Bacterial endotoxin: the assay

The lysate, the control standard endotoxin and the water with their lots and certificates, the standard series, the aliquot and its timing, the plate map, the read and its validity.

Not yet approved
No approval of this revision is on file. This form is a controlled record once approved; until then it is the proposed layout of the bench record its procedure names.

Worksheet	
Number	WS-07
Revision	1, first issue
Governs	SOP-04 Bacterial endotoxin by kinetic chromogenic LAL, revision 1
Status	Not yet approved
Effective	Not yet in effect; takes effect when approved
Applies to	Test codes LAL, FULL
Supersedes	Nothing; first issue
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Laboratory	
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1 Header

Accession, or the set id before logging

Analyte, as labelled

Analyst (the “Working as” name)

Date of the work (UTC)

Reviewer: line-by-line check (initials, date)

Attached to the set as (caption “WS-07 page p”)

2 How this form is used

- This worksheet is the original record of every value measured away from the backend. It is filled in ink at the moment of measurement; each line carries the time of the measurement and the analyst’s initials.
- A correction is a single line through the value, the new value, initials, the date and the reason; nothing is overwritten or erased.
- The completed form is photographed or scanned the same day and attached to the set at /photo/<id>/<name> with the caption “WS-07 page p”, each file hashed into the set’s trail as a “photo” entry; the values are typed into the form from it, and the reviewer checks the typed set against these pages line by line before signing.
- Lines marked “model only” feed a key the backend’s form does not yet expose: the value is typed into the section’s notes until it does. Lines marked “worksheet only” stay on this paper and in the notes.
- A failed criterion stops the work at that line: the time and what was done are written here, and the event goes to the set the same day as a note, a stop or a deviation (SOP-08).

3 Record

Reader and reagents

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
1	Reader id; software; set-point and displayed block temperature at the start; thermometer check date lal.instrument.id lal.instrument.software	°C, as displayed	37 ± 1 °C (SOP-04)		
2	Lysate: lot; lambda; expiry checked; certificate or insert lal.lysate_lot lal.lambda_eu_ml lal.lysate_expiry_utc lal.lysate_certificate_ref	EU/mL, 3 decimals	lambda = the lowest standard		
3	Lysate reconstitution: volume; time; use-by worksheet only	mL, as displayed			
4	CSE: name, manufacturer, lot, certificate; potency for this lysate lot; its uncertainty; expiry checked lal.cse.name lal.cse.manufacturer lal.cse.lot lal.cse.certificate_ref lal.cse.potency_eu_ng lal.cse.potency_u_rel_pct lal.cse.expiry_utc	EU/ng, 1 decimal	default u 7% relative when the certificate states none		
5	CSE reconstitution: date, time, volume, vortex time; reconstituted expiry worksheet only	text	vortex 15 min (or as the insert says) after reconstitution and 1 min before every use (SOP-04)		
6	LAL reagent water: lot, certificate, expiry checked, bottle opened; Tris medium lot (lipidated) lal.water_lot lal.water_certificate_ref lal.water_expiry_utc qnt.medium.lot	hh:mm UTC			
7	Consumables: plate, tip and tube lots and certificates; depyrogenation cycle for any glass worksheet only	text	at 250 °C for at least 30 min (SOP-04)		
8	Pipettes: id, volume, check reference lal.pipettes[].id lal.pipettes[].volume_ul lal.pipettes[].calibration_ref	µL			

Standard series and sample

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
9	Standard series: step, volumes (CSE + water), tube, vortex, resulting EU/mL lal.standards[].eu_ml	EU/mL, 3 decimals	at least 3 levels over 2 decades; 5, 0.5, 0.05, 0.005 EU/mL (SOP-04)		

Record, continued

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
10	Sample: stock source; stock concentration; stock volume; time of dissolution (WS-03) lal.sample.preparation_source lal.sample.reconstitution_mg_ml lal.sample.stock_volume_ml	mg/mL			
11	Aliquot drawn; dilution 1 + 39; vortex lal.sample.aliquot_utc lal.sample.dilution	x	within 15 min of the clarity record; 100 µL of stock into 3.90 mL LAL reagent water (1 + 39, D = 40), vortexed 30 s; dilution is used within 1 h		
12	pH of the test dilution mixed 1 + 1 with lysate, when required worksheet only	pH, 1 decimal	pH 6.0–8.0 (SOP-04)		
13	Positive product control: recipe; spike lal.ppc.spike_eu_ml	EU/mL, 1 decimal	within 0.5 decade of the curve's log midpoint		

Plate, timing and read

#	Field, and the result-set key it feeds	Unit, decimals	Criterion	Value	Time (UTC), initials
14	Pre-incubation start and end; lysate addition start and end; read start lal.acquired_utc	hh:mm UTC	Pre-incubate the loaded plate 10 min at 37 ± 1 °C; in column order, within 2 min		
15	Run time; onset threshold; wavelength lal.run_time_s lal.onset_threshold_od lal.read_wavelength_nm	s; OD; nm, 1 decimal			
16	Onset times, standards (duplicates) lal.standards[].onset_s	s	CV at most 10% per well		
17	Onset times: negative control; sample; PPC; medium control lal.negative_control.no_onset lal.negative_control.onset_s lal.sample.onset_s lal.ppc.onset_s	s			
18	Validity at the bench: |r|; PPC recovery; NC; valid; repeat planned worksheet only	text	|r| at least 0.980; PPC 50–200%; NC below lambda		
19	Data file; assay date; vials consumed lal.data_file lal.assay_date_utc lal.vials_consumed	hh:mm UTC			
20	Deviations (text) audit trail: deviation entry	text			

Record, continued

Plate map: the well of every solution

Standards in duplicate wells, the negative control, the sample, the positive product control and, when the stock is the Tris medium, the medium control; write each well's content in its square.

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												

Every solution container is labelled with the accession, the solution name (CSE stock, CSE working series, LAL 1:40, PPC), the concentration, the date and time made, the analyst and the expiry.

4 Completion

Completed by (signature) and time (UTC)

Reviewed line by line by (initials) on (date)

5 Revision history

Revision	Change	Approval
1	First issue.	Not yet approved

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Current revisions

End of document