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) – Bioburden (ISO)

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 Suitability test. Sample packaging will not be included unless specified in special instructions) Complete the suitability section on the second page.

DEVICE 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 ☐ Powder ☐ Gel ☐ Other:	
Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:	
Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:	
*Suitability - PBL Report Number: Guideline Number: Specification:	
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 ☐ Powder ☐ Gel ☐ Other:	
Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:	
Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:	
*Suitability - PBL Report Number: Guideline Number: Specification:	
Sample 3 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 ☐ Powder ☐ Gel ☐ Other:	
Controlled Substance: ☐ No ☐ Yes Schedule: NDC #: Concentration:	
Hazardous: ☐ NOT Hazardous ☐ Reactive ☐ Biohazard ☐ Toxic ☐ Other:	
*Suitability - PBL Report Number: Guideline Number: Specification:	

PACIFIC BIOLABS
The Service Leader in Life Science Testing

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

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 ☐ Powder ☐ Gel ☐ Other:

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

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

*Suitability - PBL Report Number: Guideline Number: Specification:

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

List part(s) of the Sample to be tested:

Final Intended Sterilization Method/Dose:

Final Intended Use/Application of Sample:

Test Article: ☐ Pharmaceutical ☐ Medical Device
Method: ☐ Pour Plate ☐ Membrane Filtration

Bioburden Suitability (ISO/AAMI)	**Bioburden Routine Testing** *(check all that apply)*
☐ Aerobic Bacteria/Fungi	☐ Aerobic Bacteria/Fungi
☐ Spores (must indicate sterilization method above)	☐ Spores (must indicate sterilization method above)
☐ Anaerobes	☐ Anaerobes
Liquids/Powders	☐ Verification Dose Calculation
☐ Suitability to be conducted by Pacific BioLabs	
Medical Devices	
☐ Suitability to be conducted by Pacific BioLabs Method:	
☐ Spore Recovery Study (For sterile or near sterile samples)	
☐ Exhaustive Recovery (For samples with ≤300 and ≥100 CFU)	

Microbial Confirmation Tests *(check all that apply, include quantity of each test)*

☐ Bacterial ID, Qty. ☐ Yeast/Mold ID, Qty. ☐ Gram Stain/Colony Morphology, Qty.

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)