

ASSAY INFORMATION:

Assay Name: CRL-21071027-420230209-002					
Analyst: LMR	Assay Date/Time: 2/9/2023 2:14:24 PM EST				
Lab Name: N/A					
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230				

SAMPLE RESULTS:

Channel	Reaction	CV%	Sample Value	Channel	Reaction	CV%	Spike	Spike Recovery
SAMPLE DATA			SPIKE DATA					
Alert Limit: N/A			Spike Recovery Range: 50- 200% Status: VALID					
Endotoxin L	imit: No Limi	t Stat ı	ıs: N/A	Spike CV Limit: <25% Status: VALID				
Endotoxin V	/alue: <0.050	EU/mL		Sample CV Limit: <25% Status: VALID				
Range: 203-978 seconds			Y-Intercept: +2.205 Slope: -0.341					
Calibration Code: 420357846981			Archived Spike Concentration: 0.089 EU/mL					
Cartridge Lo	ot Number: 2	792144		Cartridge Ra	ange: 0.5-0.0	005 EU/mL		
Sample Con	nments: N/A							
Sample ID:	N/A			Sample Lot: MB-3 Dil./Conc.: 1:10 mL/mL				
Sample Nan	ne: PPB-4891							
Serial Numb	oer/Bay: MCS	3 21071027/4		Start/End Temp (°C): 37.0:37.0				

Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %
1	>978	0.0 %	<0.050.511/ml	2	394	2.2 %	0.070	79 %
3	>978	0.0 %	<0.050 EU/mL	4	382	2.2 %	EU/mL	79 %

Report Comments: N/A

Analyst:	Date:
Poviower	Date:



ASSAY INFORMATION:

Assay Name: CRL-21071036-220230209-002					
Analyst: LMR	Assay Date/Time: 2/9/2023 2:14:18 PM EST				
Lab Name: N/A					
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230				

SAMPLE RESULTS:

Channel	Reaction	CV%	Sample Value	Channel	Reaction	CV%	Spike	Spike Recovery
	S	AMPLE DA	ГА	SPIKE DATA				
Alert Limit: N/A			Spike Recovery Range: 50- 200% Status: VALID					
Endotoxin L	_imit: No Limi	t Stat	us: N/A	Spike CV Limit: <25% Status: VALID				
Endotoxin V	/alue: <0.050	EU/mL		Sample CV Limit: <25% Status: VALID				
Range: 203-978 seconds			Y-Intercept: +2.205 Slope: -0.341					
Calibration Code: 420357846981			Archived Spike Concentration: 0.089 EU/mL					
Cartridge Lo	Cartridge Lot Number: 2792144				ange: 0.5-0.0	005 EU/mL		
Sample Con	mments: N/A							
Sample ID:	N/A			Sample Lot: MB-1 Dil./Conc.: 1:10 mL/mL				
Sample Nan	ne: 1D11							
Serial Numb	oer/Bay: MCS	21071036/2	2	Start/End Temp (°C): 37.0:37.0				

Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %
1	>978	0.0 %	<0.050 EU/mL	2	378	5.7 %	0.067	75 %
3	>978	0.0 %	\0.030 E0/IIIL	4	410	3.7 %	EU/mL	13%

Report Comments: N/A

Analyst:	Date:
Reviewer:	Date:



ASSAY INFORMATION:

Assay Name: CRL-21071034-320230209-002			
Analyst: LMR	Assay Date/Time: 2/9/2023 2:14:11 PM EST		
Lab Name: N/A			
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230		

SAMPLE RESULTS:

Serial Numb	oer/Bay: MCS	21071034/3		Start/End Temp (°C): 37.0:37.0				
Sample Nan	ne: PPB-23616							
Sample ID:	N/A			Sample Lot:	MB-2	Dil./C	Conc.: 1:10 m	ıL/mL
Sample Comments: N/A								
Cartridge Lo	ot Number: 27	792144		Cartridge Ra	ange: 0.5-0.0	005 EU/mL		
Calibration	Code: 420357		Archived Spike Concentration: 0.089 EU/mL					
Range: 203-978 seconds				Y-Intercept: +2.205 Slope: -0.341				
Endotoxin \	/alue: 0.388 E	:U/mL		Sample CV Limit: <25% Status: VALID				
Endotoxin L	imit: No Limit	Statu	s: N/A	Spike CV Limit: <25% Status: VALID				
Alert Limit: N/A			Spike Recovery Range: 50- 200% Status: VALID					
SAMPLE DATA				SPIKE DATA				
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %

