

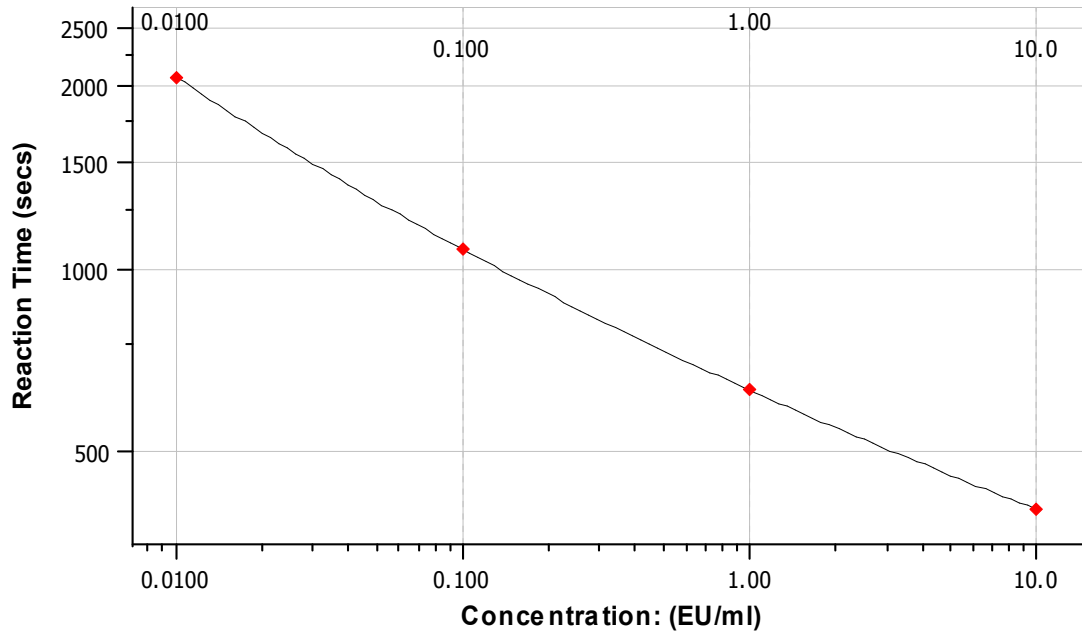
## Product Testing Unit SNBTS - Default

ELx808 reader

Lonza - WinKQCL Version 5.1.2

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Performed By : F.MITCHELL	LAL Lot No. : XL041KRP2Y	Exp : 02/04/2023	Time : 12:11:25
PYROGENT-5000 - Routine Test	Water Lot No. : 0001098994	Exp : 10/03/2024	Date : 05/10/2022
Template : 051022/01	Endotoxin Lot No. : 0001011300	Exp : 02/06/2025	ELx808
Temperature : 36.9°C - 37.0°C	Recon. Buffer Lot No. : 0001019067	Exp : 01/07/2023	S/N 253635
Linear Regression :	Correlation Coefficient = -0.997	Slope = -0.238	Y-Intercept = 2.820
PowerCurve :	A = 2.8000	B = -0.2119	C = 0.0179
		D = -0.0028	E = 0.0000

**Standards Results**

Standards	Conc./Dil.	Average Reaction Time (sec)	Back Prediction (Power Curve)	% CV	Status	Notes
Blank	Blank	****	****	N/A	Undefined	*
Standard 1	0.0100	2078	0.0100	1.19%	PASS	
Standard 2	0.100	1078	0.100	0.66%	PASS	
Standard 3	1.00	631	1.00	2.69%	PASS	
Standard 4	10.0	401	10.0	3.88%	PASS	

**Product Results**

Samples	Conc./Dil.	Lot Number	Product ID	Results (Power Curve)	%CV	% PPC Recovery	% PPC Rec. Status	PPC %CV	Notes
<u>OM-MSC + Antibiotic</u>									
1	40	CS022-01 (1) +	033804	< 0.400		102%	PASS	2.18%	*
<u>OM-MSC + Antibiotic</u>									
1	40	CS022-02 (2) +	033806	< 0.400		113%	PASS	0.34%	*
<u>OM-MSC + Antibiotic</u>									
1	40	CS022-03 (3) +	033808	< 0.400		138%	PASS	2.28%	*

