



# Biocompatibility - JMHLW TEST REQUEST FORM

Biocompatibility testing to be conducted:

Non-GLP  GLP

*This form may be used for GLP test orders only when a master copy of the GLP protocol is on file.*

Complete both pages of this form and include it with your test article shipment. Ship samples to:

**WuXi AppTec • 2540 Executive Drive • St. Paul, MN 55120**

(1) 651.675.2000 TOLL FREE 888.794.0077 FAX 651.675.2008

UPON TEST COMPLETION: [CHECK ONE]

DISCARD all test articles      RETURN (\$50 fee applies):  All test articles     Unused only

Provide courier company and account # (\$25 fee applies if not provided):

P.O. #

## CLIENT INFORMATION

ACCOUNT NUMBER/CLIENT CODE:

COMPANY NAME

CONTACT NAME / TITLE

ADDRESS

PHONE

FAX

CITY / STATE / ZIP

EMAIL

## TEST ARTICLE INFORMATION

TEST ARTICLE IDENTIFICATION [As to be described on the final report]

PHYSICAL DESCRIPTION [For Test Article Prep section of the final report]

LOT #

EXPIRATION DATE

QTY. SUBMITTED

INTENDED USE / APPLICATION

SURFACE AREA MEASUREMENT

Total surface area of component(s) being tested: \_\_\_\_\_ cm<sup>2</sup>     N.A.

PHYSICAL STATE

Insoluble to be extracted     Soluble  
 Liquid     Other (Specify):

SAFETY PRECAUTIONS     MSDS Enclosed  
 None/Unknown     Flammable  
*(Use standard precautions)*

CONTROLLED STORAGE CONDITIONS (Check one)

Room temperature     Refrigerated (2°C to 8°C)     Frozen (-10°C to -60°C)  
 Ultracold (<-60°C)     Other (Specify):

SUBMITTED STERILE?

Yes  
 No

STERILIZATION METHOD

N.A.  
 EO     Radiation  
 Steam     Other (Specify):

WUXI APTEC TO EXPOSE TO:     N.A.

EO (55°C for 1hr with 12 hr aeration)  
 Steam (Autoclave) Parameters: \_\_\_\_\_

NOTE: Additional fees apply for this service.

Do NOT cut test article.

*Test article should be cut into small pieces (per JMHLW guidelines).*

Do NOT test entire article. [Entire article will be tested unless box is checked.]

Specify components/materials to be excluded:

## COMPARISON / CONTROL ARTICLE – FOR IMPLANTATION TESTING ONLY [OPTIONAL]

N.A.

COMPARISON / CONTROL ARTICLE IDENTIFICATION

PHYSICAL DESCRIPTION OF CONTROL ARTICLE

LOT #

EXPIRATION DATE

QTY SUBMITTED

## COMMENTS / SPECIAL HANDLING

See Page 2 of this form to provide testing information and signed authorization.

**REQUESTED TESTING**

If applicable and as indicated, extraction information must be provided below by Sponsor.  
For assistance, contact WuXi AppTec – St. Paul Client Relations at 888-794-0077, Ext. 2030.

**CYTOTOXICITY**

- 140470** [JMHLW]  
Extract Colony Assay Cytotoxicity Test  
**EXTRACTION RATIO:**  
 2g/20mL  120cm<sup>2</sup>/20mL

**GENOTOXICOLOGY**

- 190812** [JMHLW]  
Bacterial Reverse Mutation Assay Using Four  
Salmonella Strains and One E. coli Strain
- 190827** [JMHLW]  
In Vitro Chromosome Aberration Analysis in  
Chinese Hamster Ovary (CHO) Cells

**HEMOLYSIS**

- 150400** [JMHLW]  
Hemolysis Assay  
**EXTRACTION RATIO:**  
 60cm<sup>2</sup>/20mL (thickness ≥0.5mm)  
 120cm<sup>2</sup>/20mL (thickness <0.5mm)  
 4g/20mL (irregularly shaped)  
 2g/20mL (lightweight/low density materials)  
**EXTRACTION CONDITIONS:**  
 37°C/72hrs  50°C/72hrs  70°C/24hrs  
 121°C/1hr  Room Temp/72hrs

**IMPLANTATION**

All include histopathology assessment

- 902515** [JMHLW]  
Intramuscular Implant Test - 1 week
- 902520** [JMHLW]  
Intramuscular Implant Test - 2 week
- 902525** [JMHLW]  
Intramuscular Implant Test - 4 week
- 902530** [JMHLW]  
Intramuscular Implant Test - 8 week
- 902533** [JMHLW]  
Intramuscular Implant Test - 13 week

**PYROGENICITY**

- 900775** [JMHLW]  
Materials Mediated Rabbit Pyrogen  
**EXTRACTION RATIO:**  
 60cm<sup>2</sup>/20mL (thickness ≥0.5mm)  
 120cm<sup>2</sup>/20mL (thickness <0.5mm)  
 4g/20mL (irregularly shaped)  
 2g/20mL (lightweight/low density materials)  
**EXTRACTION CONDITIONS:**  
 37°C/72hrs  50°C/72hrs  70°C/24hrs  
 121°C/1hr  Other \_\_\_\_\_

**LAB USE ONLY****IRRITATION**

- 910695** [JMHLW]  
Primary Skin Irritation
- 9107011** [JMHLW]  
Intracutaneous Irritation Test  
**TYPE(S) OF EXTRACTS:**  
 Normal Saline (NS) and Cottonseed Oil (CSO)  
 Other \_\_\_\_\_
- EXTRACTION RATIO:**  
 60cm<sup>2</sup>/20mL (thickness ≥0.5mm)  
 120cm<sup>2</sup>/20mL (thickness <0.5mm)  
 4g/20mL (irregularly shaped)  
 2g/20mL (lightweight/low density materials)  
**EXTRACTION CONDITIONS:**  
 37°C/72hrs  50°C/72hrs  70°C/24hrs  
 121°C/1hr  Other \_\_\_\_\_

**SENSITIZATION**

- 900851** [JMHLW]  
Guinea Pig Maximization Sensitization Test  
(Method for Biomaterial Extracts)
- 900852** [JMHLW]  
Adjuvant and Patch Sensitization Test [JMHLW]

**SYSTEMIC AND SUBACUTE TOXICITY**

- 9017715** [JMHLW]  
Acute Systemic Injection Test  
**TYPE(S) OF EXTRACTS:**  
 Normal Saline (NS) and Cottonseed Oil (CSO)  
 Other \_\_\_\_\_
- EXTRACTION RATIO:**  
 60cm<sup>2</sup>/20mL (thickness ≥0.5mm)  
 120cm<sup>2</sup>/20mL (thickness <0.5mm)  
 4g/20mL (irregularly shaped)  
 2g/20mL (lightweight/low density materials)  
**EXTRACTION CONDITIONS:**  
 37°C/72hrs  50°C/72hrs  70°C/24hrs  
 121°C/1hr  Other \_\_\_\_\_
- 800595** [JMHLW]  
Subacute (28 Day) Intravenous Toxicity Study in  
Rats (28 Repeat Dose Exposure)

**OTHER**

- TEST CODE** \_\_\_\_\_  
**TEST NAME**  
\_\_\_\_\_  
\_\_\_\_\_  
**EXTRACTION INFO** (type, ratio, conditions or mark "N.A.")  
\_\_\_\_\_

**LAB USE ONLY****TESTING AUTHORIZATION**

Sponsor signature is required before testing will be initiated.

SIGNATURE

PRINT NAME

DATE