PBL Pacific BioLabs
The Service Leader in Bioscience Testing

551 Linus Pauling Drive
Hercules, CA 94547
510.964.9000 ph.
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PacificBioLabs.com

LABORATORY SERVICE REQUEST (LSR) - BACTERIAL ENDOTOXIN (LAL)

CLIENT INFO

(**Instructions**: Use ONE form for each group of similar samples requiring the same storage, handling, analyses, and compliance. Fill in the form as completely as possible. Submit the form along with sample(s). Initiation of sample analysis will be delayed if form is not complete.)

Sponsor: (Send Report To)	☐ **Invoice To:** (Check Box if same as Sponsor)
Contact Name:	AP Contact Name:
Company Name:	Company Name:
Address:	Address:
City/State/Zip:	City/State/Zip:
Country:	Country:
Phone:	Fax:
Email:	
PBL Quote Number:	Client P.O. Number:

TEST ARTICLE INFO

Test Article ID (Please use the exact wording you want to appear in the final report.)

Lot Number:

Part Number:

Other Identifier:
(ex. Sample Code)

Expiration Date:

Quantity of Test Articles Submitted: (Please indicate the number of units, volume, and/or weight of test article.)

Physical Description:

☐ Device ☐ Solid ☐ Liquid ☐ Powder ☐ Gel ☐ Other:

Storage Condition:	Controlled Substance:	Hazardous: (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.)	Sample Disposition: (Check one box) (Samples will be discarded 30 days after report unless otherwise indicated)
☐ 20 to 25°C	☐ No	☐ Not Hazardous	☐ Return to Sender
☐ 2 to 8°C		☐ Reactive	Carrier: _____
☐ -16 to -24°C	☐ Yes	☐ Biohazard	Account: _____
☐ -60 to -80°C	Schedule: _____	☐ Toxic	☐ Dispose in Municipal waste
		☐ Other:	☐ Dispose in hazardous waste

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TEST ARTICLE INFO (CONT.)

List part(s) of the Test Article that should be tested:

List part(s) of the Test Article that should be excluded:

Final intended use/application of Test Article?:

Can Test Article be cut? ☐ Yes ☐ No

Sterility Status: ☐ Non-Sterile ☐ Sterile (Please indicate method) _____

Surface Area in cm^2 if Known: _____ Thickness: _____

Surface Area Calculations Completed By:

☐ Client ☐ To be completed by PBL

ISO 10993-12, *The standard surface area can be used to determine the volume of extraction vehicle needed. This area includes the combined area of both sides of the sample and excludes indeterminate surface irregularities. When surface area cannot be determined due to the configuration of the sample, a mass/volume of extracting fluid shall be used.*

Unusually complex surface area calculations that are to be performed by PBL may incur additional charges.

Extraction of large samples may incur additional media charges.

SERVICE INFO

Regulatory Treatment: ☐ Non-regulatory ☐ cGMP ☐ GLP

Complete the following section if GLP:

GLP Stability Testing and Test Article Characterization (Certificate of Analysis):

☐ Will be provided during study ☐ Will not be provided during study

Note: GLP testing requires, by Federal regulation, accurate identification of the test and control articles (e.g., a lot number, batch number or sample code) that allows unambiguous traceability of the tested material. GLP testing also requires that the testing laboratory document characterization of the test and control articles for stability, strength, purity, and composition, or other characteristics which will appropriately define the test or control article. This information is typically provided by the Sponsor and is required for each batch of test or control article tested; this documentation is often in the form of a Certificate of Analysis (C of A). For testing of biomedical devices that contain no drugs, Pacific BioLabs requires documentation of the identity, composition, and stability of the material tested.

Failure to provide this information will be noted as noncompliance with GLP regulations in the Final Report.

Rush Services: ☐ No ☐ Yes (will incur a 50% surcharge)

Report Format: ☐ PDF ☐ PDF and Paper ☐ Paper (Note: A fee will apply for paper copy of report.)

VALIDATION

Inhibition and Enhancement Test (USP/EP/JP) *(Required by GMP regulations)*

☐ Validation Completed - PBL Report No.: _____

☐ Validation Declined *(Please call PBL regarding testing parameters.)*

☐ Validation to be conducted by Pacific BioLabs *(Check method and Specify limit):*

Method: ☐ Liquid ☐ Powder ☐ Device-Immersion ☐ Device-Exhaustive Fluid Path

Specify Limit: _____

Check number of lots to be validated: ☐ One Lot ☐ Two Lots ☐ Three Lots (Recommended for AAMI ST72)

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TEST PROCEDURE

☐ **Pharmaceutical**	☐ **Medical Device**
Method ☐ Liquids - specify endotoxin limit: _____ ☐ Powders - specify endotoxin limit: _____	Method ☐ Immersion ☐ Exhaustive Fluid Path Limit ☐ 20 EU ☐ 2.15 EU (limit for cerebral spinal fluid) ☐ Other- specify limit: _____

OTHER TESTS/SPECIAL INSTRUCTIONS:

TESTING AUTHORIZED BY (Please Sign): _____ DATE: _____

(Signature and date, or electronic signature is required for testing to begin; unsigned LSR forms will not be processed)