



## 2006 SCHEDULE OF TESTING SERVICES

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### **INTRODUCTION TO PACIFIC BIOLABS**

Pacific BioLabs is an independent testing laboratory offering comprehensive capabilities in microbiology, sterility assurance, biocompatibility, toxicology, pharmacology and immunology. Quality customer service is the cornerstone of our relationship with our clients. Our experienced and conscientious staff is dedicated to providing the most reliable and timely results possible. To ensure prompt and precise communication, we welcome direct contact between clients and our technical staff. Additionally, we encourage our clients to visit and audit our facilities and meet our staff.

Pacific BioLabs is registered with FDA. Our animal science program is accredited by the AAALAC (The Association for the Assessment and Accreditation of Laboratory Animal Care). Pacific BioLabs is ISO 9001:2000 Certified by Intertek Testing Services NA, Inc.

Pacific BioLabs has outstanding quality assurance systems and excellent regulatory compliance. We conduct all tests in accordance with applicable Good Manufacturing Practice (GMP) and, when requested, Good Laboratory Practice (GLP) regulations. To insure the quality of data for our clients and the FDA, our quality assurance managers routinely perform internal audits in all divisions of the laboratory. Our Operations Manual, consisting of an extensive body of Standard Operating Procedures, is a key component of our quality systems. Pacific BioLabs has a thorough, documented training system to insure that all technical staff can capably perform designated procedures and remain current with SOP revisions.

Clients ranging from small specialty companies to Fortune 500 corporations have benefited from over 30 years of Pacific BioLabs' outstanding customer service. Over the years, we have gained a national reputation for quality in service and excellence in science.

Pacific BioLabs provides high quality testing services at fair and competitive prices. This list of services contains many tests that we routinely perform for many different clients. We also perform many additional client and compendial procedures that are not listed here. Please inquire regarding your special test requirements.

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## SAMPLE SUBMISSION

A thorough written request for analysis must be included with all samples submitted for testing. Pacific BioLabs has several types of "Request for Analysis" forms which we encourage you to use. Our complete collection of "[Request for Analysis](#)" forms can be found on our website at [PacificBioLabs.com](http://PacificBioLabs.com).

All samples should be accompanied by written instructions which include the following information:

1. Report To Name, address, phone number, and fax number of the person who should receive "Report of Analysis".
2. Invoice To Name, address and phone number of the person or department to whom the invoice should be sent.
3. Sample Description Complete sample description (including quantity) and identification numbers as they should appear on your final "Report of Analysis". Please include a description of the sample container or packaging.
4. P.O. Number A P.O. Number is required for all testing. Many clients issue standing P.O.'s for routine testing
5. Test Required Specify all tests to be performed. Indicate duration of test (e.g. 7-day Implant) and extraction conditions, when applicable.
6. Procedure Reference Include procedure references. Send written procedures unless Pacific BioLabs or compendial procedures are to be used.
7. Expected Levels List specifications for product attributes to be tested. (This will alert us to notify you quickly of unexpected results.)
8. Safety & Storage Special storage and safety information. NOTE: Hazardous samples must be accompanied by an MSDS or other adequate safety information.
9. GLP Request Some studies intended for submission to EPA and FDA must be performed in accordance with GLP regulations. There is an additional charge for GLP treatment. Please indicate if GLP treatment is required.
10. Special Instructions Information on preparation, handling or testing of samples, report format, report or invoice copies etc.
11. Need Results Date If you need your test results by a certain date, indicate the date on your Request for Analysis. If we cannot meet your target date and/or if a rush surcharge is applicable, we will call you.
12. Disposition of Samples Indicate whether samples should be returned or discarded. For samples to be returned, write the *declared value* on your sample submission form. We reserve the right to return any samples. NOTE: Unless you request otherwise, all non-hazardous, non-GLP samples are discarded within 30 days after a report is issued.
13. Signature/Date Please sign and date the Request for Analysis form.

### **NOTE:**

For each test requested, please submit separately packaged, labeled samples. This will expedite the testing of your samples. This does not apply to samples for strictly chemistry or strictly microbiological analysis (except sterility tests).

The submission of a complete "Request for Analysis" with your samples will reduce the turnaround time of your test and insure that the information on the "Report of Analysis" meets your expectations.

## **SERVICE NOTES, TERMS, AND CONDITIONS**

### **CONFIDENTIALITY**

Pacific BioLabs is an independent testing laboratory. Testing services are our only business. We maintain strict confidentiality of all client information. We will execute your confidentiality agreements or we can provide you with copies of our standard agreement.

### **QUALITY AGREEMENTS**

Some companies require quality agreements with their key vendors. We will review and execute your quality agreement or we can provide you with a copy of our standard agreement. Our sales or QA staff can make arrangements to execute quality agreements.

### **QUOTES FOR PACIFIC BIOLABS' TESTING SERVICES**

This fee schedule is a guidance document that lists typical fees for a range of more common tests. Custom quotes are required for most sample submissions. Pacific BioLabs sales staff promptly issues quotes. To receive a quote for your testing needs, please call our sales department or complete or go to [PacificBioLabs.com](http://PacificBioLabs.com) and complete the online [Request for Quotation](#) form.

### **PREPAYMENT POLICY**

For new clients prepayment is required before testing can be initiated. We also require a payment schedule for certain larger studies, especially in toxicology (e.g. 50% at initiation, 40% at completion of inlife phase, 10% at issue of final report).

### **PAYMENT TERMS**

Our terms are net 10 days upon receipt of our invoice. We accept checks drawn on U.S. banks, wire transfer or Visa and Master Credit Cards. A 1½% per month surcharge will be assessed on accounts not paid within 30 days. Past due accounts must be made current before new work will be accepted.

### **INTERNATIONAL ORDERS**

Complete documentation is required to facilitate the shipping process for samples sent to the U.S. from other countries. Shipping documents should identify the shipment contents as "SAMPLES FOR TESTING ONLY – NOT FOR HUMAN USE." Any customs related fees are the responsibility of the client. All invoices are payable in U.S. Dollars. To minimize banking fees, we suggest payment by wire transfer to our bank account.

### **TEST FEES**

The fees listed in this schedule are for tests in which routine procedures are used. Products which require extraordinary handling (e.g. unusual sample preparation, unique laboratory supplies, extra safety measures, disposal of excess hazardous samples, etc.) will incur additional charges. Revisions to USP, international compendia, ISO and other standards may affect test procedures, and consequently test fees, at any time. All fees in this schedule are subject to change without notice.

### **RUSH SERVICE**

Rush service may incur a surcharge. For regular clients, we try to accommodate occasional special requests to expedite turnaround time for routine tests without assessing any additional charge. However, many rush requests require overtime, weekend or holiday work and result in costly operating inefficiencies and cause significant disruption of our testing schedule. On these occasions, there will be a minimum of \$100 or 50% additional charge.

## **VOLUME DISCOUNTS**

Volume discounts are available for many of the tests listed. Please call for a quotation on your volume testing requirements.

## **GLP STUDIES**

Some studies that will be submitted to EPA or FDA must be performed according to Good Laboratory Practice regulations. It is the responsibility of the test sponsor to request GLP treatment prior to the initiation of testing. GLP treatment includes a custom protocol approved by the sponsor, observation of the performance of the testing procedure by our Quality Assurance Department, Q.A. review of all test data, and a detailed final report. GLP fees are generally an additional 10 to 20%. The minimum GLP fee is \$200.00 per procedure per sample. GLP treatment will generally add 3 to 7 work days to standard turnaround times for routine tests.

## **HAZARDOUS SAMPLES**

Special precautions must be taken to safely test hazardous samples. Handling fees will be added to all projects which require work with hazardous or biohazardous agents. These fees will vary depending on the material, the nature of the hazard, and the project protocol. There may also be a fee for sample disposal. We reserve the right to return all hazardous samples to the test sponsor. For hazardous sample return, there is a minimum Hazmat processing fee of \$35.00. Shipping charges are additional.

## **TEST PROCEDURES**

Pacific BioLabs has an extensive library of SOPs for commonly performed tests. Most Pacific BioLabs SOPs are based on USP procedures, ANSI/AAMI/OSP standards or other recognized references. Our library includes the most current editions of the USP, BP, EP, and JP. We welcome client methods. If test methods are not available, we offer method development and validation services.

## **METHODS TRANSFER**

A method transfer is a study that is performed to verify that a test method developed in one lab can be accurately performed in another lab. The GMP regulations have been interpreted to require method transfer studies for many non compendial test methods. Please call for a quote for a method transfer study for your specific test method.

