GENEVA LABORATORIES, INC.

1001 Proctor Drive • Elkhorn, WI 53121-0140
Phone: (262) 723-5669 • 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.

Please complete and sign this test request for each product, then return via email or with the test sample(s). Following receipt, Geneva Laboratories, Inc. will provide you with the protocol(s).

ADDRESS REPORT TO:

*COMPANY:

*ADDRESS:

*CONTACT/ATTN TO:

Phone:

*Email:

BILLING ADDRESS (if different):

*Geneva Labs Quote:

*P.O. No.:

(P.O. No. must be provided for GLP testing to begin.)

*Specify Guideline to follow: ☐ ISO 10993 ☐ USP

GLP

TEST ARTICLE INFORMATION

It is the responsibility of the sponsor to assure the listed test article has been characterized for stability, identity, purity, strength, and composition as required by FDA Good Laboratory Practice for Nonclinical Studies 21 CFR Part 58.105.

Test Article Name:** ***(Please use exact wording as this is how it will appear on the GLP reports and test data records.)

GLP

If Sterilization is required prior to testing product, parameters need to be provided (see Pg. 2 - Condition of Test Article).

Identification:** ***(Be sure to specify Identification as CAS No., Ref. No., Part No., Lot No., etc., as is applicable.)

***Test Article Exp. Date:**

***Qty. Submitted:**

Is sample a Biohazard? ☐ Yes ☐ No

Storage Condition: ☐ Room Temperature ☐ 5° ±3°C ☐ -20° ±4°C
☐ Other (specify):

CAN TEST ARTICLE BE CUT: ☐ Yes ☐ No *(Note: For tests requiring extractions, test article is usually cut and thus destroyed.)*

List any parts of the test article that should be excluded from testing:

GLP

TEST(S) TO BE PERFORMED:

(Extraction testing is performed, where needed, unless Direct Contact is checked):

GENEVA LABS USE ONLY

1.	☐ Direct Contact	JN_____
2.	☐ Direct Contact	JN_____
3.	☐ Direct Contact	JN_____
4.	☐ Direct Contact	JN_____
5.	☐ Direct Contact	JN_____
6.	☐ Direct Contact	JN_____
7.	☐ Direct Contact	JN_____

***Required fields. Use "N/A" where applicable.**

GENEVA LABORATORIES REQ. NO.: _____

* **Condition of Test Article:** ☐ N/A - Not a Medical Device

Tests for biocompatibility are to be conducted on a medical device (or representative surrogate) in its "Final Finished Form".

If Test Article is a Medical Device, is it: ☐ Non-Sterile (as used) ☐ Non-Sterile (but sterilized at point of use)

☐ Sterile (indicate method):

Geneva Laboratories to provide steam sterilization processing prior to testing for an additional charge: ☐ Yes ☐ No

If Yes, list parameters here:

TOTAL SURFACE AREA PER UNIT (cm²):

☐ Surface Area to be determined by Geneva Laboratories, Inc.

Note: Surface area is the preferred method of determining the amount of extraction media necessary. If surface area is not supplied by Sponsor and cannot be determined by Geneva Laboratories, Inc., the weight to volume ratio will be used. Extraction of large samples may incur additional media charges.

EXTRACTION CONDITIONS:

☐ 121°C/1 hour ☐ 70°C/24 hours ☐ 50°C/72 hours ☐ 37°C/120 hours (Hemolysis Only)

☐ 37°C/24 hours (Cytotoxicity; ≤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):

* ***INTENDED CLINICAL USE OF TEST ARTICLE (Explain below or check*** ☐ Not Applicable***):***

* ***PHYSICAL DESCRIPTION:***

☐ Medical Device ☐ Elastomeric Closure/Device ☐ Solid ☐ Other:

☐ Liquid/Gel ** ☐ Paste ** ☐ Powder ** *****An SDS must accompany submitted samples.***

☐ Fabric/Foam or Mask/Gown articles - For Direct Contact see paragraph below

☐ Moistened ** ☐ No Moistening Necessary

** *Moistening per ANSI/AAMI/ISO 10993-10:2010 Standard: When testing solids the test material shall be moistened sufficiently with water or, where necessary, an alternative solvent, to ensure good contact with the skin (see Annex A). When solvents are used, the influence of the solvent on irritation of skin caused by the test material shall be taken into account.* **Please indicate which you would prefer for your test article by checking the "Moistened" or "No Moistening" box above.**

SPECIAL INSTRUCTIONS:

SAMPLE DISPOSAL FOLLOWING TESTING:

☐ Geneva Laboratories, Inc. to Archive Unused/Untested Samples

☐ Return Unused/Untested Samples (Fill in below.)

Method of Return: ☐ FedEx ☐ UPS ☐ Other (Specify):

Shipping Account No.:

NOTE: At least one (1) untested sample will be retained by Geneva Laboratories, Inc. for archival purposes.

CONTROL ARTICLE CHARACTERIZATION:

Geneva Laboratories, Inc. provides controls for most routine studies. Geneva Laboratories, Inc. is responsible for characterizing and providing the appropriate control article(s) per FDA 21 CFR Part 58.105.
If Sponsor is providing control, characterizing and providing control article(s) per FDA 21 CFR Part 58.105 is Sponsor's responsibility.

Sponsor Signature: _____ Date: _____