



1001 Proctor Drive • Elkhorn, WI 53121  
 Phone: 262.723.5669 [www.genevalabs.com](http://www.genevalabs.com)  
 Email: [custservice@genevalabs.com](mailto: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 submissions 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) <small>Use Special instructions below for more space.</small>	Identification (P/N, Lot #, or other) <small>(Note: N/A is not recognized by FDA) Use Special Instructions below for more space.</small>	Expiration Date	Number of Samples Submitted
<p><b>Sample Stability - Must choose one (1) of the following:</b></p> <p><input type="checkbox"/> Stability testing is in progress and sponsor affirms that test article is stable for duration of intended testing.</p> <p><input type="checkbox"/> Stability testing is complete and on file with sponsor.</p> <p><input type="checkbox"/> Marketed product stability is characterized by its labeling. Label with expiration date must appear on the product.</p>			
<p><b>Specify portion of sample to be tested or other Special Instructions:</b> <input type="checkbox"/> Entire sample <input type="checkbox"/> Part of sample (specified below):</p>			
<p><b>Is sample a Biohazard?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No      <b>Can product be cut for testing?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No</p>			
<p><b>Storage Conditions:</b> <input type="checkbox"/> Room Temp. <input type="checkbox"/> Refrigerate (5° ±3°C) <input type="checkbox"/> Freeze (-20° ±4°C) <input type="checkbox"/> Other:</p>			
<p><b>Condition of Test Article:</b> <input type="checkbox"/> N/A - Not a Medical Device <input type="checkbox"/> Non-Sterile (as used) <input type="checkbox"/> Non-Sterile (but sterilized at point of use)</p> <p>Sterile by this method: <input type="checkbox"/> Ethylene Oxide <input type="checkbox"/> Gamma Irradiation <input type="checkbox"/> Other:</p> <p><input type="checkbox"/> Steam sterilization by Geneva Laboratories required (extra charge will apply). Parameters:</p>			

**GLP TESTING GUIDELINES**

(Extraction testing is performed unless Direct Contact has been checked.)

Test Name from Quote	Reference Standard/Method	*Geneva Labs Job Number
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	
	<input type="checkbox"/> ISO or <input type="checkbox"/> USP <input type="checkbox"/> Direct Contact	

\* For office use only

GLP  
  
GLP



1001 Proctor Drive • Elkhorn, WI 53121  
 Phone: 262.723.5669 [www.genevalabs.com](http://www.genevalabs.com)  
 Email: [custservice@genevalabs.com](mailto:custservice@genevalabs.com)

# 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 (cm <sup>2</sup> ):
<input type="checkbox"/> Surface area unknown – Geneva Laboratories to determine

Physical Description:
<input type="checkbox"/> Medical Device
<input type="checkbox"/> Elastomeric Closure/Device
<input type="checkbox"/> Solid
<input type="checkbox"/> Liquid/Gel <i>(SDS must accompany sample)</i>
<input type="checkbox"/> Paste <i>(SDS must accompany sample)</i>
<input type="checkbox"/> Powder <i>(SDS must accompany sample)</i>
<input type="checkbox"/> Other:
<input type="checkbox"/> 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: <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(Please check NO if sample is water-resistant.)</i>

Extraction Conditions: <input type="checkbox"/> N/A (Direct Contact testing)
<input type="checkbox"/> 121°C/1 hour
<input type="checkbox"/> 70°C/24 hours
<input type="checkbox"/> 50°C/72 hours
<input type="checkbox"/> 37°C/120 hours (Hemolysis Only)
<input type="checkbox"/> 37°C/24 hours (Cytotoxicity; ≤30 days contact duration)
<input type="checkbox"/> 37°C/72 hours (Cytotoxicity; >30 days contact duration)
<input type="checkbox"/> To Be Determined by Geneva Laboratories, Inc.
Special Extraction Instructions (if applicable):

Sample disposal following testing:	
<input type="checkbox"/> Keep and Archive Unused/Untested Samples	<input type="checkbox"/> Return Unused Samples - FedEx or UPS # for Return:

Other Special Instructions: <input type="checkbox"/> Not Applicable

**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.**

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

\* For office use only