

**Biotherapeutics Section, TGA - Biotherapeutics**

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:17PM (UTC+11)

**SpectraMax M5 reader**

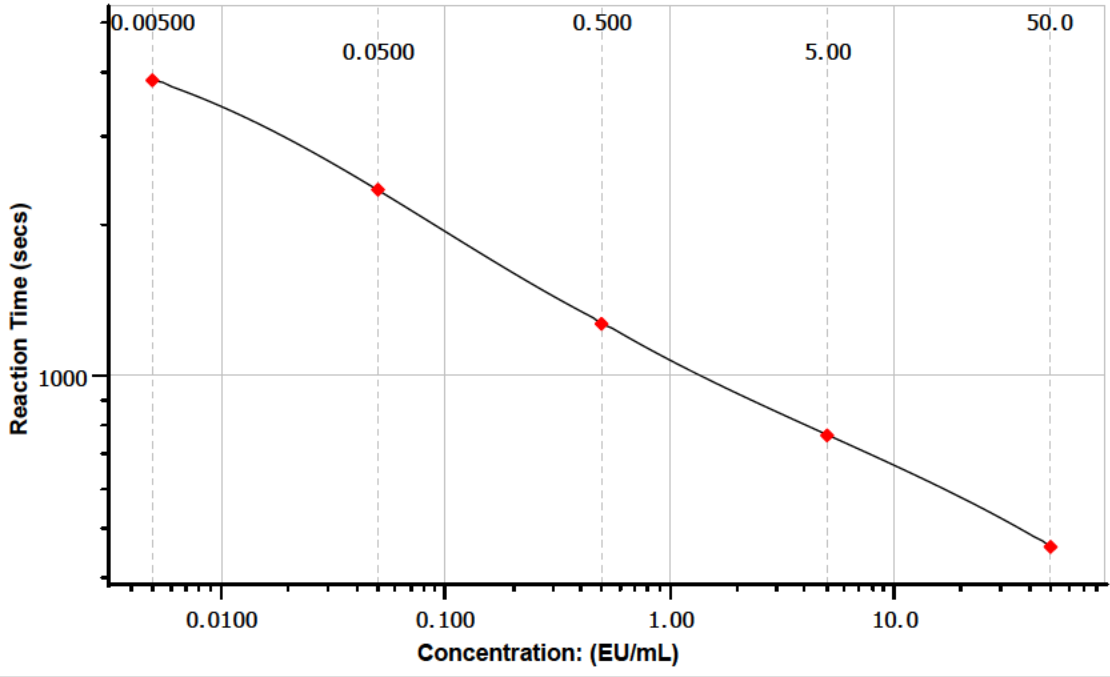
Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

**Lonza - WinKQCL Version 6.0.2**

Page 1 of 6

Performed By : ██████████	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 10:39:41AM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 18/11/2021
Template : 2021 Nov 18 - Pfizer Cominary & section 22	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAmax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.233	Y-Intercept = 3.051	
PowerCurve :	A = 3.0333	B = -0.2280	C = 0.0278	D = -0.0031      E = -0.0057



<b>Standards Results</b>						
Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)	
Blank	Blank	A 1	4492	4429	< 0.00500	
		A 2	4366			
Std. 1	0.00500	B 1	3922	3846	0.00500	
		B 2	3769			
Std. 2	0.0500	C 1	2333	2332	0.0500	
		C 2	2331			
Std. 3	0.500	D 1	1269	1272	0.500	
		D 2	1275			
Std. 4	5.00	E 1	764	768	5.00	
		E 2	771			
Std. 5	50.0	F 1	456	461	50.0	
		F 2	466			

<b>Product Results</b>							
Unique Id: 000343-001381		Pfizer Covid vaccine - Comirnaty		Lot No. FL5333	ID. 2111004115-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	G 1	4555	4602	< 0.00500	< 5.00	██████████
		G 2	4648				

Signed By : ██████████ (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : ██████████ Date/Time : 18/11/2021 12:18:14PM(UTC+11)

**Biotherapeutics Section, TGA - Biotherapeutics**

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:18PM (UTC+11)

