

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

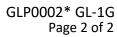
Email: custservice@genevalabs.com

## **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.

If your product will not be submitted for FDA approval, you may not need GLP testing. Please consult with us.

Quote No.: GLQ-	P.O. No.:	*REQ. NO.:			
Send Final Report to:	Billing I	nformation:			
Company:	Compar	Company:			
Contact:	Contact	Contact:			
Address:	Address	Address:			
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 (This will be printed on all reports.)  If more space is needed - use Comments below.	Identificatio   (Part No. and/or Lot No. ro   If more space is needed - use Co	ecommended)	Expiration Date	Number of Samples Submitted	
Sample Stability - Please answer 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.					
Comments or Special Handling Instructions (List device parts not to be included in test, etc.):					
Is sample a Biohazard?					
Storage Conditions: Room Temp. Refrigerate (5° ±3°C) Freeze (-20° ±4°C) Other:					
Condition of Test Article: N/A - Not a Medical Device Non-Sterile (as used) Non-Sterile (but sterilized at point of use)  Sterile by this method: Ethylene Oxide Gamma Irradiation Other:  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		ndard/Method		bs Job Number	
	☐ ISO ☐ USP	Direct Contact			
	☐ ISO ☐ USP	Direct Contact			
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	ISO USP Direct Contact				
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Must fill-in or check a box in ALL areas. Indicate not applicable with an "N/A". *REQ. NO.:					
Intended clinical use of product:   Not Applicable					
Total Surface Area per Unit (cm²):					
Surface area unknown – Geneva Laboratories to determine					
Surface area unknown – Geneva Laboratories to determine					
Physical Description:	<b>Extraction Conditions:</b> N/A (Direct Contact testing)				
Medical Device	121°C/1 hour				
Elastomeric Closure/Device					
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	Special Extraction Instructions (if applicable):				
Indicate if moistening with water or, where necessary, an alternative					
solvent, to ensure good contact with the skin is permitted:  \[ \sum \cong \text{Yes} \sum \text{No} \]					
Sample disposal following testing:					
Keep and Archive Unused/Untested Samples					
Other Special Instructions:					
CONTROL ARTICLE CHARACTERIZATION:					
Geneva Laboratories, Inc. provides controls for most routine studies and is responsible for characterizing and					
providing the appropriate control article(s) per FDA 21 CFR Part 58.105. If Sponsor provides control and characterizing, control article(s) must meet the same FDA 21 CFR Part 58.105 criteria.					
Before signing, please make sure all areas of this test request are complete to prevent delays with your testing.					
2. 1. 1. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2.					

Sponsor Signature:\_\_\_\_\_ Date:\_\_\_