

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071027/4				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-4891								
Sample ID: N/A				Sample Lot: MB-3			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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		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 %
1	>978	0.0 %	<0.050 EU/mL	2	394	2.2 %	0.070 EU/mL	79 %
3	>978			4	382			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071036/2				Start/End Temp (°C): 37.0:37.0				
Sample Name: 1D11								
Sample ID: N/A				Sample Lot: MB-1			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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		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 %
1	>978	0.0 %	<0.050 EU/mL	2	378	5.7 %	0.067 EU/mL	75 %
3	>978			4	410			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071034/3				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-23616								
Sample ID: N/A				Sample Lot: MB-2			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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: 0.388 EU/mL				Sample CV Limit: <25%			Status: VALID	
Endotoxin Limit: No Limit		Status: 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 %
1	484	0.6 %	0.388 EU/mL	2	330	3.5 %	0.091 EU/mL	102 %
3	488			4	314			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

<b>Assay Name:</b> CRL-21071045-120230209-002	
<b>Analyst:</b> LMR	<b>Assay Date/Time:</b> 2/9/2023 2:14:11 PM EST
<b>Lab Name:</b> N/A	
<b>Instrument Type:</b> nexgen PTS/MCS	<b>Instrument Serial Number:</b> 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 mL/mL	
Sample Comments: 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: 0.054 EU/mL				Sample CV Limit: <25%			Status: VALID	
Endotoxin Limit: No Limit		Status: 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 %
1	976	3.1 %	0.054 EU/mL	2	368	1.1 %	0.080 EU/mL	90 %
3	934			4	374			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071027/4				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-65320								
Sample ID: N/A				Sample Lot: KM-1			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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: 0.084 EU/mL				Sample CV Limit: <25%			Status: VALID	
Endotoxin Limit: No Limit		Status: 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 %
1	962	24.7 %	0.084 EU/mL	2	374	1.5 %	0.078 EU/mL	87 %
3	676			4	366			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071036/2				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-64963_1mg/mL								
Sample ID: N/A				Sample Lot: WM-2			Dil./Conc.: 0.100 mg/mL	
Sample Comments: 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: <0.051 EU/mg				Sample CV Limit: <25%			Status: VALID	
Endotoxin Limit: No Limit		Status: 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 %
1	>978	0.9 %	<0.051 EU/mg	2	378	1.1 %	0.074 EU/mL	83 %
3	966			4	384			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### 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 Name: PPB-64961_1mg/mL								
Sample ID: N/A				Sample Lot: WM-1			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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: <0.051 EU/mL				Sample CV Limit: <25%			Status: VALID	
Endotoxin Limit: No Limit		Status: N/A		Spike CV Limit: <25%			Status: INVALID	
Alert Limit: N/A				Spike Recovery Range: 50-200%			Status: UNDEFINED	
SAMPLE DATA				SPIKE DATA				
Channel	Reaction Time	CV%	Sample Value	Channel	Reaction Time	CV%	Spike Value	Spike Recovery %
1	960	1.3 %	<0.051 EU/mL	2	<203	47.8 %	>0.144 EU/mL	>162 %
3	>978			4	410			

Report Comments: N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

## Detailed Endotoxin Cartridge Report:

### ASSAY INFORMATION:

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

### SAMPLE RESULTS:

Serial Number/Bay: MCS 21071034/3				Start/End Temp (°C): 37.0:37.0				
Sample Name: PPB-65297								
Sample ID: N/A				Sample Lot: JJ-1			Dil./Conc.: 1:10 mL/mL	
Sample Comments: 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		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 %
1	>978	0.0 %	<0.050 EU/mL	2	364	0.4 %	0.085 EU/mL	95 %
3	>978			4	366			

**Report Comments:** N/A

Analyst: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_