0.388 EU/mL

2

4

330

314

Report Comments: N/A

484

488

0.6 %

1

3

Analyst:	Date:
Daviowar	Date:

0.091

EU/mL

102 %

3.5 %



ASSAY INFORMATION:

Assay Name: CRL-21071045-120230209-002	
Analyst: LMR	Assay Date/Time: 2/9/2023 2:14:11 PM EST
Lab Name: N/A	
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230

SAMPLE RESULTS:

Serial Number/Bay: MCS 21071045/1				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-65158								
Sample ID: N/A				Sample Lot:	ST-1	Dil	/Conc.: 1:10 m	nL/mL
Sample Con	nments: N/A							
Cartridge Lo	ot Number: 2	792144		Cartridge Ra	ange: 0.5-0.0	05 EU/mL		
Calibration	Code: 42035	7846981		Archived Spike Concentration: 0.089 EU/mL				
Range: 203	3-978 seconds			Y-Intercept: +2.205 Slope: -0.341				
Endotoxin V	/alue: 0.054	EU/mL		Sample CV Limit: <25% Status: VALID				
Endotoxin L	imit: No Lim	it Sta	tus: N/A	Spike CV Limit: <25% Status: VALID				
Alert Limit: N/A			Spike Recovery Range: 50- 200% Status: VALID					
SAMPLE DATA				SPIKE DATA				
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %

0.054 EU/mL

2

4

368

374

Report Comments: N/A

976

934

3.1 %

1

3

Analyst:	Date:
Reviewer:	Date:

0.080

EU/mL

1.1 %

90 %



ASSAY INFORMATION:

Assay Name: CRL-21071027-420230209-001				
Analyst: LMR	Assay Date/Time: 2/9/2023 1:49:21 PM EST			
Lab Name: N/A				
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230			

SAMPLE RESULTS:

Serial Number/Bay: MCS 21071027/4				Start/End Temp (°C): 37.0:37.0				
Sample Nan	ne: PPB-6532	20						
Sample ID: N/A				Sample Lot:	KM-1	Dil./C	conc.: 1:10 m	L/mL
Sample Con	nments: N/A							
Cartridge Lo	ot Number: 2	792144		Cartridge Ra	ange: 0.5-0.0	005 EU/mL		
Calibration	Code: 42035	7846981		Archived Spike Concentration: 0.089 EU/mL				
Range: 203	3-978 seconds			Y-Intercept: +2.205 Slope: -0.341				
Endotoxin V	/alue: 0.084 E	EU/mL		Sample CV Limit: <25% Status: VALID				
Endotoxin L	imit: No Limi	it St a	atus: N/A	Spike CV Limit: <25% Status: VALID				
Alert Limit: N/A				Spike Recovery Range: 50- 200% Status: VALID				
SAMPLE DATA						SPIKE DATA	4	
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %

0.084 EU/mL

2

4

374

366

Report Comments: N/A

962

676

24.7 %

1

3

Analyst:	Date:
Raviawar:	Data:

0.078

EU/mL

1.5 %

87 %



ASSAY INFORMATION:

Assay Name: CRL-21071036-220230209-001				
Analyst: LMR	Assay Date/Time: 2/9/2023 1:49:14 PM EST			
Lab Name: N/A				
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230			

SAMPLE RESULTS:

Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %
SAMPLE DATA						SPIKE DATA	\	
Alert Limit: N/A				Spike Recovery Range: 50- 200% Status: VALID				
Endotoxin L	_imit: No Lim	it Statu	s: N/A	Spike CV Limit: <25% Status: VALID				
Endotoxin V	/alue: <0.05	I EU/mg		Sample CV Limit: <25% Status: VALID				
Range: 203	3-978 seconds	i		Y-Intercept: +2.205 Slope: -0.341				
Calibration	Code: 42035	7846981		Archived Spike Concentration: 0.089 EU/mL				
Cartridge Lo	ot Number: 2	2792144		Cartridge Ra	ange: 0.5-0.0	005 EU/mL		
Sample Con	nments: N/A							
Sample ID:	N/A			Sample Lot:	: WM-2	Dil./C	onc.: 0.100	mg/mL
Sample Nan	ne: PPB-649	63_1mg/mL						
Serial Number/Bay: MCS 21071036/2				Start/End Temp (°C): 37.0:37.0				

<0.051 EU/mg

2

4

378

384

Report Comments: N/A

>978

966

0.9 %

1

3

Analyst:	Date:
Daviowar	Date:

0.074

EU/mL

83 %

1.1 %



ASSAY INFORMATION:

Assay Name: CRL-21071045-120230209-001				
Analyst: LMR	Assay Date/Time: 2/9/2023 1:49:07 PM EST			
Lab Name: N/A				
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230			

SAMPLE RESULTS:

Serial Number/Bay: MCS 21071045/1				Start/End Temp (°C): 37.0:37.0				
Sample Nam	ne: PPB-6496	61_1mg/mL						
Sample ID: N/A				Sample Lot:	WM-1	Dil	/Conc.: 1:10 m	nL/mL
Sample Con	nments: N/A							
Cartridge Lo	ot Number: 2	792144		Cartridge Ra	ange: 0.5-0.0	005 EU/mL		
Calibration (Code: 42035	7846981		Archived Spike Concentration: 0.089 EU/mL				
Range: 203	Range: 203-978 seconds				Y-Intercept: +2.205 Slope: -0.341			
Endotoxin V	/alue: <0.051	EU/mL		Sample CV Limit: <25% Status: VALID				
Endotoxin L	.imit: No Lim	it Stat	us: N/A	Spike CV Limit: <25% Status: INVALID				
Alert Limit: N/A			Spike Recovery Range: 50- 200% Status: UNDEFINED			IED		
	SAMPLE DATA					SPIKE DA	TA	
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %
1	960	1 2 %	<0.051 EU/ml	2	<203	47 9 %	>0.144	>162.9/

4

410

<0.051 EU/mL

Report Comments: N/A

>978

3

Analyst:	Date:
Daviowar	Date:

1.3 %

>162 %

EU/mL

47.8 %



ASSAY INFORMATION:

Assay Name: CRL-21071034-320230209-001				
Analyst: LMR	Assay Date/Time: 2/9/2023 1:49:07 PM EST			
Lab Name: N/A				
Instrument Type: nexgen PTS/MCS	Instrument Serial Number: 21161230			

SAMPLE RESULTS:

Serial Number/Bay: MCS 21071034/3				Start/End Temp (°C): 37.0:37.0					
Sample Nar	ne: PPB-6529	97							
Sample ID: N/A				Sample Lot:	JJ-1	1 Dil./Conc.: 1:10 mL/mL			
Sample Cor	nments: N/A					-			
Cartridge Lot Number: 2792144				Cartridge Range: 0.5-0.005 EU/mL					
Calibration Code: 420357846981				Archived Spike Concentration: 0.089 EU/mL					
Range: 203-978 seconds				Y-Intercept: +2.205 Slope: -0.341					
Endotoxin Value: <0.050 EU/mL				Sample CV Limit: <25% Status: VALID					
Endotoxin Limit: No Limit Status: N/A			tatus: N/A	Spike CV Limit: <25% Status: VALID					
Alert Limit:	N/A			Spike Recovery Range: 50-200%			Status: VALID		
SAMPLE DATA				SPIKE DATA					
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %	

<0.050 EU/mL

2

4

364

366

Report Comments: N/A

>978

>978

0.0 %

1

3

Analyst:	Date:
Daviowar:	Date:

0.085

EU/mL

95 %

0.4 %