**SpectraMax M5 reader**

Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

**Lonza - WinKQCL Version 6.0.2**

Page 2 of 6

Performed By : <span style="background-color: black; color: black;">[REDACTED]</span>	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 10:39:41AM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 18/11/2021
Template : 2021 Nov 18 - Pfizer Cominary <small>section 22</small>	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAMax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.233	Y-Intercept = 3.051	
PowerCurve :	A = 3.0333	B = -0.2280	C = 0.0278	D = -0.0031
				E = -0.0057

**Product Results**

Unique Id: 000343-001381		Pfizer Covid vaccine - Comirnaty		Lot No. FL5333	ID. 2111004115-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
PPC	1000	H 1	1242	1231	0.573		
		H 2	1219				
PPC Value: 0.5		% PPC Recovery :		115%	(PPC - SAMPLE 1) Endotoxin Recovered : 0.573		

Unique Id: 000343-001382		Pfizer Covid vaccine - Comirnaty		Lot No. FK0738	ID. 2111004218-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	A 3	4804	4774	< 0.00500	< 5.00	<span style="background-color: black; color: black;">[REDACTED]</span>
		A 4	4744				
PPC	1000	B 3	1239	1232	0.570		
		B 4	1225				
PPC Value: 0.5		% PPC Recovery :		114%	(PPC - SAMPLE 1) Endotoxin Recovered : 0.570		

Redacted under section 22 of the FOI Act

Signed By : [REDACTED] (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : [REDACTED] Date/Time : 18/11/2021 12:18:14PM(UTC+11)

**Biotherapeutics Section, TGA - Biotherapeutics**

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:18PM (UTC+11)

**SpectraMax M5 reader**

Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

**Lonza - WinKQCL Version 6.0.2**

Page 3 of 6

Performed By	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 10:39:41AM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 18/11/2021
Template : 2021 Nov 18 - Pfizer Cominary section 22	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAMax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.233	Y-Intercept = 3.051	
PowerCurve :	A = 3.0333	B = -0.2280	C = 0.0278	D = -0.0031 E = -0.0057

**Product Results**

Redacted under section 22 of the FOI Act

**Curve Parameters**

Parameter	Value	Specification	Status
Correlation Coefficient	-0.999	-1.000 to -0.980	PASS
Slope	-0.233	-0.400 to -0.100	PASS
Y Intercept	3.051	2.500 to 3.500	PASS

**Standards AER**

Concentration	CV	Specification	Status	Notes
0.00500	2.81%	<10.00%	PASS	
0.0500	0.06%	<10.00%	PASS	
0.500	0.33%	<10.00%	PASS	
5.00	0.64%	<10.00%	PASS	
50.0	1.53%	<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. FL5333 ID. 2111004115-R1					
1000	%CV	1.43%		PASS	
	Endotoxin	< 5.00 EU/mL		PASS	
PPC	%CV	1.32%		PASS	
PPC	% PPC Recovery	115%		PASS	

Signed By : \_\_\_\_\_ (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : \_\_\_\_\_ Date/Time : 18/11/2021 12:18:14PM(UTC+11)

Biotherapeutics Section, TGA - Biotherapeutics

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:18PM (UTC+11)

SpectraMax M5 reader

Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

Lonza - WinKQCL Version 6.0.2

Page 4 of 6

Performed By : [Redacted] LAL Lot No.: VL136G9FFR Exp : 30/06/2022 Time : 10:39:41AM (UTC+11)

KQCL - Routine Test Water Lot No.: 0000837899 Exp : 18/03/2022 Date : 18/11/2021

Template : 2021 Nov 18 - Pfizer Cominary Endotoxin Lot No.: 0000837915 Exp : 30/09/2023 SPECTRAMax M5

section 22

Temperature : 36.7°C - 37.0°C S/N mv05705

Linear Regression : Correlation Coefficient = -0.999 Slope = -0.233 Y-Intercept = 3.051

PowerCurve : A = 3.0333 B = -0.2280 C = 0.0278 D = -0.0031 E = -0.0057

**Product AER**

Concentration/ Dilution	Parameter	Results (Power Curve)	Specification	Status	Notes
Pfizer Covid vaccine - Comirnaty — Lot No. FK0738 ID. 2111004218-R1					
1000	%CV	0.89%	[Redacted]	PASS	
	Endotoxin	< 5.00 EU/mL	[Redacted]	PASS	
PPC	%CV	0.80%	[Redacted]	PASS	
PPC	% PPC Recovery	114%	[Redacted]	PASS	

