



Bacterial Endotoxin Gel Clot Validation
Preliminary 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 Control Dilutions

Replicate Assay No.	Product dilution with W.F.I.								Highest Positive Dilution
	1:0	1:2	1:4	1:8	1:16	1:32	1:64	1:128	
1.	[]	[]	[]	[]	[]	[]	[]	[]	
2.	[]	[]	[]	[]	[]	[]	[]	[]	

2. Product Compatibility

Product endotoxin spiking concentration = _____ EU/ml = 2 x Lysate sensitivity.

Replicate Assay No.	Product dilution spiked with Endotoxin								Lowest Positive Dilution
	1:0	1:2	1:4	1:8	1:16	1:32	1:64	1:128	
1.	[]	[]	[]	[]	[]	[]	[]	[]	
2.	[]	[]	[]	[]	[]	[]	[]	[]	

3. Negative Controls

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

4. 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.	[]	[]	[]	[]	[]	[]	[]	



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Interpretation of Results:

<u>Test</u>		<u>Result</u>	<u>Acceptance Levels</u>
A1	Product Control Dilution, Part 1	Pos/Neg	Should be negative
B1	Product Compatibility, Part 2 (Lowest dilution positive)		Less than MVD
C1	Negative controls, Part 3	Pos/Neg	Must be negative.
D1	Positive Controls, Part 4 (Highest dilution positive)		= _____ EU/ml (0.5 – 2 x Lysate sensitivity)

Have all the acceptance levels been met? YES / NO

If YES, proceed with Final Inhibition and Enhancement Test

The result of B above is the product dilution to be used in the Final Test