## **VALIDATION OF TESTING PROCEDURES**

USP procedures for products listed in the USP are generally considered to be validated. Many other test procedures should be validated for the particular products being tested. It is the client's responsibility to insure that the validation status of test procedures used on their products is approved by their quality assurance department. The test fees listed in this schedule do not include the validation of that test for the sample that is submitted. Pacific BioLabs offers test procedure validation services. Please call any of our technical managers to discuss validation issues regarding the test procedures used for your products.

## **RETESTS**

Retesting is generally governed by our SOP for handling out-of-specification findings. Client authorized retesting will be billed accordingly.

## **REPORTS**

All test results are issued on a clear and accurate Report of Analysis. Pacific BioLabs' reporting system allows us substantial flexibility in the preparation of reports. We can generate customized reports to meet special client requirements. Reports will be sent out via First Class Mail unless otherwise requested by the client.

Reports are submitted for exclusive use by our clients. No reference to the work, the results, or to Pacific BioLabs may be made in any form of advertising, news release or other public announcement without written authorization.

## **ELECTRONIC REPORTS**

Lab reports can be sent via email. The report will be an electronic image of the final signed paper copy of the report. The fee for this service is \$6.00 per report.

## **FAX REPORTS**

Laboratory reports will be faxed when requested. The minimum fee for this service for any report 1 to 4 pages is \$6.00 for the first page within the United States and \$10.00 outside of the United States. Each page faxed is an additional \$1.00. Fax fees include priority report preparation and review of reports by administrative, technical and quality assurance staff.

## **MINIMUM REPORT FEE**

The minimum fee for testing a sample and issuing a lab report is \$70.00.

## **REISSUED REPORTS**

There is a \$50.00 minimum charge for a reissued report.

## **SAMPLE RETENTION AND RETURN**

Following completion of testing, Pacific BioLabs will generally discard excess samples in accordance with our sample retention SOP (< 30 days). When requested, we will return remaining samples to the client. There is a minimum fee of \$10.00 plus shipping expenses for the return of samples. Fees vary according to quantity and weight of samples, special handling or packaging requirements and whether the sample is hazardous. (See Hazardous Samples section on page 5). For any single or group of samples submitted concurrently, valued over \$100.00, and for which return is required, the client must include a declared value. If no value is declared, Pacific BioLabs cannot be held liable for any amount in excess of \$100.00 for any loss of samples, whether at Pacific BioLabs or lost in transit.

For GLP studies, all unused sample will be held for approximately one month after completion of testing, then returned (unless you instruct us otherwise). The test sponsor is responsible for retaining reserve samples in accordance with FDA and EPA GLP regulations. If the sponsor is unable to meet these requirements, Pacific BioLabs can store small amounts of reserve sample. The minimum sample storage fee is \$15.00 per month.

## **COOLER RETURN**

For environmental and/or cost reasons, many clients request that the cooler boxes in which they ship their samples be returned to them. If you want your cooler returned, please note it on your sample submission documents. To cover our expenses, Pacific BioLabs charges only the return shipping costs plus a \$5.00 repackaging fee. Alternatively, we can have the shipping charges billed to your UPS account if you provide us with your UPS shipper number.

## **RECORD RETENTION**

For all non-GLP studies, Pacific BioLabs retains all report related data and documentation for 5 years. After 5 years, all paper documentation is destroyed. GLP test data is retained indefinitely.

Clients who need data and documentation for greater than 5 years can request copies of data at the time of sample submission. There is an additional charge for raw data collection and copying.

## **AUDIT POLICY**

Pacific BioLabs welcomes prospective client audits of our laboratories and quality systems. There is no charge for an initial audit of up to one full day. We also recognize our clients' need to re-audit their contract service providers in accordance with their company SOPs. We welcome re-audits of our laboratories. In most cases, there is no fee related to re-audits. Under certain circumstances for extended audit times, an hourly fee will be assessed for hours beyond a preset schedule. If applicable, our QA managers will discuss this when the audit is scheduled.

## **PACIFIC BIOLABS' POLICY ON ALTERNATIVE METHODS**

Pacific BioLabs encourages the use of non-animal alternatives where available and supports the application of the three R's – reduction, refinement and replacement. It is a policy at Pacific BioLabs to keep clients abreast of current testing guidelines as they relate to the prudent use of animals. A senior member of the in vivo testing staff is available to consult with clients regarding alternative methods. Please contact client services at 510/964-9000 with inquiries regarding alternative methods.

## **CONDITIONS OF SALE, WARRANTY AND LIMIT OF LIABILITY**

Pacific BioLabs provides services to its clients on a fee-for-service basis. All services are performed by Pacific BioLabs in accordance with the service notes, terms and conditions specified in this fee schedule. Any deviation to the terms must be agreed to in writing by Pacific BioLabs' executive management prior to the performance of service.

The only warranty that Pacific BioLabs offers is that it will perform its services with due care in accordance with Pacific BioLabs procedures and generally prevailing industry standards and applicable government regulations. The only remedy for breach of this warranty will be to require Pacific BioLabs to repeat the services or to be credited for fees paid for services performed.

Test results are not necessarily indicative of the characteristics of any other samples from the same or any other lots. Pacific BioLabs assumes no responsibility for any purpose for which a client chooses to use test results. Pacific BioLabs or its subsidiary companies shall not be liable under any circumstances for any amount in excess of the cost of the test performed.

## MEDICAL DEVICE TESTING SERVICES – INTRODUCTION

Since 1984, Pacific BioLabs has been offering high quality testing services to medical device companies. From product development to finished product quality control, Pacific BioLabs' services are targeted to meet the medical device manufacturer's testing requirements. Our services include biocompatibility, toxicology, microbiology and sterility assurance testing. Test procedures are based on AAMI, ISO, FDA, USP, client SOPs and other methods and guidelines. Our medical device testing services and fees are presented in pages 8 to 20.

**For a quote, fax the “[Request for Quotation](#)” form on the inside of the front cover or use the online form at [PacificBioLabs.com](http://PacificBioLabs.com).**

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## **BIOCOMPATIBILITY TESTING – ISO AND BLUE BOOK MEMO GUIDELINES**

For over 20 years, Pacific BioLabs has conducted biocompatibility testing for the medical device industry. Our staff of toxicologists has tested hundreds of devices with a variety of configurations, applications and component materials. They can help you design a cost effective safety testing program for your device. Please call client services at 510/964-9000 to discuss your requirements.

Pacific BioLabs has published an informative booklet called “[\*Assessing Biocompatibility\*](#),” which summarizes ISO and FDA biocompatibility requirements. To receive a complimentary copy of this booklet, please call or view it online at [PacificBioLabs.com](http://PacificBioLabs.com).

### **BIOCOMPATIBILITY TESTING NOTES**

All samples submitted for biocompatibility testing should be sterilized under the same conditions that will be used for the final product. Extracts and extraction conditions must be specified when samples are submitted for testing.

Extracting media are selected based on the biological environment in which the material will be used. Sodium Chloride for Injection, USP (SCI) is a polar or hydrophilic solvent which simulates the aqueous fluids found in the body. Vegetable oil is a non-polar lipophilic solvent, simulating the lipids in the body. If the device will come in contact with drugs, alcohol in SCI and PEG 400 may be considered for use as well, depending on the solvent properties of the drug.

Extraction of large samples requiring use of extra media may incur additional fees.

Extracting conditions (temperature and time) should be based on the actual use of the final product or on the highest temperature the device or material will encounter during production, sterilization and use.

#### EXTRACTING MEDIA

- Sodium Chloride for Injection
- Vegetable Oil (usually Cottonseed Oil)
- Alcohol in Sodium Chloride for Injection
- Polyethylene Glycol 400
- Acetone/Olive Oil
- DMSO

#### CONDITIONS

- 121°C for 1 hour
- 70°C for 24 hours
- 50°C for 72 hours
- 37°C for 72 hours
- 37°C for 24 hours

### **STERILIZATION SERVICES**

All samples submitted for biocompatibility testing should be exposed to the same process that will be used for the final product. If you cannot submit sterile samples, please select the appropriate sterilization process.

