

**LABORATORY SERVICE REQUEST- STERILITY ASSURANCE**

<b>Client Info</b>	Report To <i>(Please include contact name and company info.)</i>		Invoice To <i>(If different than Report To info.)</i>	
	Phone	Fax		P.O.
	Email			Quote

<b>Test Article Info</b>	Test Article ID <i>(Please use the exact wording you want to appear in the final report.)</i>		
	Quantity	Lot No.	Code
	Storage Conditions	<input type="checkbox"/> 20 to 25°C <input type="checkbox"/> 2 to 8°C <input type="checkbox"/> -16 to -24°C <input type="checkbox"/> -60 to -80°C	
	Controlled Substance	<input type="checkbox"/> No <input type="checkbox"/> Yes    Schedule _____	
	Hazardous	<input type="checkbox"/> No <input type="checkbox"/> Yes    Type of Hazard _____ <i>(Please include MSDS if samples are hazardous. Client will incur charges for disposal of hazards.)</i>	
Return Test Articles	<input type="checkbox"/> No <input type="checkbox"/> Yes    Carrier _____ Account # _____ <i>(Client will incur charges for shipping and handling.)</i>		

<b>Service</b>	Regulatory Treatment <input type="checkbox"/> cGMP <input type="checkbox"/> GLP <input type="checkbox"/> Non-regulatory <i>(GLP will incur an additional fee.)</i>
	Rush <i>(Will incur a 50% surcharge.)</i> <input type="checkbox"/> No <input type="checkbox"/> Yes
	Do You Want Report Date Confirmation? <input type="checkbox"/> No <input type="checkbox"/> Yes
	Report Format <input type="checkbox"/> Paper <input type="checkbox"/> PDF <input type="checkbox"/> Paper and PDF <i>(First format No Charge, \$6.00 for each additional.)</i>
	Archive Options <b>(for Paper Records)</b> All paper records will be scanned and stored at PBL indefinitely by a system that is validated to comply with GMP and GLP regulations.
	<b>Paper Records (Choose One)</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Discard (after one year) – <b>Non-GLP Default</b></li> <li><input type="checkbox"/> Return to Client (after one year) – <b>GLP Default</b> (Shipping charges apply)</li> <li><input type="checkbox"/> Return Immediately to Client (at study completion) – (Shipping charges apply)</li> <li><input type="checkbox"/> Extended Storage by PBL (after one year) - Invoiced annually per Fee Schedule at <a href="http://www.PacificBioLabs.com/archivefeeschedule.asp">www.PacificBioLabs.com/archivefeeschedule.asp</a></li> </ul>

<b>Sterilization</b>	Radiation <input type="checkbox"/> Validation <input type="checkbox"/> Dose Audit <input type="checkbox"/> VD max- AAMI TIR33 ( _____ kGy) <input type="checkbox"/> VD max- ANSI/AAMI/ISO 11137-2 ( _____ kGy) <input type="checkbox"/> Mthd 1- ANSI/AAMI/ISO 11137-2 ( _____ kGy)	EO <input type="checkbox"/> Fractional Cycle <input type="checkbox"/> Half Cycle <input type="checkbox"/> Full/Production Cycle	Steam Cycle <input type="checkbox"/> Vacuum <input type="checkbox"/> Gravity <input type="checkbox"/> Liquid <input type="checkbox"/> Half Cycle (°C _____, min _____) <input type="checkbox"/> Full Cycle (°C _____, min _____)
	Dry Heat Cycle <input type="checkbox"/> Half Cycle (°C _____, min _____) <input type="checkbox"/> Full Cycle (°C _____, min _____)	Chemical Sterilant Type of Chemical: _____ Exposure Time: min. _____	
	Other _____		

<b>Sterility Validation</b>	Validation– Bacteriostasis/Fungistasis: <input type="checkbox"/> To be conducted by Pacific BioLabs ( <b>Check method</b> ): <input type="checkbox"/> Direct Transfer USP <input type="checkbox"/> Direct Transfer AAMI <input type="checkbox"/> Membrane Filtration <input type="checkbox"/> Completed – <i>PBL Report No.</i> _____ <input type="checkbox"/> Declined ( <i>Please call PBL regarding testing parameters.</i> )
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<b>Sterility Test</b>	Sample Type : <input type="checkbox"/> Parenteral <input type="checkbox"/> Antibiotic <input type="checkbox"/> Ophthalmic/ Other Noninjectable <input type="checkbox"/> Device Production Lot Size: _____    Volume Per Container: _____	
	Method of Sterilization: ( <b>MUST check one</b> ) <input type="checkbox"/> Radiation <input type="checkbox"/> EO <input type="checkbox"/> Filtration <input type="checkbox"/> Steam <input type="checkbox"/> Other _____	
	Direct Transfer: <input type="checkbox"/> Product Testing <input type="checkbox"/> USP/EP/JP <input type="checkbox"/> CFR  <input type="checkbox"/> Biological Indicator Testing	Membrane Filtration: <input type="checkbox"/> Product Only- Steritest

<b>Other Testing</b>	Other Tests/Services: <input type="checkbox"/> Validation Protocol <input type="checkbox"/> Sample Item Portion Preparation (SIP) Bio Indicator Population Verification: <input type="checkbox"/> Label Claim Verification <b>OR</b> <input type="checkbox"/> Exposed B.I.– Determine Remaining Level
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OTHER TESTS/SPECIAL INSTRUCTIONS :
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<b>TESTING AUTHORIZED BY (Please sign)</b> _____ (Signature and date is required for testing to begin, unsigned LSR forms will not be processed)	<b>DATE:</b> _____
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