GENEVA LABORATORIES
1001 Proctor Drive • Elkhorn, WI 53121
Phone: 262.723.5669 www.genevalabs.com
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:
Company:
Contact:
Address:

Email:
Phone:

Billing Information:
Company:
Contact:
Address:

Email:
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.*	**Identification** (Part No. and/or Lot No. recommended) *If more space is needed - use Comments below.*	**Expiration Date**	**Number of Samples Submitted**

GLP

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? ☐ Yes ☐ No **Can product be cut for testing?** ☐ Yes ☐ No

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

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 ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	
	☐ ISO ☐ USP ☐ Direct Contact	

* For office use only

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*REQ. NO.: _____

Intended clinical use of product: ☐ Not Applicable

Total Surface Area per Unit (cm^2):	
☐ Surface area unknown – Geneva Laboratories to determine	

Physical Description:
☐ Medical Device
☐ Elastomeric Closure/Device
☐ Solid
☐ Liquid/Gel ***(SDS must accompany sample)***
☐ Paste ***(SDS must accompany sample)***
☐ Powder ***(SDS must accompany sample)***
☐ Other:
☐ 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

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

Sample disposal following testing:	
☐ Keep and Archive Unused/Untested Samples	☐ Return Unused Samples - FedEx or UPS # for Return:

Other Special Instructions: ☐ 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:_____