#### **Sterilization Processes for Biocompatibility Test Samples**

- 5994 Ethylene Oxide (100% ETO – 12 hour cycle)
- 6001 E-beam or Gamma Sterilization (~ 25 kGy)
- 6000 Steam Sterilization (121°C for 15 to 30 minutes)
- 5990 Chemical Sterilization

## **BIOCOMPATIBILITY TESTING – *IN VITRO* PROCEDURES**

### **Cytotoxicity (Tissue Culture)**

- 6521 Elution Test – ISO - L929 Cells (triplicate plates)
- 6522 Agar Diffusion – ISO - L929 Cells (triplicate plates)
- 6523 Direct Contact – ISO - L929 Cells (triplicate plates)
  
- 6540 Elution Test – USP - L929 Cells (duplicate plates)
- 6541 Agar Diffusion – USP - L929 Cells (duplicate plates)
- 6542 Direct Contact – USP - L929 Cells (duplicate plates)
  
- 6537 Cell Viability Quantification and % Reactivity
- 6538 Surface Area Calculation and Sample Preparation  
– *This may be required for elution testing of complex devices.*

### **Inhibition of Cell Growth**

- 6525 1 Dose Level (L929 Cells)
- 6526 ICH - additional dose

### **Hemocompatibility Testing**

- Hematology – *In Vitro*
- 6512 Hemolysis – Direct Contact, Rabbit Blood (duplicate tubes)
- 6550 Hemolysis – Direct Contact, Rabbit Blood (triplicate tubes)
- 6513 Hemolysis – Sample Extract, Rabbit Blood (duplicate tubes)
- 6551 Hemolysis – Sample Extract, Rabbit Blood (triplicate tubes)
- 6575 JP Hemolysis Test
- 6548 Hemolysis – ASTM Direct Contact
- 6549 Hemolysis – ASTM Elution
  
- Coagulation – *In Vitro*
- 6536 Prothrombin Time Test (PT)
- 6537 Partial Thromboplastin Time Test (PTT)
  
- Complement System
- 6511 Complement Activation Assay
- Platelets
- 6539 Platelet Aggregation

### **Genotoxicity Testing**

- 6530 Ames Mutagenicity Test – Five strains, saline or DMSO Extracts
- 6517 Mouse Lymphoma
- 6518 Chromosomal Aberration
- 6519 Mouse Micronucleus Assay

**Other genotoxicity tests are available – *please inquire.***

## BIOCOMPATIBILITY TESTING – *IN VIVO* PROCEDURES

### Systemic Toxicity – Acute

- 7209 Systemic Injection Test – USP  
– plastics or elastomeric closures, per extract (see page 9 for extracts and conditions)
- 7263 Systemic Injection Test – JP  
– plastics or elastomeric closures, per extract (see page 9 for extracts and conditions)
- 7198 Material Mediated Pyrogen  
– Sham Test (per rabbit)

### Intracutaneous and Irritation Tests

- 7210 Intracutaneous Tests – USP (2 rabbits)  
– plastics or elastomeric closures, per extract (see page 9 for extracts and conditions)
- 7925 Intracutaneous Test – ISO (3 rabbits)
- 7282 Primary Eye Irritation (FHSA guidelines)  
– 6 rabbits, 24, 48, and 72 hour observations
- 7284 Primary Skin Irritation (FHSA guidelines)  
– 6 rabbits, 24 and 72 hour observations
- 7920 Intraocular Irritation
- 7232 Oral Mucosa Irritation Test (includes histology)
- 7235 Vaginal Irritation Test – ISO (6 rabbits, includes histology)
- 7285 Ocular Irritation Test – ISO  
– 3 rabbits, 1, 24, 48, and 72 hour observations
- 7286 Skin Irritation Test – ISO  
– 3 rabbits, 1, 24, 48, and 72 hour observations
- Other Mucosal Irritation Studies

### Skin Sensitization Studies

- 7501 Closed Patch Test (ISO)
- 7502 Buehler Method (EPA)
- 7507 Dose Level Determination
- 7503 Maximization Test – Magnusson Kligman Method (12 test guinea pigs)\*\*
- 7505 Maximization Test – Magnusson Kligman Method (11 test guinea pigs)\*\*  
– Each additional guinea pig
- 7510 Re-challenge (including 5 naive controls)
- 7508 Positive Controls (historical validation)
- 7509 Positive Controls (concurrent)
- 7512 Murine Local Lymph Node Assay (LLNA) (includes positive control)

*\* These test fees include historical positive controls. A positive control group is a group treated with a known sensitizing agent. A positive control group must be included with a sensitization test to demonstrate that a sensitization response can be elicited under the conditions of the test. There are two types of positive controls. A concurrent positive control group is one conducted at the same time as a particular test. Alternatively, Pacific BioLabs runs a historical positive control group at least once a year. Any test performed during the year under the same conditions can be compared to this control. The historical control minimizes cost and the use of animals.*

*\*\* The Maximization Test using 12 test animals is recommended for all critical sensitization determinations. The larger test group size allows for a more accurate assessment of sensitization potential and has a lower incidence of false positives.*

### Thrombosis – *In Vivo*

- 6516 ISO Dog Thrombogenicity Testing

## **BIOCOMPATIBILITY TESTING – *IN VIVO* PROCEDURES**

### **ISO Intramuscular Implant Test – 3 rabbits \***

- 7930 7 day observation period
- 7931 14 day observation period
- 7932 30 day observation period
- 7933 60 day observation period
- 7934 90 day observation period
- 7935 180 day observation period
- 7936 365 day observation period
- 7230 Histopathology of Implant Sites (required)

### **Intramuscular Implant Test – 2 rabbits \***

- 7212 5 day observation period (USP)
- 7213 7 day observation period (USP)
- 7230 Histopathology of Implant Sites (per site)

*\* Fees include implantation of samples by percutaneous deposition. If surgical implants are required, there will be an additional charge of \$150.00 per rabbit.*

### **Classification of Plastics Tests – USP (Class I to VI)**

- 7220 Class I
- 7221 Class II
- 7222 Class III
- 7223 Class IV (includes 7 day implant)
- 7225 Class V
- 7227 Class VI (includes 7 day implant)

### **Subacute/Subchronic Toxicity (OECD/ISO)**

- 7233 IP Subacute Toxicity with Histopathology
- 7234 IV Subacute Toxicity with Histopathology
- 7258 IP Subchronic Toxicity with Histopathology
- 7259 IV Subchronic Toxicity with Histopathology

### **7299 Preclinical Device Evaluation – Surgical Procedures**

### **Contact Lens and Ophthalmic Product Studies**

- 7290 21 Day Ocular Irritation
  - includes corneal oxygen metabolism determination
- 7291 Microbiological Validation of Lens Disinfection Regimen

## **PYROGEN AND BIOLOGICAL SAFETY TESTS**

### **Pyrogen Tests (For LAL tests, see page 19. For EP and JP pyrogen tests, see page 28)**

- United States Pharmacopeia (USP)
- 7201 – 3 Rabbit Test (non-pyrogenic)
- 7202 – Retest 5 Rabbits
- 7236 – Sham Test (per rabbit)
- 7198 Material Mediated Pyrogen

*For substances determined to be pyrogenic, there will be an additional charge of \$45.00 per rabbit.*

### **Safety Tests**

- 7204 USP Safety Test (mice)
- 7219 EP Safety Test (mice)

## **MANUFACTURING ENVIRONMENT TESTING**

### **PROCESS WATER TESTING**

Water is a key component in the manufacturing process of most medical devices. Many device manufacturers have installed water purification systems to improve and control the quality of the water that is used in their manufacturing processes. Water purification systems should be validated to insure that the specified quality of water is consistently produced. Pacific BioLabs is the leading provider of laboratory testing services for water system validation projects. Microbiological testing will be started the same day samples are received. Bacterial endotoxin and chemistry testing are often completed within three working days. Please call client services to discuss your water system validation and for a quote on your volume testing requirements.

All water purification systems must be monitored regularly to verify the quality of the water produced. Because water purification systems remove chlorine from the municipal feed water, they can potentially harbor high levels of bacteria. This could cause high bioburden levels and/or excessive levels of pyrogens in the finished product. Pacific BioLabs can supply sterile and nonpyrogenic containers for collecting water samples. Please call client services to request supplies.

