Template Provided By:

Cancer Imaging Program

National Cancer Institute

LAL-Non-Interfering Concentration Form

(Refer to GEN-Q114)

Manufacturing Batch Number: _____ **Date Performed:** _____

LAL Lot Sensitivity: _____ **Expiration Date:** _____

CSE Rehydration Date: _____

20λ Standard Number: _____ **Expiration Date:** _____

MATERIALS:

Description	ITC	Quantity	Amount Used	ITN/Lot
Syringe, 1 mL with 25G x $^5/_8$ Needle	**N/A**	1		
LAL Reagent Water or Sterile Water for Injection (SWFI)	**SS-LRW** or **SS-WFI**	QS		SS-
Limulus Amebocyte Lysate (LAL)	**SS-LAL**	56		SS-LAL-L
Control Standard Endotoxin (CSE)	**SS-CSE**	QS		SS-CSE-L
Final Product		1.0 mL		

ENDOTOXIN LIMIT OF FINAL PRODUCT

EL = $\frac{175 \text{ EU/dose}}{\text{Dose volume in mL/dose}}$ 175 EU ÷ _____ mL = _____ EU/mL

MAXIMUM VALID DILUTION

MVD = EL ÷ λ _____ EU/mL ÷ _____ EU/mL = _____ : _____

Enhancement Enter (+) for gel formation (Positive) or (-) for no gel formation (Negative)

Tube Number	Final Product Dilution Ratio					Start Time	Start Temperature
	1:2	1:10	1:40	1:80	1:100		
1						End Time	End Temperature
2							

Inhibition Final product at 2λ Enter (+) for gel formation (Positive) or (-) for no gel formation (Negative)

Tube Number	Final Product Dilution Ratio					Start Time	Start Temperature
	1:2	1:10	1:40	1:80	1:100		
1						End Time	End Temperature
2							

Non-Interfering Concentration: _____ The least dilute solution that does not enhance (- for both duplicates) And does not inhibit (+ for both duplicates).

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Controls, Water

Tube Number	CSE Concentration					Start Time	Start Temperature
	2λ	λ	0.5 λ	0.25 λ	NC		
1							
2						End Time	End Temperature
3							
4							

EndPoint EU/mL	log_{10} End Point	
_____	_____	
_____	_____	Mean $Antilog_{10}$
_____	_____	_____
_____	_____	_____

LAL Label Claim Confirmed? _____ **Yes** _____ **No**

Validation of Non-Interfering Concentration

Tube Number	CSE Concentration					Start Time	Start Temperature
	NIC-2λ	NIC-λ	NIC-0.5 λ	NIC-0.25 λ	NC		
1							
2						End Time	End Temperature
3							
4							

EndPoint EU/mL	log_{10} End Point	
_____	_____	
_____	_____	Mean $Antilog_{10}$
_____	_____	_____
_____	_____	_____

LAL Label Claim Confirmed? _____ **Yes** _____ **No**

Performed By: _____ **Date:** _____

QC Review: _____ **Date:** _____

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