Bacterial Endotoxin Gel Clot Validation

Final Inhibition and Enhancement Test

(Ref. MICLAB 105)

PRODUCT		PYROGENT LOT NO	
BATCH		SENSITIVITY	EU/mL
POTENCY		RECONSTITUTION DATE	
PRODUCT MVD	Mg/mL		
ASSAY DATE		ENDOTOXIN: LOT NO	
ANALYST		RECONSTITUTION DATE	

Test Results

Key + = firm gel

\- = no gel or viscous gel

1. Product Endotoxin Dilutions

Product dilutions level (as determined from Preliminary Test result B1) = _____

Replicate Assay No.	Endotoxin concentration EU/mL							Highest Positive Dilution
	1.0	0.5	0.25	0.125	0.06	0.03	0.015	
1.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
2.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
3.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
4.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	

2. Positive Controls

Replicate Assay No.	Endotoxin concentration EU/mL							Highest Positive Dilution
	1.0	0.5	0.25	0.125	0.06	0.03	0.015	
1.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
2.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
3.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	
4.	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	

3. Negative Controls

Replicate Assay No.	Result
1	[ ]
2.	[ ]

Bacterial Endotoxin Gel Clot Validation

Final Inhibition and Enhancement Test

(Ref. MICLAB 105)

Result sheet – Bacterial Endotoxin test (U.S.P.) Pyrogent

Interpretation of Results:

Test		Result	Acceptance Levels
A2	Product Endotoxin Dilution series endpoint, Part 1 (Highest dilution positive)		=_____EU/mL (0.5 – 2 x Lysate sensitivity)
B2	Positive Controls, Part 2 (Highest dilution positive)		=_____EU/mL (0.5 – 2 x Lysate sensitivity)
C2	Negative controls, Part 3	Pos / Neg	Must be negative.
D2	Lowest dilution giving positive Lysate in Preliminary test. (Product Compatibility Test, B1 result)		Less than MVD.
E2	Comparison of Endotoxin determinations in Product A2and Water B2. (ie Dilution level they differ by)		Must not differ by more than plus or minus a 2 fold dilution.

Have all the acceptance levels been met? YES / NO