#### **Purified Water System Validation Projects**

##### **Chemical and Physical Tests**

- 3131 Purified Water Monograph – USP (conductivity and TOC)
- 3980 Total Organic Carbon (TOC)
- 3150 Particulate Matter (2 to 100 microns) – Light Obscuration Method
- 6560 LAL – Bacterial Endotoxins Test – Kinetic Chromogenic or Turbidimetric

##### **Microbiological Analyses – Water**

- 1334 Total Heterotrophic Count – Plate Count
- 1335 Total Heterotrophic Count – Membrane Filtration  
(For potential CFU > 1000, subsequent filtrations are \$20.00 each.)
- 1337 Total Coliform – Membrane Filtration  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1344 Total Coliform – MPN  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1339 Fecal Coliform – MPN (includes total coliform)
- 1342 *Pseudomonas aeruginosa* – Membrane Filtration

*Other procedures from Standard Methods for the Examination of Water and Wastewater are available upon request.*

##### **Water Sampling Supplies**

- 1379 Polycarbonate Bottle, 1 Liter  
(For each purified water monograph, fill one bottle to capacity.)
- 1380 Glass Bottle with Teflon Lined Cap, 1 Liter (reusable)  
(For each purified water monograph, fill one bottle to capacity.)
- 1368 Specimen Cups, Sterile, 120 mL  
(For each microbiological analysis, fill one cup to capacity.)
- 1383 TOC Sample Vials, 40 mL  
(For each TOC test, fill 2 vials to capacity.)
- 1384 Test Tubes, Sterile, Non-pyrogenic, 15 mL  
(For each LAL test, fill one tube to capacity.)

## **MICROBIAL ENVIRONMENTAL MONITORING**

Medical device manufacturers use microbial environmental monitoring programs to evaluate the effectiveness of cleaning and disinfection procedures and to assess the overall microbial cleanliness of their manufacturing environment. An effective program to control microorganism levels in the manufacturing environment is essential to minimize the bioburden on the medical device being manufactured and reduce potential for bioburden spikes. Spikes in the bioburden of finished medical devices can cause a reduction in the sterility assurance level for the product.

Pacific BioLabs works with many of its clients to establish and maintain cost-effective programs to meet FDA requirements for monitoring the microbial cleanliness of their manufacturing environments and assessing the efficacy of production area disinfection procedures. Our microbiologists can travel to your facility to perform a microbiological survey.

Air and surface samples are taken during routine production operations to obtain a microbiological profile of the manufacturing environment. Observation of work practices are made during the survey. Test data and other information are evaluated to determine what actions can be taken to reduce or stabilize the bioburden of the medical device. Once an intensive survey has been conducted and strategic sampling locations are determined, our microbiologist can train the manufacturer's personnel to collect microbial samples on a regular schedule. Pacific BioLabs can provide the necessary supplies for microbiological sampling. Exposed materials are returned to Pacific BioLabs for enumeration and report.

Please call client services to order supplies or for more information.

6301 Environmental Survey – Microbiological  
(Performed by Pacific BioLabs Personnel)

### **Microbial Environmental Monitoring Supplies\***

- 1354 Fallout Plate, 100 mm, Tryptic Soy Agar (TSA), pack of 10
- 1355 Fallout Plate, 100 mm, Sabouraud Dextrose Agar (SDA), pack of 10
- 1350 Contact Plate, DE Neutralizing Agar, pack of 10
- 1356 Contact Plate, Tryptic Soy Agar, pack of 10
- 1357 Contact Plate, Sabouraud Dextrose Agar, pack of 10
- 1358 Biotest Air Sampler Strip, TSA
- 1366 Biotest Air Sampler Strip, SDA or Rose Bengal Agar
- 1365 Biotest Centrifugal Air Sampler – Daily Rental
- 1359 Sterile Buffer Solution w/Dacron Swab
- 1368 Sterile Specimen Cups, Screw Cap, 120 mL
- 1386 Surgeon's Gloves, Latex, Sterile (available in sizes 6 to 8 ½)
- 1387 Antiseptic Gel Hand Rinse, 4 oz. bottle

*\* Microbial monitoring supplies are usually shipped in coolers. There is a \$12.00 packaging charge per supply order. Shipping charges are billed at cost. It is advisable to order supplies 7 – 10 days prior to the scheduled sampling date.*

### **Microbial Samples – Incubation, Enumeration and Report**

- 1360 Fallout Plate Count
- 1361 Contact Plate Count
- 1362 Biotest Air Sampler Strip Count
- 1363 Buffer Solution – Aerobic Count (Membrane Filtration)

*For anaerobic counts, add \$10.00 per sample.*

## MICROBIOLOGICAL ANALYSES

Antimicrobial Preservative Effectiveness Tests – *see page 25*

Microbial Limits – USP – *see page 25*

Microbial Identification – *see page 26*

## REUSABLE MEDICAL DEVICE TESTING

To address regulatory and liability concerns, manufacturers of medical devices that are intended for reuse and sterilization in health care facilities must provide specific cleaning, disinfection and/or sterilization instructions to their customers. To insure that reliable cleaning, disinfection and/or sterilization will result, the instructions must be validated. For more information, refer to *AAMI TIR 12: 1994 Design, testing and labeling of reusable medical devices of reprocessing in health care facilities – A guide for device manufacturers.*

Pacific BioLabs can simulate most conventional hospital cleaning and sterilization procedures. Fees for the cleaning and sterilization validation studies will vary depending on the validation protocol. Please call client services to discuss your requirements. We can perform testing according to our protocol or prepare a protocol in consultation with you.

- Cleaning, Disinfection and Sterilization Validation Protocols
- Cleaning Validation Studies
- Disinfection Validation Studies
- Sterilization Validation Studies
  - Ethylene Oxide
  - Steam Sterilization at 121°C to 132°C
  - Flash, Gravity and High Vacuum Cycles
  - Liquid Chemical Sterilization
  - Dry Heat Sterilization and Depyrogenation
  - VHP (Hydrogen Peroxide Gas)

*Please call about Sterrad hydrogen peroxide gas plasma sterilization or Steris System 1 Processor Sterilization.*

## BIOLOGICAL INDICATORS

### Product Inoculation

6702 – *B. subtilis* (ethylene oxide),  $10^3$  to  $10^8$ /sample

6703 – *G. stearothermophilus* (steam),  $10^3$  to  $10^6$ /sample

### Spore Strips

6401 Spore Strip Population Verification – USP Method – 3 spore strips

6404 Exposed Spore Strip Population (count unknown)

For sterility testing of exposed biological indicators – *see page 18*

## STERILITY ASSURANCE TESTS

Established in 1972, Pacific BioLabs is among the most experienced labs in sterility assurance testing for medical device manufacturers. Pacific BioLabs is the only independent lab that has sterility testing suites and microbiology laboratories at three different locations across the United States – in California, Illinois and South Carolina.

Our technical staff is readily accessible and will help guide you through the regulatory requirements for sterile medical devices. Pacific BioLabs publishes an informative booklet, “[\*Sterility Assurance Compliance – a Guide for Medical Device Manufacturers\*](#).” The booklet summarizes AAMI/ISO standards and technical information of sterile medical devices. For a complimentary copy of this booklet, please call, fax the form on the inside back cover or view it online at [PacificBioLabs.com](http://PacificBioLabs.com).

### **Bacteriostasis/Fungistasis (Sterility test and dose audit method validation)**

- Immersion (Direct Transfer)
- 6100 – 3 organisms – SCDM (Dose Audits)
- 6101 – 6 organisms – 3 in FTM and 3 in SCDM (USP Sterility Tests)
  
- B/F for Sterility Tests by Membrane Filtration Method – *see page 27*
  
- 6102 Growth Promotion of Media (per organism, in duplicate)

### **Bioburden Method Validation – Recovery Study**

- 6220 Exhaustive Recovery (3 – 5 extractions per sample)
- 6218 Simulated Recovery (spore inoculation, per sample)
- 6230 Screening for the Release of Substances Adversely Affecting Bioburden Estimates (from AAMI/ISO 11737-1: 3 organisms, in triplicate)

### **Bioburden Analyses**

- Total Aerobic Bacteria and Fungi by Membrane Filtration Method
- 6201 – Small Devices
- 6202 – Medium Size Devices, Small Kits
- 6203 – Large Devices, Large Kits, Papers, Fabrics
  
- 6206 Bioburden – Total Aerobic Bacteria by Plate Count Method
  
- Total Aerobic Bacteria Only by Membrane Filtration Method
- 6240 – Small Devices
- 6241 – Medium Size Devices, Small Kits
- 6242 – Large Devices, Large Kits, Papers, Fabrics
  
- 6207 Bioburden – Total Anaerobic (with Total Aerobic Bacteria and Fungi)
- 6209 Bioburden – Total Aerobic Spores (with Total Aerobic Bacteria and Fungi)

