

CHECKLIST FOR BACTERIAL ENDOTOXIN TEST (BET)

Validation test		
1.	Confirmation of Labeled Lysate Sensitivity (Gel Clot) / Standard Curve (Photometric Method)	<p style="text-align: center;">Method</p> <p>Gel Clot Method:</p> <ul style="list-style-type: none"> - At least 4 concentration of standard endotoxin (2 λ, λ, 0.5 λ, 0.25 λ) - 4 replicates - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric Method: For the generation of standard curve applicant must provide the following information:</p> <ul style="list-style-type: none"> - 3 endotoxin concentration to generate standard curve - 3 replicates for each concentration - correlation coefficient (r) must be ≥ 0.98 (linear graph must be demonstrated) <hr/> <p style="text-align: center;">Result (raw data)</p> <p>Gel Clot:</p> <ul style="list-style-type: none"> - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric:</p> <ul style="list-style-type: none"> - Standard Curve following the criteria set in Method.
2.	Test for Interfering Factor (Gel Clot/ Photometric Method)	<p style="text-align: center;">Method</p> <p>Gel Clot Method must consist of the following information:-</p> <ul style="list-style-type: none"> - Detailed method for Test for Interfering Factor - A: sample only - 4 replicates - B: sample + endotoxin (2λ or 4 different λ concentration)- 4 replicates - C: LAL water + endotoxin (4 different λ concentration) - 2 replicates - D: LAL water only - 2 replicates <p>Photometric Method:</p> <ul style="list-style-type: none"> - PPC Recovery must be between 50% - 200% <hr/> <p style="text-align: center;">Result (raw data)</p> <p>Gel Clot:</p> <ul style="list-style-type: none"> - A and D must be negative - Geometric Mean of End Point= 0.5 λ - 2 λ <p>Photometric:</p> <ul style="list-style-type: none"> - PPC Recovery between 50% - 200%

3.	MVD Calculation & ELC Calculation (if applicable) (Gel Clot/Photometric Method)	Method
		Result (raw data)
		<ul style="list-style-type: none"> - Calculation of MVD or ELC (if applicable) (Formula) - Actual calculation - Product specific

Routine Test		
1.	Preparation of Reagents, Endotoxin Standard and Sample. (Gel Clot/ Photometric Method)	<ul style="list-style-type: none"> - Preparation of reagent, endotoxin standard and sample - Dilution steps
2.	MVD Calculation & ELC Calculation (if applicable) (Gel Clot/Photometric Method)	<ul style="list-style-type: none"> - Calculation of MVD or ELC (if applicable) - Actual calculation - Product specific
3.	Limit Test /Semiquantitative Test (Gel Clot/ Photometric Method)	<p style="text-align: center;">Method</p> <p>Gel Clot Method:</p> <ul style="list-style-type: none"> - Protocol of analysis for bacteria endotoxin test (routine test procedure) - Acceptance criteria <p>Photometric Method:</p> <ul style="list-style-type: none"> - Protocol of analysis for bacteria endotoxin test (routine test procedure) - Acceptance criteria

Updated : 5 July 2018