

LABORATORY SERVICE REQUEST- STERILITY ASSURANCE

Client Info	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

Test Article Info	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>

Service	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 NC, \$6.00 for each additional.)</i>																	
	Archive Options (for Paper Records) All paper records will be scanned and stored at PBL indefinitely by a system that is validated to comply with GMP and GLP regulations. Paper records will be stored by PBL at no charge for the first year after study completion. If no options are selected, default options will take effect. Extended storage will be invoiced annually per Fee Schedule at www.PacificBioLabs.com/archivefeeschedule.asp .																	
	<table border="1"> <thead> <tr> <th>Non GLP RPT</th> <th>GLP RPT</th> <th>Archive Options</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>Discard (after one year) – Non-GLP Default</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>Return to Client (after one year) – GLP Default (Shipping charges apply)</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>Return Immediately to Client (at study completion) – (Shipping charges apply)</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>Extended Storage by PBL (after one year) - Invoiced annually for continued PBL retention.</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>Client Default – Previously selected options by Client</td> </tr> </tbody> </table>	Non GLP RPT	GLP RPT	Archive Options	<input type="checkbox"/>	<input type="checkbox"/>	Discard (after one year) – Non-GLP Default	<input type="checkbox"/>	<input type="checkbox"/>	Return to Client (after one year) – GLP Default (Shipping charges apply)	<input type="checkbox"/>	<input type="checkbox"/>	Return Immediately to Client (at study completion) – (Shipping charges apply)	<input type="checkbox"/>	<input type="checkbox"/>	Extended Storage by PBL (after one year) - Invoiced annually for continued PBL retention.	<input type="checkbox"/>	<input type="checkbox"/>
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Test	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 _____)
	Other		
	Validation– Bacteriostasis/Fungistasis: <input type="checkbox"/> To be conducted by Pacific BioLabs <i>(Check method)</i> <input type="checkbox"/> Direct Transfer USP <input type="checkbox"/> Direct Transfer AAMI <input type="checkbox"/> Membrane Filtration <input type="checkbox"/> Completed – PBL Report No. _____ <input type="checkbox"/> Declined <i>(Please call PBL regarding testing parameters.)</i>		

Sterility and Other Testing	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: (MUST check one) <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"/> Biological Indicator Testing <input type="checkbox"/> Product Testing <input type="checkbox"/> USP/EP/JP <input type="checkbox"/> CFR	Membrane Filtration: <input type="checkbox"/> Product Only- Steritest
Other Tests/Services: Bio Indicator Population Verification <input type="checkbox"/> Label Claim Verification OR <input type="checkbox"/> Exposed B.I.– Determine Remaining Level <input type="checkbox"/> Validation Protocol <input type="checkbox"/> Sample Item Portion Preparation (SIP)		
OTHER TESTS/SPECIAL INSTRUCTIONS :		

TESTING AUTHORIZED BY (Please sign) _____	DATE: _____
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