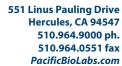


LABORATORY SERVICE REQUEST (LSR) - MEDICAL DEVICE REPROCESSING VALIDATION

CLIENT INFO			
		imples requiring the same storage, handling, the sample (s). Initiation of sample analysis will	
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:		Fax:	
Email:			
PBL Quote Number:		Client P.O. Number:	
TEST ARTICLE INFO			
Lot Number:			
Part Number:			
Other Identifier: (ex. Sample Code)			
Expiration Date:			
Quantity of Test Articles	Submitted: (Please indicate the	number of units, volume, and/or weight of test arti	cle.)
Physical Description:			
Device	Solid Liquid	☐ Powder ☐ Gel	Other:
Storage Condition:	Controlled Substance:	Hazardous: (include MSDS if samples are hazardous, client will incur charges for disposal of hazards.)	Sample Disposition: (Check one box) (Samples will be discarded 30 days after report unless otherwise indicated)
☐ 20 to 25°C	□No	☐ Not Hazardous	Return to Sender
☐ 2 to 8°C		☐ Reactive	Carrier:
☐ -16 to -24°C	Yes	☐ Biohazard	Account:
☐ -60 to -80°C	Schedule:	☐ Toxic	☐ Dispose in Municipal waste
		Other:	☐ Dispose in hazardous waste

Page 1 of 3





TEST ARTICLE INFO (CONT.)
What is the classification of the test article? Non-Critical Environmental (Does not come in contact with patient)
Non-Critical (Intact skin)
Semi-Critical (Mucous Membrane)
Critical (Blood barrier)
inal Intended Use:
Can the test article be immersed in liquid?
Client Provided Surface Area in cm ² (required for cleaning validations):
SERVICE INFO
Regulatory Treatment: Non-regulatory CGMP GLP
Complete the following section if GLP:
GLP Stability Testing and Test Article Characterization (Certificate of Analysis):
☐ Will be provided during study ☐ Will not be provided during study
Note: GLP testing requires, by Federal regulation, accurate identification of the test and control articles (e.g., a lot number, batch number or sample code) that allows unambiguous traceability of the tested material. GLP testing also requires that the testing laboratory document characterization of the test and control articles for stability, strength, purity, and composition, or other characteristics which will appropriately define the test or control article. This information is typically provided by the Sponsor and is required for each batch of test or control article ested; this documentation is often in the form of a Certificate of Analysis (C of A). For testing of biomedical devices that contain no drugs, Pacific BioLabs requires documentation of the identity, composition, and stability of the material tested. Failure to provide this information will be noted as noncompliance with GLP regulations in the Final Report.
Rush Services: No Yes (will incur a 50% surcharge)
Report Format: PDF PDF and Paper Paper (Note: A fee will apply for paper copy of report.)
TESTING REQUIRED (Please check all required tests)
CLEANING VALIDATION:
Cleaning Procedure: PBL will develop a method
Client Provided (Specify):
Method of Cleaning:
Automated (Please Specify Type):
Cleaning Chemical?
Biomarkers for evaluation: Protein Hemoglobin Carbohydrates
Note: A recovery efficiency validation is required for both the cleaning and disinfection validations.
Project Deadline:
DISINFECTION VALIDATION:
Level of Disinfection: High Intermediate Low
Disinfection Procedure: 🔲 PBL will develop a method
Client provided (Specify):
Method of Disinfection:
Disinfectant (Specify):
☐ Thermal (Please Specify Parameters):
Automated (Please Specify Type):
Disinfectant residual evaluation? None Biocompatiblity Other:
Note: A recovery efficiency validation is required for both the cleaning and disinfection validations.
Project Deadline:

Page 2 of 3 Form No. PBLLSR MDRV-1.2©





OTHER TESTS/SPECIAL INSTRUCTIONS:		
TESTING AUTHORIZED BY (Please Sign):	DATE:	

Page 3 of 3 Form No. PBLLSR MDRV-1.2©