**Curve Parameters**

Parameter	Value	Specification	Status
Correlation Coefficient	-0.997	-1.000 to -0.980	PASS
Slope	-0.238	-0.400 to -0.100	PASS
Y Intercept	2.820	2.500 to 3.500	PASS

Signed By : Fiona Mitchell (et1-sig) Date/Time : 05/10/2022 13:51:03  
Fiona Mitchell (F.MITCHELL)

Reviewed By : Stuart Doig (et1-sig) Date/Time : 05/10/2022 14:00:56  
Stuart Doig (S.DOIG)

( !! = Masked, \*\*\*\* = reaction time > 2100, ???? = atypical, # = Modified, >>>> = High OD, See Comment Page)

( In Notes : ! = Masked Point(s), \* = Point(s) Did Not React, ? = Atypical Point(s), # = Modified, > = High OD, <LS = Less than the lowest standard)

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		D = -0.0028	E = 0.0000

**Product AER**

Dil./Conc.	Parameter	Results (Power Curve)	Specification	Status	Notes
<b>OM-MSc + Antibiotic — Lot No. CS022-01 (1) + ID. 033804</b>					
40	%CV	N/A	< 10%	Undefined	*<LS or Undefined
	Endotoxin	< 0.400 EU/ml		N/A	
PPC	%CV	2.18%	< 10%	PASS	
PPC	% PPC Recovery	102%	50 to 200	PASS	
<b>OM-MSc + Antibiotic — Lot No. CS022-02 (2) + ID. 033806</b>					
40	%CV	N/A	< 10%	Undefined	*<LS or Undefined
	Endotoxin	< 0.400 EU/ml		N/A	
PPC	%CV	0.34%	< 10%	PASS	
PPC	% PPC Recovery	113%	50 to 200	PASS	
<b>OM-MSc + Antibiotic — Lot No. CS022-03 (3) + ID. 033808</b>					
40	%CV	N/A	< 10%	Undefined	*<LS or Undefined
	Endotoxin	< 0.400 EU/ml		N/A	
PPC	%CV	2.28%	< 10%	PASS	
PPC	% PPC Recovery	138%	50 to 200	PASS	

**Reader Parameters:** Delta t (s) = 60 Measurement Filter (nm) = 340 Delta mOD = 30 Actual/Max Reads = 36/100

**Accessories Summary**

Name	Lot No.	Manufacturer	Cal. Due Date	Exp
200ul Pipette Tip	L131916G	Star Lab		31/12/2026
5ml Sample Tube	05322005	Corning		28/02/2027
ClipTip Pipette Tips	20350B0	Thermo Scientific		31/12/2025
Costar 96 Well Plate	25721035	Corning		13/09/2024
F1 ClipTip 8 Channel	OH51795	Thermo Scientific	26/03/2023	
Finnpipette 100-1000	CH83006	Thermo Electron Corp	23/03/2023	
Finnpipette 30-300	CH95841	Thermo Electron Corp	23/03/2023	
Finnpipette5-50	CH14831	Thermo Scientific	23/03/2023	
Microplate Reader	253635	Lonza	31/03/2023	31/03/2023
Pipet Tips 1250uL	222269	VWR		30/09/2025
Reagent Reservoirs	518741	SLS		15/07/2025

**Log Summary**

Description (Comment)	User ID	Date
Routine Test RunDateTime: 05/10/2022 12:11:26 (GMT Daylight Time) Serial # : 253635	F.MITCHELL	05/10/2022 12:11:25
Analyst E-sig applied - F.MITCHELL Run Date/Time - Oct 05 2022 12:11:25 PM (GMT Daylight Time) Number - 0	F.MITCHELL	05/10/2022 13:51:03
Reviewer E-sig applied - S.DOIG Run Date/Time - Oct 05 2022 12:11:25 PM (GMT Daylight Time) Number - 0	S.DOIG	05/10/2022 14:00:56

Signed By : Fiona Mitchell (et1-sig) Date/Time : 05/10/2022 13:51:03

Fiona Mitchell (F.MITCHELL)

Reviewed By : Stuart Doig (et1-sig) Date/Time : 05/10/2022 14:00:56

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