

Test report: Quantitative 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) Method used

Turbidimetric: Endpoint Kinetic **Chromogenic:** Endpoint Kinetic

E) Instrument Tube Reader Plate Reader Manufacturer: _____

Modell: _____ Software: _____

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: _____



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

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Test results

A) Parameter of standard curve

Standard concentrationen: _____ in _____
 observed **slope**: _____
 observed **y-intercept**: _____
 observed **correlation coefficient**: _____
 number of replicates: _____

B) Sample

| dilutionfactor 1: n | Number of replicates | endotoxin concentration of sample EU/ml; IU/ml | spike concentration EU/ml; IU/ml | recovery % |
|------------------------|-------------------------|---|-------------------------------------|---------------|
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2.) Controls

Water Negative Control: yes Number _____ result: _____ no

Water Positive Control: yes Number _____ result: _____
 Observed Recovery %: _____ no

Further controls?: _____

Is the test valid? yes no

Comments: _____

Date: _____ Signature: _____