	Exp : 21/10/2022	Time : 4:40:50PM (UTC+10)
KQCL - Routine Test	Water Lot No.:	0000830072	Exp : 1/03/2022	Date : 19/07/2021
Template : 2021 July 19 - Covid Vaccine - s22 Pfizer	Endotoxin Lot No.:	0000820346	Exp : 1/07/2023	SPECTRAmax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.997	Slope = -0.226	Y-Intercept = 3.146	
PowerCurve :	A = 3.1435	B = -0.2504	C = 0.0208	D = 0.0042
				E = -0.0052



**Standards Results**

Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4329	4329	< 0.00500
		A 2	4328		
Std. 1	0.00500	B 1	4241	4304	0.00500
		B 2	4367		
Std. 2	0.0500	C 1	2981	3024	0.0500
		C 2	3066		
Std. 3	0.500	D 1	1640	1662	0.500
		D 2	1684		
Std. 4	5.00	E 1	945	953	5.00
		E 2	960		
Std. 5	50.0	F 1	565	570	50.0
		F 2	574		

**Product Results**

Unique Id: 000294-001183		Pfizer Covid vaccine - Comirnaty		Lot No. FE3430	ID. 2107002694		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	A 3	5588	5540	< 0.00500	< 5.00	██████
PPC	1000	A 4	5492				
		B 3	1722	1699	0.460		
		B 4	1676				
PPC Value: 0.500		% PPC Recovery : 92%		(PPC - SAMPLE 1) Endotoxin Recovered : 0.460			

Signed By : ██████ (et1-sig) Date/Time : 20/07/2021 8:32:15AM(UTC+10)

Reviewed By : ██████ (et1-sig) Date/Time : 20/07/2021 8:32:46AM(UTC+10)

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

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**Biotherapeutics Section, TGA - Biotherapeutics  
SpectraMax M5 reader  
Lonza - WinKQCL Version 6.0.2**

Displayed in Version: 6.0.2  
Calculated in Version: 6.0.2  
Page 2 of 3

Report Generated: 20/07/2021 8:32:50AM (UTC+10)  
Results Generated: 19/07/2021 6:19:32PM (UTC+10)

Performed By : ██████████ (VA) LAL Lot No.: WL029JJCAW Exp : 21/10/2022 Time : 4:40:50PM (UTC+10)  
KQCL - Routine Test Water Lot No.: 0000830072 Exp : 1/03/2022 Date : 19/07/2021  
Template : 2021 July 19 - Covid Vaccine - Endotoxin Lot No.: 0000820346 Exp : 1/07/2023 SPECTRAMax M5  
s22 Pfizer  
Temperature : 36.7°C - 37.0°C S/N mv05705  
Linear Regression : Correlation Coefficient = -0.997 Slope = -0.226 Y-Intercept = 3.146  
PowerCurve : A = 3.1435 B = -0.2504 C = 0.0208 D = 0.0042 E = -0.0052

**Product Results**

Redacted under section 22 of the FOI Act

**Curve Parameters**

Parameter	Value	Specification	Status
Correlation Coefficient	-0.997	-1.000 to -0.980	PASS
Slope	-0.226	-0.400 to -0.100	PASS
Y Intercept	3.146	2.500 to 3.500	PASS

**Standards AER**

Concentration	CV	Specification	Status	Notes
0.00500	2.07%	<10.00%	PASS	
0.0500	1.99%	<10.00%	PASS	
0.500	1.87%	<10.00%	PASS	
5.00	1.11%	<10.00%	PASS	
50.0	1.12%	<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. FE3430 ID. 2107002694					
1000	%CV	1.23%	██████████	PASS	
	Endotoxin	< 5.00 EU/mL	██████████	PASS	
PPC	%CV	1.91%	██████████	PASS	
PPC	% PPC Recovery	92%	██████████	PASS	

Redacted under section 22 of the FOI Act

**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 : 20/07/2021 8:32:15AM(UTC+10)

Reviewed By : ██████████ (et1-sig) Date/Time : 20/07/2021 8:32:46AM(UTC+10)

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**Biotherapeutics Section, TGA - Biotherapeutics**  
**SpectraMax M5 reader**  
**Lonza - WinKQCL Version 6.0.2**

Displayed in Version: 6.0.2  
 Calculated in Version: 6.0.2  
 Page 3 of 3

Report Generated: 20/07/2021 8:32:50AM (UTC+10)  
 Results Generated: 19/07/2021 6:19:32PM (UTC+10)

Performed By : ██████ (VA)	LAL Lot No.:	WL029JJCAW	Exp : 21/10/2022	Time : 4:40:50PM (UTC+10)
KQCL - Routine Test	Water Lot No.:	0000830072	Exp : 1/03/2022	Date : 19/07/2021
Template : 2021 July 19 - Covid Vaccine - s22 Pfizer	Endotoxin Lot No.:	0000820346	Exp : 1/07/2023	SPECTRAmax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.997	Slope = -0.226	Y-Intercept = 3.146	
PowerCurve :	A = 3.1435	B = -0.2504	C = 0.0208	D = 0.0042
				E = -0.0052

**Accessories Summary**

Name	Comment	Lot No.	Manufacturer	Cal. Due Date	Exp
Biopur Blue Tips		H177688K-2215	Eppendorf		28/05/2023
Biopur Yellow Tips		1183614K-2416	Eppendorf		28/05/2024
Multichannel Pipette		32199	Eppendorf	21/09/2021	
Cal: 07Jun2021					
Pipette (100-1000)		5707	Eppendorf	19/08/2021	
Pipette (20-200)		32678	Biohit	13/08/2021	
Cal using LAL epp tip on: 13July2021					
Pipette (2-20)		32704	eppendorf	30/07/2021	
Cal: 13Apr2021					
Plate		12919601	costar		8/05/2022
Pyrogen free tubes		0000891400	Lonza		31/03/2024
Pyrogen free tubes		0000900927	Lpnza		30/04/2024
Pyrosperser		0000843500	LONZA		2/10/2021
Use by: 23/07/2021					
Reagent reservoirs		4215899	Lonza		27/07/2023

**Log Summary**

Description	Comment	User ID	Date
Routine Test RunDate/Time: 19/07/2021 4:40:51 PM (AUS Eastern Standard Time) Serial # : mv05705		██████	19/07/2021 4:40:50PM
Analyst E-sig applied - ██████ Run Date/Time - Jul 19 2021 04:40:50 PM (AUS Eastern Standard Time) Number - 0		██████	20/07/2021 8:32:15AM
Reviewer E-sig applied - ██████ Run Date/Time - Jul 19 2021 04:40:50 PM (AUS Eastern Standard Time) Number - 0		██████	20/07/2021 8:32:46AM

Signed By : ██████ (et1-sig) Date/Time : 20/07/2021 8:32:15AM(UTC+10)

Reviewed By : ██████ (et1-sig) Date/Time : 20/07/2021 8:32:46AM(UTC+10)

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