PACIFIC BIOLABS
The Service Leader in Life Science Testing
PBL

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

LABORATORY SERVICE REQUEST (LSR) – Sterility Assurance

CLIENT INFORMATION	
Instructions: Submit the form along with sample(s). Initiation of sample analysis will be delayed if form is not complete.	
PBL Quote Number:	**PO Number:** *Credit Card to be used for payment* ☐
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:	Invoice To Email:
Email:	AP Email:

SERVICE INFORMATION	
Regulatory Treatment: ☐ Non-regulatory ☐ cGMP ☐ GLP	**Rush Service** *(will incur a surcharge)*: ☐ YES ☐ NO
Suitability (required by GMP regulations): ☐ Suitability Completed* ☐ Suitability Declined (please specify testing parameters in the Special Instructions) ☐ Suitability to be conducted by Pacific BioLabs (Sterile samples required for B&F/Validation test. Sample packaging will not be included unless specified in special instructions) Method: ☐ USP ☐ AAMI ☐ Other	

SAMPLE INFORMATION	
Sample 1 Identification Please use the exact wording you want to appear in the final report.	**Quantity of Samples Submitted** Please indicate the number of units, volume, and/or weight of samples.
Lot Number:	Part Number:
Other Identifier:	Expiration Date:
Physical Description: ☐ Device ☐ Solid ☐ Liquid ☐ Gel ☐ Other:	
Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:	
Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:	
*Suitability - PBL Report Number: Guideline Number:	
Sample 2 Identification Please use the exact wording you want to appear in the final report.	**Quantity of Samples Submitted** Please indicate the number of units, volume, and/or weight of samples.
Lot Number:	Part Number:
Other Identifier:	Expiration Date:
Physical Description: ☐ Device ☐ Solid ☐ Liquid ☐ Gel ☐ Other:	
Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:	
Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:	
*Suitability - PBL Report Number: Guideline Number:	

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Sample 3 Identification Please use the exact wording you want to appear in the final report.	**Quantity of Sample Submitted** Please indicate the number of units, volume, and/or weight of samples.

Lot Number: | Part Number:

Other Identifier: | Expiration Date:

Physical Description: ☐ Device ☐ Solid ☐ Liquid ☐ Gel ☐ Other:

Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:

Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:

*Suitability - PBL Report Number: Guideline Number:

Sample 4 Identification Please use the exact wording you want to appear in the final report.	**Quantity of Samples Submitted** Please indicate the number of units, volume, and/or weight of samples.

Lot Number: | Part Number:

Other Identifier: | Expiration Date:

Physical Description: ☐ Device ☐ Solid ☐ Liquid ☐ Gel ☐ Other:

Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:

Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:

*Suitability - PBL Report Number: Guideline Number:

Storage Condition

☐ Room Temperature
☐ 2 to 8C
☐ -10 to -25C
☐ -60 to -90C

Sample Disposition

Samples will be discarded per PBL SOP unless otherwise indicated.

☐ Return UNTESTED Samples to Client
☐ Return TESTED Samples to Client *(must be preapproved by PBL)*

If return address is different than Client address above, indicate address in Special Instructions below.

Carrier:
Account:

Dispose in: ☐ municipal waste ☐ hazardous waste

TESTING REQUIRED

Test Article: ☐ Device ☐ Parenteral ☐ Antibiotic ☐ Ophthalmic/Other Non-injectable Preparation ☐ Other

Method: ☐ Direct Transfer ☐ Membrane Filtration

Purpose of Testing: ☐ Quarterly Dose Audit ☐ Verification Dose ☐ Lot Release ☐ Other

Method of Sterilization *(MUST check one)*: ☐ Radiation ☐ EO ☐ Filtration ☐ Steam ☐ Other

Routine Testing

☐ Sterility Audit - USP (SCDM and FTM Media)
Production Lot Size:
Volume per Container:
☐ Sterility Audit - AAMI (SCDM Media)
☐ Biological Indicator Testing – ***Certificate of Analysis for the lot being sent must be attached***

OTHER TESTS/SPECIAL INSTRUCTIONS

Note that samples will be reported separately per lot unless otherwise indicated.

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)