GENEVA LABORATORIES, INC.

GLP TEST REQUEST FORM AND TEST SPECIFICATIONS

1001 Proctor Drive, Elkhorn, WI 53121-0140 Telephone (262) 723-5669 Fax (262) 723-4015

Please complete and sign the following and return along with the test sample.
Following receipt, Geneva Laboratories, Inc. will provide you with a protocol(s).

Reference Geneva Laboratories, Inc. Quote #: _____

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

SEND REPORT TO:

COMPANY*: _____
ADDRESS*: _____
_____
_____
ATTN*: _____
Phone: _____
Email: _____

BILLING ADDRESS (if different):

_____
_____
_____
_____
P.O. No.: _____

TEST ARTICLE INFORMATION:

Name of Product*: _____

Identification*: _____

(Include REF#, Part #, Batch#, and/or Lot # as listed on you packaging label(s), if applicable)

Example 1: REF#: XX-XXX; Lot No. XXX-XX-XXX **Example 2**: Batch No. XXXX-XX-XX-XXXX

Storage Conditions (if not room temperature): _____

Quantity Submitted: _____

Note: Studies lasting >28 days require a representative test sample to be retained.

****Exact wording to be used on the Protocol(s) and All Report(s).***

TEST(S) TO BE PERFORMED:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

STERILITY STATUS:

☐ Non-Sterile ☐ Sterile (Indicate Method): _____

☐ Geneva Labs to sterilize (Indicate Method and Parameters): _____

(Additional charges for sterilization may apply)

Note: Testing is expected to be performed on the Final Finished Form of the device (including sterilization, when applicable).

TOTAL SURFACE AREA PER UNIT (in cm^2): _____ or Thickness (cm): _____

☐ 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.*

INTENDED CLINICAL USE OF TEST ARTICLE: _____

_____

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

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

PHYSICAL DESCRIPTION: ☐ Medical Device ☐ Solid

☐ Liquid/Gel** ☐ Paste** ☐ Powder** ***An SDS must accompany test articles of these types.***

☐ Other: _____

***EXTRACTION CONDITIONS*:** ☐ 121°C/1 hour ☐ 70°C/24 hours ☐ 50°C/72 hours ☐ 37°C/72 hours

☐ 37°C/24 hours (Cytotoxicity Only) ☐ 37°C/72 hours (Cytotoxicity Implant Device Only)

☐ 37°C/120 hours (Hemolysis Only)

☐ To be determined by Geneva Laboratories, Inc.

Special Instructions: _____

SAMPLE DISPOSITION (AFTER TESTING):

☐ Geneva Laboratories, Inc. to archive unused test article(s)

☐ Return unused Test Article

Method of Return Shipment: ☐ UPS ☐ Other: _____ Account # _____

TEST ARTICLE CHARACTERIZATION:

It is the responsibility of the sponsor to assure the above 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.

***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.

Optional sponsor provided control: _____

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

***SPECIAL INSTRUCTIONS*:** _____

_____

_____

Sponsor Signature: _____ Date: _____