Redacted under section 22 of the FOI Act

Signed By : [Redacted] (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : [Redacted] Date/Time : 18/11/2021 12:18:14PM(UTC+11)

**Biotherapeutics Section, TGA - Biotherapeutics**

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:18PM (UTC+11)

**SpectraMax M5 reader**

Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

**Lonza - WinKQCL Version 6.0.2**

Page 5 of 6

Performed By : <span style="background-color: black; color: black;">[REDACTED]</span>	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 10:39:41AM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 18/11/2021
Template : 2021 Nov 18 - Pfizer Cominary section 22	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAMax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.233	Y-Intercept = 3.051	
PowerCurve :	A = 3.0333	B = -0.2280	C = 0.0278	D = -0.0031
				E = -0.0057

**Product AER**

Concentration/ Dilution	Parameter	Results (Power Curve)	Specification	Status	Notes
Redacted under section 22 of the FOI Act					

**Reader Parameters:**

Delta t (s) = 150	Measurement Filter (nm) = 405	Delta mOD = 200
Shake (s) = 30	Actual/Max Reads = 34/40	

**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	19/02/2022	
Cal: 03Nov2021					
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	30/01/2022	
Cal: 18Oct2021					
Plate (3596)		0000991045	LONZA		12/02/2024
Pyrogen free tubes		0000953458	Lonza		31/10/2024
Pyrospense		0000904583	Lonza		29/06/2022
Opened: 22Oct2021, Use by: 19Nov2021					
Reagent reservoir		4665026	Lonza		14/12/2023

**Log Summary**

Description	Comment	User ID	Date
Routine Test RunDate/Time: 18/11/2021 10:39:42 AM (AUS Eastern Daylight Time) Serial # : mv05705		<span style="background-color: black; color: black;">[REDACTED]</span>	18/11/2021 10:39:41AM
Analyst E-sig applied - <span style="background-color: black; color: black;">[REDACTED]</span> Run Date/Time - Nov 18 2021 10:39:41 AM (AUS Eastern Daylight Time) Number - 0 (Sample B#:327570P L#:2111004286, need to re-test. Due to miss loading the PPC in the well.)		<span style="background-color: black; color: black;">[REDACTED]</span>	18/11/2021 12:11:22PM
Reviewer E-sig applied - <span style="background-color: black; color: black;">[REDACTED]</span> un Date/Time - Nov 18 2021 10:39:41 AM (AUS Eastern Daylight Time) Number - 0 (no PPC for one of the wells 2111004286)		<span style="background-color: black; color: black;">[REDACTED]</span>	18/11/2021 12:18:14PM

Signed By : [REDACTED] (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : [REDACTED] Date/Time : 18/11/2021 12:18:14PM(UTC+11)

Biotherapeutics Section, TGA - Biotheraputics

Displayed in Version: 6.0.2

Report Generated: 18/11/2021 12:18:18PM (UTC+11)

SpectraMax M5 reader

Calculated in Version: 6.0.2

Results Generated: 18/11/2021 12:03:53PM (UTC+11)

Lonza - WinKQCL Version 6.0.2

Page 6 of 6

Performed By : [REDACTED]	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 10:39:41AM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 18/11/2021
Template : 2021 Nov 18 - Pfizer Cominary section 22	Endotoxin Lot No.:	0000837915	Exp : 30/09/2023	SPECTRAmax M5
Temperature : 36.7°C - 37.0°C				S/N mv05705
Linear Regression :	Correlation Coefficient = -0.999	Slope = -0.233	Y-Intercept = 3.051	
PowerCurve :	A = 3.0333	B = -0.2280	C = 0.0278	D = -0.0031      E = -0.0057

**Analyst** [REDACTED] **omment :**  
Sample B#:327570P L#:2111004286, need to re-test. Due to miss loading the PPC in the well.

**Reviewer** [REDACTED] **omment :**  
no PPC for one of the wells 2111004286

Signed By : [REDACTED] \_\_\_\_\_ (et1-sig) Date/Time : 18/11/2021 12:11:22PM(UTC+11)

Reviewed By : [REDACTED] \_\_\_\_\_ Date/Time : 18/11/2021 12:18:14PM(UTC+11)