

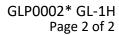
1001 Proctor Drive • Elkhorn, WI 53121 Phone: 262.723.5669 <u>www.genevalabs.com</u>

Email: custservice@genevalabs.com

GLP TEST REQUEST

Good Laboratory Practices (GLP) testing is used for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration undergoing testing for 510(k) or IND submittals only.

Quote No.: GLQ-	P.O. No.:	*REQ. NO.:	
Send Final Report to:	Billing Information:		
Company:	Company:		
Contact:	Contact:		
Address:	Address:		
Country:	Country:		
Email:	Email:		
Phone:	Phone:		
SAMPLE SUBMISSION INFORMATION Must fill-in or check a box in ALL areas. Indicate not applicable with an "N/A".			
Test Article Name for Report(s) Use Special instructions below for more space.	Identification (P/N, Lot #, or other) (Note: N/A is not recognized by FDA) Use Special Instructions below for more space.	Expiration Date Number of Samples Submitted	
Sample Stability - Must choose one (1) of the following: Stability testing is in progress and sponsor affirms that test article is stable for duration of intended testing. Stability testing is complete and on file with sponsor. Marketed product stability is characterized by its labeling. Label with expiration date must appear on the product. Specify portion of sample to be tested or other Special Instructions:			
Steam sterilization by Geneva Laboratories required (extra charge will apply). Parameters:			
GLP TESTING GUIDELINES (Extraction testing is performed unless Direct Contact has been checked.)			
Test Name from Quote	Reference Standard/Method	*Geneva Labs Job Number	
	☐ ISO or ☐ USP ☐ Direct Conta	act	
	☐ ISO or ☐ USP ☐ Direct Conta	act	
	☐ ISO or ☐ USP ☐ Direct Conta		
	☐ ISO or ☐ USP ☐ Direct Conta		
	☐ ISO or ☐ USP ☐ Direct Conta		
	☐ ISO or ☐ USP ☐ Direct Conta		
	☐ ISO or ☐ USP ☐ Direct Conta		





1001 Proctor Drive • Elkhorn, WI 53121 Phone: 262.723.5669 <u>www.genevalabs.com</u>

Email: custservice@genevalabs.com

Sponsor Signature:

GLP TEST REQUEST

Must fill-in or check a box in ALL areas. Indicate not applicable with an "N/A". *REQ. NO.:			
Description and/or intended clinical use of test article:			
Total Surface Area per Unit (cm²):			
Surface area unknown – Geneva Laboratories to determine			
Physical Description:	Extraction Conditions: N/A (Direct Contact testing)		
Medical Device	121°C/1 hour		
Elastomeric Closure/Device	70°C/24 hours		
Solid	50°C/72 hours		
Liquid/Gel (SDS must accompany sample)	37°C/120 hours (Hemolysis Only)		
Paste (SDS must accompany sample)	☐ 37°C/24 hours (Cytotoxiciity; ≤30 days contact duration)		
Powder (SDS must accompany sample)	37°C/72 hours (Cytotoxicity; >30 days contact duration)		
Other:	☐ To Be Determined by Geneva Laboratories, Inc.		
☐ Fabric/Foam or Mask/Gown Article Indicate if moistening with water or, where necessary, an alternative solvent, to ensure good contact with the skin is permitted: ☐ Yes ☐ No (Please check NO if sample is water-resistant.)	Special Extraction Instructions (if applicable):		
Sample disposal following testing:			
☐ Keep and Archive Unused/Untested Samples ☐ Return Un	used Samples - FedEx or UPS # for Return:		
Other Special Instructions: Not Applicable			
CONTROL ARTICLE CHARACTERIZATION: Geneva Laboratories, Inc. provides controls for most reproviding the appropriate control article(s) per FDA 21 characterizing, control article(s) must meet the same F			
Before signing, please make sure all areas of this test	t request are complete to prevent delays with your testing.		

Date:_