Template Provided By:

Cancer Imaging Program

National Cancer Institute

GEL-CLOT ASSAY: Bacterial Endotoxins LAL Test Form

(Refer to GEN-Q114)

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

MATERIALS:

Description	ITC	Quantity	Amount Used	ITN/Lot
Final Product	**MBR-[^{18}F]FMISO**	0.1 mL		MBR-[^{18}F]FMISO-
LAL Reagent Water or Sterile Water for Injection (SWFI)	**SS-LRW** or **SS-WFI**	QS		SS-
Limulus Amebocyte Lysate (LAL)	**SS-LAL**	1		SS-LAL-
Control Standard Endotoxin (CSE)	**SS-CSE**	1		SS-CSE-

Depyrogenation Log Number: _____ **CSE Standard Number:** _____

LAL Reconstitution Date: _____ **LAL Sensitivity (λ):** _____ **EU/mL**

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

CSE Dilution Prep Date: _____ **Final Block Temperature:** _____ **°C**

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

Results with CSE Standard Series (+ = gel clot formed, - = no gel clot formed)

Tube	Sample	Dilution	20 Minutes	One Hour Duplicate Test	
1	Negative Water Control				
2	Positive Water Control (0.25λ)				
3	Positive Water Control (0.5λ)				
4	Positive Water Control (λ)				
5	Positive Water Control (2λ)				
6	Positive Product Control at NIC (2λ)				
7	Product at NIC				
8	Positive Product Control at NIC (80λ)				

OR

Limit Test (+ = gel clot formed, - = no gel clot formed)

Tube	Sample	Dilution	20 Minutes	One Hour Duplicate Test	
1	Negative Water Control				
5	Positive Water Control (2λ)				
6	Positive Product Control at NIC (2λ)				
7	Product at NIC				
8	Positive Product Control at NIC (80λ)				

20-Minute In-Process Test: **Pass** ___ **Fail** ___

____ **Gel Clot Test with CSE Standard Series:** **Pass** ___ **Fail** ___

OR

____ **Gel-Clot Limit Test:** **Pass** ___ **Fail** ___

Performed By: _____ **Date:** _____

QC Review: _____ **Date:** _____

Cancer Imaging Program, *Confidential--Use and restriction of this document is set forth in Transfer Agreement executed with the National Cancer Institute (NCI).*