Verification Assay Result Sheet
Verification Assay For Microbiology Laboratory Technicians
(Ref. MICLAB 105)

Verification Assay Date:

Name of Technician:

Test Reagents

Reagents	Lot No.	Reconstitution Date	Expiry date	
Pyrogent				EU/mL sensitivity
Endotoxin				EU/mL potency
Pyrosperse		NA		2% working concentration
Test kit		NA		

L.A.L, Endotoxin & Endotoxin Working Standards diluent.

Any sterile batch (WFI) (Tested to be L.A.L. negative) Batch No.:   Expiry:

Test Session Standards - Results
Key: (+) firm gel, (-) no gel or viscous gel.

Replicate Assay Number	Endotoxin Concentration & Gelation Results (EU/mL)							Endpoint	
	1	0.5	0.25	0.125	0.06	0.03	0.015	EU/mL	Log_{10}
1.									
2.									
3.									
4.									

Negative Controls
Key: (+) firm gel, (-) no gel or viscous gel.

Replicate Assay No.	Control Results
1	
2	

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NEGATIVE CONTROL/S
<u>Calculations</u>:

SDy =

$$\sqrt{\dfrac{n \left(\sum_{1}^{n} Y_i{}^2 \right) - \left(\sum_{1}^{n} Y_i \right)^2}{n\,(\,n\,-\,1\,)}}$$

SDy =

$$\sqrt{\dfrac{(\qquad) - (\qquad)}{(\qquad - 1)}}$$

=

Where $Y_i = \log_{10} X_i$ $(i = 1,2^n\ldots n)$
X_i = Gelation end-point in EU/mL
And n = number of replicate end-point assays

<u>Standard:</u>   99 % upper limit on SD $\log_{10} x$ (Lysate sensivity) where n = 4 is 0.365.

SDy = _____

Has the standard been met?   YES/NO

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Calculations:

$GMx = 10^{\breve{y}}$

where $\breve{y} =$

$$\frac{\left(\sum\limits_{1}^{n} y_i \right)}{n}$$

Where $\breve{y} = \dfrac{(\qquad\qquad)}{\rule{3cm}{0.4pt}}$

$=$

$GMx = 10^{\breve{y}}$

$=$

$=$

Standard: GM sensitivity value should fall within the range 0.03 – 1.25 EU/mL.

GMx = _____ EU/mL

Has the standard been met?   YES/NO

Comments about Session: _____

_____

_____

Signature of Technician:	Approved by:
Date:	Date: