

Biotherapeutics Section, TGA - Biotherapeutics

Displayed in Version: 6.0.2

Report Generated: 28/10/2021 4:50:37PM (UTC+11)

SpectraMax M5 reader

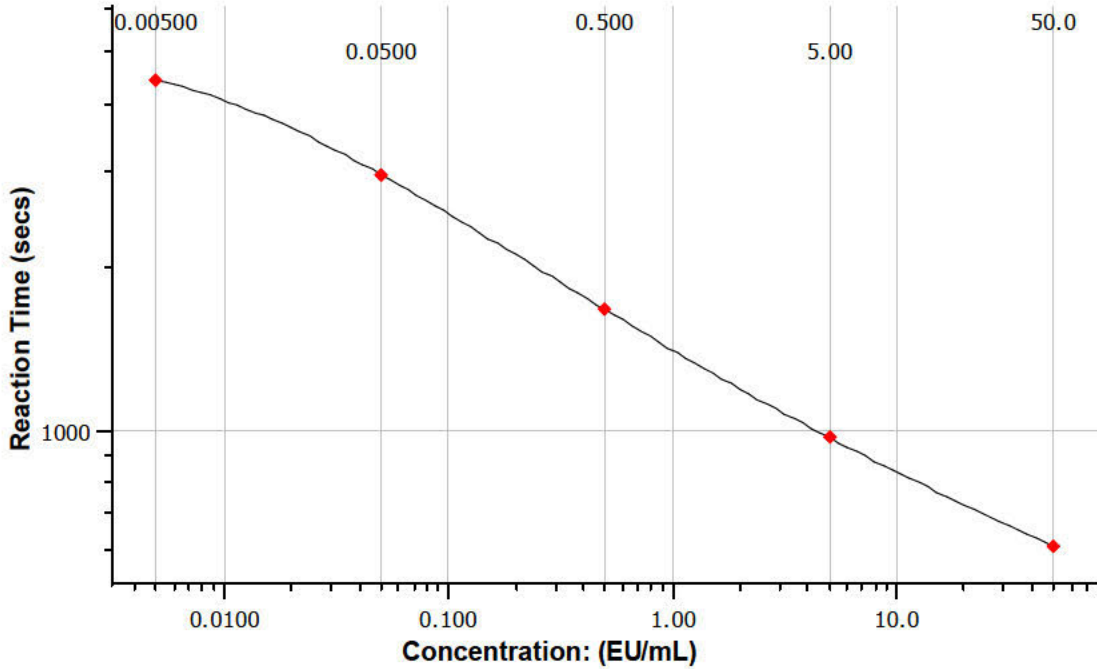
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Results Generated: 28/10/2021 4:45:13PM (UTC+11)

Lonza - WinKQCL Version 6.0.2

Page 1 of 3

Performed By : █████ (VA)	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 3:18:07PM (UTC+11)
KQCL - Routine Test	Water Lot No.:	0000837899	Exp : 18/03/2022	Date : 28/10/2021
Template : 2021 Oct 28/2 - Pfizer Covid Vaccine	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 = -0.221	Y-Intercept = 3.156	
PowerCurve :	A = 3.1474	B = -0.2449	C = 0.0158	D = 0.0062
				E = -0.0026



Standards Results					
Standards	Conc./Dil.	Well	Reaction Time (sec)	Average Reaction Time (sec)	Back Prediction (Power Curve)
Blank	Blank	A 1	4906	4802	< 0.00500
		A 2	4698		
Std. 1	0.00500	B 1	4444	4419	0.00500
		B 2	4394		
Std. 2	0.0500	C 1	2978	2962	0.0500
		C 2	2945		
Std. 3	0.500	D 1	1678	1669	0.500
		D 2	1659		
Std. 4	5.00	E 1	962	967	5.00
		E 2	972		
Std. 5	50.0	F 1	607	611	50.0
		F 2	614		

Product Results							
Unique Id: 000338-001362		Pfizer Covid vaccine - Comirnaty		Lot No. FL7649	ID. 2110003905-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
S1	1000	G 1	****	****	< 0.00500	< 5.00	██████
		G 2	****				

Signed By : █████ (et1-sig) Date/Time : 28/10/2021 4:50:33PM(UTC+11)

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

R REVIEW ONLY

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Performed By [REDACTED]	LAL Lot No.:	VL136G9FFR	Exp : 30/06/2022	Time : 3:18:07PM (UTC+11)
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Product Results

Unique Id: 000338-001362		Pfizer Covid vaccine - Comirnaty		Lot No. FL7649	ID. 2110003905-R1		
Samples	Dilution	Well	Reaction Time (sec)	Average Reaction Time (sec)	Raw EU	Results (Power Curve) EU/mL	Release Limit
PPC	1000	H 1	1476	1474	0.822		
		H 2	1471				
PPC Value: 0.5		% PPC Recovery :	164%	(PPC - SAMPLE 1) Endotoxin Recovered : 0.822			

Curve Parameters

Parameter	Value	Specification	Status
Correlation Coefficient	-0.999	-1.000 to -0.980	PASS
Slope	-0.221	-0.400 to -0.100	PASS
Y Intercept	3.156	2.500 to 3.500	PASS

Standards AER

Concentration	CV	Specification	Status	Notes
0.00500	0.80%	<10.00%	PASS	
0.0500	0.79%	<10.00%	PASS	
0.500	0.81%	<10.00%	PASS	
5.00	0.73%	<10.00%	PASS	
50.0	0.81%	<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. FL7649 ID. 2110003905-R1	
1000	%CV	N/A	[REDACTED]	Undefined	*<LS or Undefined
	Endotoxin	< 5.00 EU/mL	[REDACTED]	PASS	
PPC	%CV	0.24%	[REDACTED]	PASS	
PPC	% PPC Recovery	164%	[REDACTED]	PASS	

Reader Parameters:

Delta t (s) = 150	Measurement Filter (nm) = 405	Delta mOD = 200
Shake (s) = 30	Actua /Max Reads = 35/40	

Signed By : [REDACTED] (et1-sig) Date/Time : 28/10/2021 4:50:33PM(UTC+11)

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

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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	30/01/2022	
Cal: 18Oct2021					
Plate (3596)		0000991045	LONZA		12/02/2024
Pyrogen free tubes		0000953458	Lonza		31/10/2024
Pyroperse		0000904583	Lonza		29/06/2022
Reagent reservoir		4665026	Lonza		14/12/2023

Log Summary

Description	Comment	User ID	Date
Routine Test RunDate/Time: 28/10/2021 3:18:08 PM (AUS Eastern Daylight Time) Serial #: mv05705		██████████	28/10/2021 3:18:07PM
Analyst E-sig applied - ██████████ Run Date/Time - Oct 28 2021 03:18:07 PM (AUS Eastern Daylight Time) Number - 0		██████████	28/10/2021 4:50:33PM

Signed By : ██████████ (et1-sig) Date/Time : 28/10/2021 4:50:33PM(UTC+11)

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