*The above bioburden fees apply when five or more samples are submitted together for testing. If fewer than five samples are submitted, there will be an additional charge of \$5.00 per sample. The total anaerobic and aerobic spore fees apply when tests are performed in conjunction with total aerobic bacteria and fungi bioburden tests. Additionally, there is a \$5.00 per isolate charge for differentiation of strict vs. facultative anaerobes. Unless otherwise requested, the membrane filtration method will be used for all samples with filterable extracts.*

- 6204 Bioburden – Packaging (Contact Plate)
- 6205 Bioburden – Packaging (Swab/Membrane Filtration)
- 6210 Bioburden – Process Fluids (Membrane Filtration)
- 1335 Bioburden – Water (Aerobic Bacteria by Membrane Filtration)

## STERILIZATION VALIDATIONS – MICROBIOLOGICAL

### 9756 Sterilization Process Validation Protocol Preparation

*For initial sterilization process validations, cGMP regulations require a written validation protocol. Pacific BioLabs will customize a sterilization validation protocol to meet individual client requirement. Once the initial validation is successfully completed, no additional validation protocols are normally required for subsequent revalidation (i.e. dose audits, EO cycle revalidation or subsequent single lot validation for the same product using the same method.)*

### Radiation Sterilization Validation – Microbiological

There are several methods for the initial validation of a sterilization dose including:

- ANSI/AAMI/ISO 11137 Method 1 (for large and frequent production batches)
- AAMI/ISO TIR 15844 (for large but infrequent production batches)
- AAMI TIR 27 VDmax (25 kGy for low bioburden products; small or large batches, frequent or infrequent production)

#### Initial Validations:

In an initial validation, a protocol, bioburden method validation and B/F test (dose audit method validation) are required. Additionally, each of the above methods also requires bioburden testing: 10 samples for single lot validations or 30 samples for frequently produced lots (10 samples from each of 3 lots). To complete the initial testing, each method requires either a dose audit of sublethally irradiated samples: 100 samples for Methods 11137-1 and 15844 or 10 samples for VDmax. For large samples that do not fit into sterility test containers, SIP preparation is also required. For related fees to all of these tests, see the information on page 17 – 19.

Please refer to Pacific BioLabs' booklet "[Sterility Assurance Compliance – A Guide for Medical Device Manufacturers](#)" for more detailed explanation about sterilization validation testing requirements. Call to receive a paper copy or view it online on our website: [PacificBioLabs.com](http://PacificBioLabs.com).

#### Revalidation – Quarterly Dose Audits:

In quarterly dose audits, bioburden of 10 samples and a dose audit of sublethally irradiated samples are required. If SIP was required in the initial validation, it will be required for any revalidation.

### Radiation Sterilization Validation – VDmax

- 9756 Validation Protocol
- 9750 Sample Item Portion (SIP) Preparation (for large products)
  - single lot validation (39 samples)
  - complete 3 lot validation (59 samples)
- 6201-3 Bioburden - Total Aerobic Spores & Fungi
  - single lot validation (10 samples)
  - complete 3 lot validation (30 samples)
- 6218, 20 Bioburden Method Validation
  - Recovery Validation
- 6230 – Adverse Substance Screening
- 6100 Bacteriostasis/Fungistasis (Dose Audit Method Validation)
  - Dose Audit – 10 samples in SCDM
- 6802 – ≤ 120 mL
- 6803 – 500 mL
- 6804 – 1000 mL
- 6805 – 2000 mL
- 6857 Verification Dose Calculation Report
  - Validation Summary Report (optional)

### **Radiation Sterilization Validation – AAMI/ISO 11137 Method 1 or AAMI Method 15844**

- 9756 Validation Protocol
- 9750 Sample Item Portion (SIP) Preparation (for large products)
  - 132 samples (AAMI 15844)
  - 152 samples (AAMI 11137)
- 6201-3 Bioburden - Total Aerobic Spores & Fungi
  - single lot validation (10 samples)
  - complete 3 lot validation (30 samples)
- 6218, 20 Bioburden Method Validation
  - Recovery Validation
- 6230 – Adverse Substance Screening
- 6100 Bacteriostasis/Fungistasis (Dose Audit Method Validation)
  - Dose Audit – 100 samples in SCDM
- 6837 – 40 mL
- 6838 – 120 mL
- 6839 – 500 mL
- 6840 – 1000 mL
- 6841 – 2000 mL
- 6857 Verification Dose Calculation Report  
Validation Summary Report (optional)

### **Radiation Sterilization Validation – AAMI/ISO 11137 Method 2**

#### **Ethylene Oxide Cycle Validation – AAMI/ISO Methods**

*A typical EO cycle validation consists of exposure of product and B. subtilis biological indicators in fractional and half cycles, followed by sterility testing. The number of samples to be tested varies with the size of the EO sterilization chamber. Fees for sterility testing associated with customized ETO sterilization validation studies will be based on the number of spore strips and products tested, and the media volume required to test product samples. Additional testing normally performed as part of the validation is bioburden, bacteriostasis/fungistasis and ethylene oxide residuals. Please call client services at any Pacific BioLabs facility for a quotation for your EO cycle validation project.*

#### **USP STERILITY TESTS**

- Product Only – Direct Transfer (Immersion) (20 products in SCDM, 20 products in FTM)
- 6812 – ≤ 120 mL media
- 6817 – 500 mL media
- 6818 – 1000 mL media
- 6825 – 2000 mL media

Liquid Products by Membrane Filtration – see page 27

*For fluid path sterility testing of medical devices, please call for a quotation.*

*Samples which are difficult to aseptically handle or divide will incur an additional charge. When extra product samples are submitted with a sterility test, there will be an additional charge per sample and per media container. The fees are the same as those listed under the Radiation Sterilization Validation section above.*

*There is a minimum charge of \$150.00 for any sterility test of product samples.*

#### **Sterility Testing of Biological Indicators**

- 6806 10 Spore Strips and 1 or 2 positive controls – 15 mL SCDM
- 6820 Each additional spore strip – 15 mL SCDM
- 6880 Self Contained Biological Indicators, 1 – 20
- 6881 Each additional S.C.B.I.

## POST-STERILIZATION TESTS

### Ethylene Oxide Residues Tests – ISO 10993-7 Standard

- Ethylene Oxide Residual Analysis (EO only)
- 4101 – Aqueous Extraction
- 4105 – Headspace Sampling (up to 5 heating cycles)
- 4107 – Acetone or DMF Extraction
- 4102 Ethylene Chlorohydrin Residuals Analysis (ECH only)
- 4103 **EO and ECH (aqueous extraction of EO residue)**  
(covers ISO limited exposure patient category)
- EO Dissipation Studies

### LAL Bacterial Endotoxins Tests – USP

#### *Gel Clot Method*

- 6499 Water
- 6500 Liquids
- 6502 Medical Devices (Immersion, < 1000 mL LAL negative water)
- 6503 Medical Devices (Immersion, > 1000 mL LAL negative water)
- 6504 Medical Devices (Fluid Path, < 1000 mL LAL negative water)
- 6505 Medical Devices (Fluid Path, > 1000 mL LAL negative water)
- 6509 Concurrent Assay of Sample Dilution
- 6508 Non-concurrent Assay of Sample Dilution

*The gel clot method is semi-quantitative. For medical devices produced in lots of greater than 100 units, 10 samples are required. One test is performed on a composite of the 10 samples. Typically, the sample composite is tested at half of the client specified endotoxin limit. For cerebrospinal fluid contact, the average device limit in a 10 sample composite test is 2.15 endotoxin units (EU). For most other devices, the average limit in a 10 sample composite test is 20 EU per device. When successful, the interpretation for the test will be reported as follows: "These samples pass the test for bacterial endotoxins at 1/2 the endotoxin limit for medical devices." For liquid samples with an EU level below test system sensitivity limits, the results will be reported as "less than (the test system limit)", e.g. 0.125 EU/mL for high purity water. If an exact EU result is required, a kinetic method must be used.*

#### *Kinetic Turbidimetric or Chromogenic Methods*

For liquids and powders – see page 28

- 6563 Medical Devices (Immersion, < 1000 mL LAL negative water)
- 6564 Medical Devices (Immersion, > 1000 mL LAL negative water)
- 6565 Medical Devices (Fluid Path, < 1000 mL LAL negative water)
- 6566 Medical Devices (Fluid Path, > 1000 mL LAL negative water)
- 6567 Concurrent Assay of Sample Dilution
- 6568 Non-concurrent Assay of Sample Dilution

*The kinetic test methods are quantitative. Generally, the resulting number of EU/mL determined in the test is reported. In some instances, a "less than detection limit quantity" may be reported.*

### LAL Validation – Inhibition and Enhancement

#### Gel Clot Method

- 6506 – LAL Validation (one lot)
- 6514 – LAL Validation (three lots, concurrently tested)
- Kinetic Turbidimetric or Chromogenic Methods
- 6552 – LAL Validation (one lot)
- 6554 – LAL Validation (three lots, concurrently tested)

## PHYSICAL TESTS

### Accelerated Aging of Medical Devices – 1 year

6609 3 weeks at 55°C w/ 75% R.H., 3 weeks at 55°C w/ <20% R.H.

