Template Provided By:

Cancer Imaging Program

National Cancer Institute

Confirmation of LAL Label Claim Sensitivity

(Refer to GEN-Q114)

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

MATERIALS:

Description	ITC	Quantity	Amount Used	ITN/Lot
LAL Reagent Water or Sterile Water for Injection (SWFI)	**SS-LRW** or **SS-WFI**	QS		SS-
Limulus Amebocyte Lysate (LAL)	**SS-LAL**	18		SS-LAL-
Control Standard Endotoxin (CSE)	**SS-CSE**	QS		SS-CSE-

CSE Reconstitution Date: _____ **Initial Block Temperature:** _____ **°C**

LAL Sensitivity: _____ **EU/mL** **Final Block Temperature:** _____ **°C**

Test Start Time: _____ **Test End Time:** _____

Results (+ = Positive, - = Negative)

Tube	0.125 EU/mL	0.0625 EU/mL	0.03125 EU/mL	0.015 EU/mL	e	Water
	2λ	λ	0.5 λ	0.25 λ		NC
A						
B						
C						
D						

Average: _____

GM: _____

Label Sensitivity Confirmed? **Yes** ___ **No** ____

Performed By: _____ **Date:** _____

QC Review: _____ **Date:** _____

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