ACC Inter Laboratory Performance Qualification (ILPQ) for the Bacterial Endotoxins Test (BET)

Test report: Gel clot method

Send by e-mail: ILPQ@ accintl.com

Company name: _____

Name of technician: _____

Sample description: _____ Storage temperature: _____

Date of sample receipt: _____ Date of investigation: _____

Material:

A) Endotoxin-Standard

☐ **Reference-Standard-Endotoxin (RSE)** name: _____

☐ **Control-Standard-Endotoxin (CSE)** Manufacturer/Lot: _____

Potency:_____ CSE Potency was: ☐ determined by ourselves; ☐ not determined; ☐ determined by manufacturer

B) Limulus Amebocyte Lysate (LAL): Manufacturer: _____

Lot: _____Sensitivity (EU/ml): _____

C) Solution for reconstitution

☐ **Limulus-Reagent-Water (LRW)** Manufacturer/Lot: _____

☐ **Reconstitution buffer** Manufacturer/Lot: _____

D) Test tubes Manufacturer: _____ ☐ Soda lime glass ☐ Borosilicate glass

E) Device for incubation Manufacturer: _____ ☐ Waterbath ☐ Thermoblock

Sample Preparation other than stated in the introduction letter:

_____

_____

Final result:

Maximum Valid Dilution (MVD): _____ (optional!)

Endotoxin limit value: _____ (optional!)

Endotoxin concentration of the sample: _____ EU/ml

Date: _____ Signature: _____

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Test results

Indicate a negative result as (-) and a positive result as (+)

A) Confirmation of lysate sensitivity

Standard dilutions:

Concentration EU/ml				
Result				

Number of replicates? _____

B) Preliminary Test

Dilution factor 1: n	**Sample**	**Sample positive control**

Water Negative Control:
☐ yes Number _____ ☐ no
result: _____

Water Positive Control:
☐ yes Number _____ ☐ no
result: _____

Further Controls?:
_____

C) Test of Inhibition and Enhancement (optional for ILPQ!)

In case you want to have an assessement of your test performance, please give us information of how you would perform this test!

Has been performed: ☐ yes At a sample dilution of **1**: _____ ☐ no

Standard diluted in LRW

Concentration EU/ml				
result				

Number of replicates? _____

Negative Controls : ☐ yes Number _____ result: _____ ☐ no

Standard diluted in sample dilution

Concentration EU/ml				
result				

Number of replicates? _____

Negative Controls : ☐ yes Number _____ result: _____ ☐ no

Is the test valid? ☐ **yes** ☐ **no**

Comments: _____

_____

Date: _____ Signature: _____