

LABORATORY SERVICE REQUEST (LSR) - Antimicrobial Effectiveness Test

CLIENT INFORMATION

Instructions: Submit the form along with sample(s). Initiation of sample analysis will be delayed if form is not complete.

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| 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

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| 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 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: |

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| 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: _____

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| Sample 5 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: _____

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| Storage Condition | Controlled Substance | Hazardous | Sample Disposition |
| <input type="checkbox"/> Room Temperature <input type="checkbox"/> 2 to 8C <input type="checkbox"/> -10 to -25C <input type="checkbox"/> -60 to -90C | <input type="checkbox"/> No <input type="checkbox"/> Yes Schedule: NDC #: Concentration: | <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: | <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 |

TEST METHOD AND PRODUCT CATEGORY

Please note test article samples must have low bioburden so it does not compete with inoculated microorganism. 110 grams or mL are needed for routine testing and 25 grams or mL are needed for validation testing.

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| USP Category <input type="checkbox"/> USP 1: Injections, other parenterals including emulsions, otic products, sterile nasal products, and ophthalmic products <input type="checkbox"/> USP 2: Topically used products made with aqueous bases or vehicles, nonsterile nasal products and emulsions, including those applied to mucous membranes <input type="checkbox"/> USP 3: Oral products other than antacids, made with aqueous bases or vehicles <input type="checkbox"/> USP 4: Antacids made with an aqueous base <input type="checkbox"/> Modified (specify client organisms and or time points, if any): | EP Category - <input type="checkbox"/> Criteria A <input type="checkbox"/> Criteria B <input type="checkbox"/> Criteria A and B <input type="checkbox"/> EP 1: Parenteral preparations, eye preparations, intruterine preparations and intramammary preparations <input type="checkbox"/> EP 2: Ear preparations, nasal preparations, preparations for cutaneous application and preparations for inhalation <input type="checkbox"/> EP 3: Oral preparations*, oromucosal preparations and rectal preparations <i>*additional organisms required for samples with high concentration of sugar, please specify in Special Instructions below.</i> |
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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)