GENEVA LABORATORIES, INC.

1001 Proctor Drive • Elkhorn, WI 53121-0140 Phone (262) 723-5669 • Email: custservice@genevalabs.com

GLP TEST REQUEST

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).

SEND REPORT TO: ***BILLING ADDRESS (if different):***

COMPANY*:

ADDRESS*:

CONTACT NAME*:
Phone:
Email:

Geneva Labs Quote:
P.O. No.*:
(P.O. No. must be provided for GLP testing to begin.)

Specify Guideline to follow: ☐ ISO 10993 ☐ USP ☐ Other:

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*:

Identification No.*:

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

Is sample a Biohazard? ☐ Yes ☐ No

Amount Submitted:

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):

Note: Geneva Laboratories can provide steam sterilization processing (additional charge). ☐ Yes, parameters:

TEST(S) TO BE PERFORMED ***(Extraction testing is performed, where needed, unless Direct Contact is checked):***

GENEVA LABORATORIES 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_____
8.	☐ Direct Contact	JN_____
9.	☐ Direct Contact	JN_____
10.	☐ Direct Contact	JN_____

If additional testing is needed, please complete another GLP Test Request.

****Exact wording to be used on the GLP test data records and reports.***

GENEVA LABORATORIES, INC. USE ONLY

RECEIVING STAMP(S):

REQUISITION NO.: _____

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 GUIDELINES (Check all that apply):

Cytotoxicity: ☐ MEM ☐ Saline ☐ SWI

Sensitization: ☐ NaCl ☐ CSO

Intracutaneous: ☐ NaCl ☐ CSO ☐ Alcohol ☐ PEG

Acute Systemic: ☐ NaCl ☐ CSO ☐ Alcohol ☐ PEG

Hemolysis: ☐ Direct & Indirect ☐ Indirect Only

Other (Specify):

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):

EXTRACTION RATIO: ☐ 0.2 g/mL (if irregular surface) ☐ 3 cm²/mL (≥0.5 mm thick) ☐ 6 cm²/mL (<0.5 mm thick)

☐ To Be Determined by Geneva Laboratories, Inc. ☐ Other (Please specify):

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

PHYSICAL DESCRIPTION:

☐ Medical Device ☐ Solid ☐ Other:

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

☐ Fabric/Foam Material (For Direct Contact only, is the fabric/foam material to be: ☐ Moistened ☐ No moistening necessary)

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:

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, Sponsor is responsible for characterizing and providing the appropriate control article(s) per FDA 21 CFR Part 58.105.

Sponsor Signature: _____ Date: _____