

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: <i>Credit Card to be used for payment</i> <input type="checkbox"/>
Sponsor (send report to):	Invoice To: <i>Check box if same as sponsor</i> <input type="checkbox"/>
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: <input type="checkbox"/> Device <input type="checkbox"/> Solid <input type="checkbox"/> Liquid <input type="checkbox"/> Gel <input type="checkbox"/> 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: <input type="checkbox"/> Device <input type="checkbox"/> Solid <input type="checkbox"/> Liquid <input type="checkbox"/> Gel <input type="checkbox"/> Other:	
*Suitability - PBL Report Number:	Guideline Number:

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.
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Lot Number:	Part Number:
Other Identifier:	Expiration Date:

Physical Description: Device Solid Liquid Gel 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.
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Lot Number:	Part Number:
Other Identifier:	Expiration Date:

Physical Description: Device Solid Liquid Gel Other:

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

Storage Condition <input type="checkbox"/> Room Temperature <input type="checkbox"/> 2 to 8C <input type="checkbox"/> -10 to -25C <input type="checkbox"/> -60 to -90C	Controlled Substance <input type="checkbox"/> No <input type="checkbox"/> Yes Schedule: NDC #: Concentration:	Hazardous <i>Include MSDS if samples are hazardous. A fee will apply for disposal of hazardous samples.</i> <input type="checkbox"/> Not Hazardous <input type="checkbox"/> Reactive <input type="checkbox"/> Biohazard <input type="checkbox"/> Toxic <input type="checkbox"/> Other:	Sample Disposition <i>Samples will be discarded per PBL SOP unless otherwise indicated.</i> <input type="checkbox"/> Return UNTESTED Samples to Client <input type="checkbox"/> Return TESTED Samples to Client <i>(must be preapproved by PBL)</i> <i>If return address is different than Client address above, indicate address in Special Instructions below.</i> Carrier: Account: Dispose in: <input type="checkbox"/> municipal waste <input type="checkbox"/> hazardous waste
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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)