*The above accelerated aging interval is based on guidance provided in ASTM 1980-99 Standard Guide for Accelerated Aging of Sterile Medical Device Packaging and ANSI/AAMI/ISO 11607-1997 Packaging for terminally sterilized medical devices.*

*Alternate temperature and humidity conditions are also acceptable and available at Pacific BioLabs.*

### Packaging Tests

6630 Package Expiration Dating Validation Protocol

*A typical package expiration dating study includes accelerated aging of packaged products plus packaging tests after each of several aging periods (e.g. 1, 3 and 5 year equivalency). Also, aged products are usually returned to the client for physical evaluation and testing. In addition to storage fees, there is usually a \$35 to \$50 fee for pulling and returning samples per storage interval. This charge varies depending on the size and quantity of samples to be pulled. Shipping charges for returning samples are billed at cost. A laboratory report specifying aging conditions, room temperature equivalency and sample storage dates is provided for each sample return date. We can follow your protocol or write a protocol to meet your specific requirements. Please call client services at 847/564-8181 or 864/574-7728 for a quotation for your project.*

6602 **Environmental Stressing (optional) plus Package Integrity by Dye Penetration** – 13 sample recommended (10 test samples and 3 positive control)

**Environmental Stressing (optional) plus Package Integrity by Microbial Challenge** – B.I. Dust Method: 13 sample recommended (10 test samples and 3 positive control)

6601 Package Integrity by Microbial Challenge - Small Device

6606 Package Integrity by Microbial Challenge - Medium Device

6607 Package Integrity by Microbial Challenge - Complex Device

6608 Package Integrity by Microbial Challenge - Large Device

6640 Package Burst Test

6641 Package Creep Test

6644 Package Distribution Simulation

6646 Seal Peel Test

### Particulate Matter – Medical Devices

3152 Light Obscuration Method (2 to 100 microns)

– 1 sample (small medical device)

– 2+ samples (per sample)

3154 Microscopic Method (>10 and >25 microns)

– 1 sample (small medical device)

– 2+ samples (per sample)

*The medical device is rinsed with filtered water (0.2 µm pore size). The particulate test is run on the rinse water. Usually, results are reported as particles per mL. There is an additional charge for the sample handling required for larger and/or more complex medical devices such as I.V. bags and tubing assemblies.*

## **PHARMACEUTICAL AND BIOPHARMACEUTICAL TESTING SERVICES – INTRODUCTION**

Since 1984, Pacific BioLabs has been offering high quality testing services to the pharmaceutical industry. Pacific BioLabs offers a wide range of services in microbiology and toxicology to support drug research, registration and production. Biopharmaceutical companies use many of the same services, and Pacific BioLabs has added new services to accommodate their unique needs. Fees for some of our more routinely performed services are listed in the next few pages. Many of the tests that we perform – particularly in the area of analytical chemistry – are client specific and not listed in this fee schedule.

**For a quote, fax the “[Request for Quotation](#)” form on the inside of the front cover or use the online form at [PacificBioLabs.com](http://PacificBioLabs.com).**

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## **R & D SUPPORT SERVICES**

Pacific BioLabs offers a complete range of antibody services, immunochemistry procedures, and preclinical studies for drug development and to support IND, NDA, and PLA submissions. Pacific BioLabs has standard protocols for many studies, or we can help you develop a custom protocol. During the last two decades, we have gained a national reputation for excellence in science, diligence in regulatory compliance, quality in service and reliable turnaround time. Please call client services at 510/964-9000 for a quotation on your project.

### **PRECLINICAL STUDIES OF PHARMACEUTICALS AND BIOLOGICS**

Pharmaceutical and biopharmaceutical tech companies rely on preclinical toxicology and pharmacology studies to:

- evaluate the efficacy of new drug products quickly and accurately
- provide critical information for clinical trials
- help ensure patient safety
- meet FDA and international requirements for new drug submissions.

Pacific BioLabs' experienced staff can work with you to design and execute cost-effective protocols for preclinical studies of biotech-derived products and traditional pharmaceuticals. Our rigorous quality assurance program and outstanding regulatory track record help guarantee there will be no surprises with your product submissions. Upon request toxicology studies can be performed with applicable GLP regulations.

For additional information, please see our booklet "[\*Preclinical Toxicology – Points to Consider in Program Design.\*](#)" To receive a free copy of this booklet, call client services at 510-964-9000, fax the form on the inside back cover to this fee schedule, or view it online at [PacificBioLabs.com](http://PacificBioLabs.com).

## **PRECLINICAL TOXICOLOGY OECD/ICH GUIDELINES**

Upon request, these services will be conducted under the direct supervision of a board certified veterinary pathologist. Full ophthalmologic evaluations are also available.

Species: mice, rat, rabbit, dog, primate

7426	Acute Toxicology
7425	Subacute Toxicology
7427	Subchronic Toxicity
7420	Surgical Method Development
7421	Product Safety Evaluations
7416	Histopathology
7417	Clinical Pathology (hematology and clinical chemistry)

## **PHARMACOKINETIC/PHARMACODYNAMIC STUDIES**

Available analytical techniques include scintillation counts of 14C and 3H labeled compounds, ELISA, LC/MS/MS, GC and HPLC.

7413	Absorption, Distribution, Metabolism, & Excretion (ADME/PK)
7415	Dose Confirmation/Analysis
7004	Radiolabel Studies (14C and 3H)

## **PRECLINICAL EFFICACY**

Wound Healing  
Infectious Disease  
Cancer/Tumor  
Skin Disease  
EAE

## R & D SUPPORT SERVICES – DISEASE MODELS

Pacific BioLabs' scientists have experience with a wide range of infectious and other disease state models for evaluating candidate therapeutics or prophylactic treatments. Our staff will conduct literature searches, collaborate with you on protocol design, and handle all aspects of IACUC review promptly and responsively.

Studies are conducted by well-trained Study Directors and technicians in compliance with Pacific BioLabs' rigorous quality systems.

### AVAILABLE SPECIES INCLUDE:

- rabbits
- rats
- mice
- guinea pigs
- hamsters
- dogs
- swine
- primate

### Treatments may be administered via the following routes of administration:

- oral
- dermal
- intravenous
- subcutaneous
- intracutaneous
- intraperitoneal
- continuous infusion (Alzet®)
- intratracheal
- intrathecal

All testing complies with applicable Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) regulations. Our animal facility is AAALAC accredited and USDA and OLAW compliant. Pacific BioLabs has an outstanding track record of regulatory compliance. We are committed to excellent client service and appreciate the opportunity to discuss your testing requirements.

## IMMUNOLOGY SERVICES

Pacific BioLabs offers custom antibody production services. Pricing of immunology projects may vary according to specific protocols, complexity of sample preparation and special handling requirements. Please call client services at 510/964-9000 for more information.

7393 Immunogenicity

## BIOLOGICAL ASSAYS

### Insulin Assay

7951 Rabbit Blood Sugar Method – Biopotency - USP

7950 Rabbit Blood Sugar Method – Bioidentity – USP\*

*\*Special pricing available when performed with microbial limits and LAL testing. Special handling fees may apply.*

### Glucagon Assay (USP)

7952 USP Glucagon

## WATER TESTING

Purified water is a key component in the manufacturing of virtually all pharmaceutical products. Water purification systems must be validated to insure that the specified quality of water is consistently produced. Pacific BioLabs is the leading provider of laboratory testing services for validation of pharmaceutical water systems. If manufacturing plants are located near any of Pacific BioLabs' laboratories, water samples can be collected by our technicians. Alternatively, the manufacturer's employees can collect the samples and ship them to Pacific BioLabs for analysis. Samples for microbiological testing will be put on test the day that the samples are received. Bacterial endotoxin and chemistry testing will be completed within five work days. Please call client services to discuss your water system validation requirements.

All water purification systems must be monitored regularly to verify the quality of the water produced. Water purification systems can potentially harbor high levels of bacteria. Bacterial or chemical purity problems with water can compromise the quality of finished products. Pacific BioLabs can supply containers for collecting water samples. Please call client services to request supplies.

### Purified Water System Validation Projects

#### Chemical and Physical Tests

- 3131 Purified Water Monograph – USP (conductivity and TOC)
- 3980 Total Organic Carbon (TOC)
- 3150 Particulate Matter (2 to 100 microns) – Light Obscuration Method
- 6560 LAL – Bacterial Endotoxins Test – Kinetic Chromogenic or Turbidimetric

#### Water Monograph – EP & JP

- 3702 Purified Water – EP
- 3704 Water for Injection – EP
- 3706 Water – Highly Purified – EP
- 3708 Water – JP
- 3710 Water for Injection – JP
- 3712 Purified Water – JP
- 1334 Total Heterotrophic Count – Plate Count
- 1335 Total Heterotrophic Count – Membrane Filtration  
(For potential CFU > 1000, subsequent filtrations are \$20.00 each.)
- 1337 Total Coliform – Membrane Filtration  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1344 Total Coliform – MPN  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1339 Fecal Coliform – MPN (includes total coliform)
- 1342 *Pseudomonas aeruginosa* – Membrane Filtration

#### Water Sampling Supplies

- 1379 Polycarbonate Bottle, 1 Liter  
(For each purified water monograph, fill one bottle to capacity.)
- 1380 Glass Bottle with Teflon Lined Cap, 1 Liter (reusable)  
(For each purified water monograph, fill one bottle to capacity.)
- 1368 Specimen Cups, Sterile, 120 mL  
(For each microbiological analysis, fill one cup to capacity.)
- 1383 TOC Sample Vials, 40 mL  
(For each TOC test, fill 2 vials to capacity.)
- 1384 Test Tubes, Sterile, Non-pyrogenic, 15 mL  
(For each LAL test, fill one tube to capacity.)

## MICROBIOLOGY TESTING

### MICROBIOLOGICAL ANALYSES

#### Antimicrobial Preservative Effectiveness Tests

- 1410 USP (duplicate plating)
  - category 1 products
  - category 2,3,4 products
- 1416 EP/BP (duplicate plating)
  - parenteral, ophthalmic
  - topical, oral
- 1417 USP/BP/EP (duplicate plating)
  - parenteral, ophthalmic
  - topical, oral
- 1411 CTFA (6 organisms)
- 1412 CTFA (14 day re–challenge)
- 1422 Japanese Pharmacopeia
- 1413 Additional organism
- 1415 Triplicate plating (per organism)
- 1420 A.P.E Plate Counts by Filtration (per organism, per time point)
- 1424 Validation of Plate Count Method used for AE Testing\*

\* Additional fees may be incurred if the initial test parameters are not successful and retesting is required.

#### Microbial Limits – USP (Please call for EP test fees)

- 1329 Preparatory Tests (test method validation – see note below)\*
  - Full Preparatory Testing Components:
    - Aerobic bacteria plate count validation
    - Yeast and Mold plate count validation
    - *E. coli* screen validation
    - *Salmonella* screen validation
    - *S. aureus* screen validation
    - *P. aeruginosa* screen validation
- 1333 Screening Tests\*\*
  - (Aerobic Plate Count, Yeast and Mold, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella* and *E. coli*)
  - Diagnostic Work on Suspect Organisms (fees are per isolate)
    - 1332 – Gram Stain
    - 1319 – *Salmonella* suspects – TSI biochemical test
    - 1320 – *E. coli* suspects – EMB agar morphology
    - 1321 – *P. aeruginosa*/*E. coli*/*Salmonella* suspects – oxidase test
    - 1322 – *S. aureus* suspects – coagulase test

\*USP requires preparatory testing to validate the specific test method that will be used in routine microbial limits testing of the product. By means of a challenge of 6 representative microorganisms, preparatory testing demonstrates the ability of the test method to recover microorganisms that could be present on a product.

This test is generally required only once per product until a change is made in the product formula or manufacturing process. The test fee indicated is typical. Additional test fees may be incurred if the initial test parameters are not successful and retesting is required.

\*\*This test fee is typical. The price may vary depending on the nature of the product and test method specifics.

## MICROBIOLOGICAL ANALYSES

### Microbial Identification

Pacific BioLabs recently added the Riboprinter microbial characterization system to its capabilities. Using powerful genetic technology, the system provides a fast and reliable DNA fingerprint, or Riboprint pattern, of virtually any bacterium. Riboprint patterns characterize environmental isolates, pathogens, spoilage organism, control strains and other bacteria that are important to the pharmaceutical, medical device and consumer product industries. The Riboprint system provides an exact genetic pattern of organisms, delivering the unparalleled power to track sources of contamination in raw materials, finished products and the manufacturing environment.

The Riboprint library includes 6400 patterns, representing 200 bacterial genera and more than 1400 species. Pacific BioLabs will also maintain a library of Riboprint patterns for each client with volume submissions. For subsequent submissions from the client, both the Riboprint and client libraries will be searched. The power to track and bacteria increases each time a sample is run. With a comprehensive picture of the microbial environment, the data can be tracked at the strain level, helping to pinpoint sources of contamination with precision and speed.

For Rush requests, we can have results in 10 to 24 hours. Because of the faster results capability, results reproducibility and the genetic strain tracking feature, Pacific BioLabs recommends the Riboprinter for bacteria identifications. Discount pricing is available for high volume projects.

#### Bacteria Identification – Riboprinter Genetic Method

- 1510 Same Day Turnaround Time\*\*
- 1511 – 1 Day\*\*
- 1513 – 3 Days
- 1517 – 7 Days
- 1520 – 14 Days

*\* If > 8 isolates are submitted together, the fee is reduced to the next longer TAT amount.*

*\*\* Pure fresh culture required for ≤ 1 day TAT.*

In addition to the genetic method, Pacific BioLabs offers alternate techniques for microbial identifications. Following gram stain and morphology of unknown bacteria, an appropriate identification method is selected. The bacteria can be identified by the MIDI method, which is based on a fatty acid profile of an extract of the bacteria, or the API biochemical method.

- |  |                                  |   |
|--|----------------------------------|---|
|  | <i>Gram positive rods – MIDI</i> | <i>Gram negative rods, Enterobacteriaceae – API</i> |
|  | <i>Gram positive cocci – API</i> | <i>Gram negative rods, other bacteria – MIDI</i>    |
- 1370 Bacteria Identification (MIDI GC with gram stain, morphology, catalase and oxidase.)\*□
    - 1 Organism
    - 2 to 5 Organisms
    - 6+ Organisms
  - 1371
    - 1 Organism
    - 2 to 5 Organisms
    - 6+ Organisms

*\* The initial results of some bacteria identification testing may indicate more than one organism as a possible identification. We can report the results of the initial test or perform additional biochemical confirmation testing to distinguish the most probable organism identification. When additional confirmation testing is required, there will be an additional fee of \$20.00 to \$60.00.*

- 1323 Bacteria Characterization – Biochemical & Morphological
- 1324 Yeast Identification
- 1325 Mold Identification
- 1332 Gram Stain
- 1343 Gram Negative Bacteria
- 1326 Microorganism Morphology

## MICROBIAL ENVIRONMENTAL MONITORING

– For a list of services and supplies, please see page 14.

### STERILITY ASSURANCE TESTS

#### Bacteriostasis/Fungistasis – USP or EP (6 Organism Test)

- 6101 Direct Transfer – Immersion
- 6103 Membrane Filtration by Vacuum Method
- 6104 Membrane Filtration by Millipore Steritest™ Method

*For Bacteriostasis/Fungistasis tests by membrane filtration, 60 product samples are normally required. This test includes performing three filtration sterility tests of 20 samples each. For each simulated sterility test, one test organism is inoculated into the final 100 mL rinse of the membrane filter. The USP/EP combination test requires 8 organisms. The fee for the USP/EP B-F test is \$480.00.*

#### Bioburden Method Validation – Recovery Study

- 6219 Liquids (per organism, in triplicate: 3 organisms recommended)
- 6221 Powders (per organism, in triplicate: 3 organisms recommended)

#### Bioburden Analyses

- 6201 Bioburden – Containers, Closures, Packaging Materials  
Total Aerobic Bacteria and Fungi by Membrane Filtration Method
- 6210 Bioburden – Process Fluids  
Total Aerobic Bacteria and Fungi by Membrane Filtration Method
- 6222 Bioburden – Powders (Total Aerobic Bacteria and Fungi)
- 6207 Bioburden – Total Anaerobic (with Total Aerobic Bacteria and Fungi)
- 6209 Bioburden – Total Aerobic Spores (with Total Aerobic Bacteria and Fungi)
- 6401 Biological Indicator Population Verification (3 spore strips)

#### Sterility Audits

- 6806 10 Spore Strips and 1 or 2 positive controls – 15 mL SCDM
- 6820 Each additional spore strip – 15 mL SCDM
- 6812 Product Only – Direct Transfer (Immersion) – < 120 mL media  
(20 products in SCDM, 20 products in FTM, 14 days incubation)

*For sterility testing - >120 ml media, please see page 18.*

#### Membrane Filtration Sterility Tests - USP\*

- 6807 Vacuum Filtration (Liquid)
- 6808 Vacuum Filtration (Powder)
- 6814 Millipore Steritest Filtration (Liquid)
- 6813 Millipore Sterisolutest Filtration (Powder)
- 6819 Extra Samples for Filtration Test (per sample)
- 6834 Extra 100 mL Filter Rinses (per rinse beyond 3)
- 6830 Steritest Filtration – Subsequent Subtest\*\*
- 6832 Vacuum Filtration – Subsequent Subtest\*\*
- 6829 Filtration Test – Exact Reconstitution (per sample)
- 6831 Filtration Test – Exact Pooling – Dilution (per sample)

*\*All standard fees for sterility tests by membrane filtration are based on testing 20 samples, using one vacuum or Millipore filter unit, three 100 mL filter rinses, and culturing of the filter in FTM and SCDM. Samples which require extraordinary preparation or filtration time will incur a surcharge.*

*\*\*For some products, it may not be possible (or desirable due to bacteriostasis or fungistasis properties) to run 20 samples through one filter unit. A subtest consists of using an additional vacuum or Millipore filter unit for a portion of the samples, three 100 mL filter rinses, and culturing of the filter in FTM and SCDM. For tests requiring subtests, one standard test fee will be billed, plus one subtest fee for each subsequent subtest that is required.*

## **LAL, PYROGEN AND SAFETY TESTS**

### **LAL Bacterial Endotoxins Tests – USP or EP**

#### *Kinetic Turbidimetric or Chromogenic Methods*

- 6560 Water
- 6561 Liquids
- 6562 Powders
- 6567 Concurrent Assay of Sample Dilution
- 6568 Non-concurrent Assay of Sample Dilution

*For LAL tests using the gel clot method, please see page 19.*

### **LAL Method Verification and Validation**

This testing is performed on products and materials for which a specific kinetic LAL test method has not yet been established. It generally involves testing additional dilutions of the product to address any inhibition or enhancement issues. The validation testing also serves as product release testing for the lot(s) tested. For some products, additional method development may be required and additional fees would apply.

#### *Kinetic Turbidimetric or Chromogenic Methods*

- 6552 – LAL Validation (one lot)
- 6554 – LAL Validation (three lots, concurrently tested)

### **Pyrogen Tests**

- United States Pharmacopeia (USP)
- 7201 – 3 Rabbit Test (non-pyrogenic)
- 7202 – Retest 5 Rabbits
- 7236 – Sham Test (per rabbit)
- European Pharmacopeia (EP)
- 7203 – 3 Rabbit Test (non-pyrogenic)
- 7237 – Sham Test (per rabbit)
- Japanese Pharmacopeia (JP)
- 7218 – 3 Rabbit Test (non-pyrogenic)
- 7239 – Sham Test (per rabbit)

*For substances determined to be pyrogenic, there will be an additional charge of \$45.00 per rabbit.*

### **Safety Tests**

- 7204 USP Safety Test (mice)  
EP Safety Test (mice)
- 7219 EP Abnormal Toxicity – general
- 7228 EP Abnormal Toxicity – immunosera/vaccines (5 mice, 2 guinea pigs)  
CFR Safety Test for Biological Products
- 7207 – 2 guinea pigs, 2 mice
- 7205 – retest (2 mice)
- 7206 – retest (2 guinea pigs)

## FOOD, COSMETIC, FABRIC AND CHEMICAL INDUSTRY TESTING SERVICES

### INTRODUCTION

Since its founding in 1984, Pacific BioLabs has been offering high quality testing services to the food, cosmetic, fabric and chemical industries. Pacific BioLabs offers a wide range of services in chemistry, microbiology and toxicology to establish product safety and support product development and quality control. Some of our more routine testing services and fees are presented on the next few pages. Many of the tests that we perform – particularly in the area of analytical chemistry – are client specific and not listed in this fee schedule.

We would be pleased to provide a quote for your testing requirements tests.

**For a quote, fax the “[Request for Quotation](#)” form on the inside of the front cover or use the online form at [PacificBioLabs.com](http://PacificBioLabs.com).**

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## **FOOD, COSMETIC, FABRIC AND CHEMICAL INDUSTRY TESTING SERVICES**

### **MICROBIOLOGICAL ANALYSES**

#### **Antimicrobial Preservative Effectiveness Tests**

– For USP, BP, JP, EP and CTFA tests, please see page 25

#### **Bacteria, Mold and Yeast Identification – see page 26**

#### **Disinfectants – AOAC Tests**

- 1403 Fungicidal Test (per sample)
- 1404 Germicidal Spray Products Test (per organism)
- 1405 Phenol Coefficient (per organism)
- 1409 Use Dilution (per organism/10 carriers)

*GLP treatment is required if data will be used to support EPA or FDA product registration.  
The minimum fee for GLP treatment is \$200.00.*

#### **Environmental Monitoring – Microbiological**

– For a list of services and supplies, please see page 14.

#### **Fabrics – Microbial Challenge Tests**

- 1801 AATCC 100 – Antibacterial Finishes on Textile Materials
  - Padding Test (per organism)
- 1804 AATCC 30 – Antifungal Activity, Assessment on Textile Materials
  - Mildew and Rot Resistance (per organism)
- 1805 AATCC 147 – Antibacterial Assessment of Textile Materials
  - Parallel Streak Test (per organism)
- 1901 Zone of Inhibition Test (per organism)

#### **Microbial Limits – USP**

The microbial limits test is a screen for common pathogenic organisms. The organisms are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella* and *E. coli*. The test also includes an aerobic plate count and a yeast and mold count. For microbial limits preparatory and screening test fees, please see page 25.

**Routine Microbiological Analyses\***

- 1301 Aerobic (Standard) Plate Count
- 1304 Aerobic Plate Count with Yeast and Mold
- 1302 Anaerobic Plate Count
- 1303 Yeast and Mold Count
- 1305 Coliform (MPN)
- 1306 Coliform (Plate Count)
- 1307 *E. coli* Screen
- 1340 *E. coli* Confirmation (API)
- 1309 *Pseudomonas aeruginosa* Screen
- 1310 *Salmonella* Screen
- 1341 *Salmonella* Confirmation (API)
- 1311 *Staphylococcus aureus* (presumptive)
- 1312 Coagulase Positive *Staphylococcus*

*\*Product specific validation testing is recommended or required for all routine microbiological analyses.  
Please call for a quote for your validation requirements.*

**Purified Water System Validation Projects****Chemical and Physical Tests**

- 3131 Purified Water Monograph – USP (conductivity and TOC)
- 3980 Total Organic Carbon (TOC)
- 3150 Particulate Matter (2 to 100 microns) – Light Obscuration Method
- 6560 LAL – Bacterial Endotoxins Test – Kinetic Chromogenic or Turbidimetric

**Microbiological Analyses – Water**

- 1334 Total Heterotrophic Count – Plate Count
- 1335 Total Heterotrophic Count – Membrane Filtration  
(For potential CFU > 1000, subsequent filtrations are \$20.00 each.)
- 1337 Total Coliform – Membrane Filtration  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1344 Total Coliform – MPN  
(There will be an additional charge of \$40.00 if suspect growth occurs.)
- 1339 Fecal Coliform – MPN (includes total coliform)
- 1342 *Pseudomonas aeruginosa* – Membrane Filtration

*Other procedures from Standard Methods for the Examination of Water and Wastewater are available upon request.*

**Water Sampling Supplies**

- 1379 Polycarbonate Bottle, 1 Liter  
(For each purified water monograph, fill one bottle to capacity.)
- 1380 Glass Bottle with Teflon Lined Cap, 1 Liter (reusable)  
(For each purified water monograph, fill one bottle to capacity.)
- 1368 Specimen Cups, Sterile, 120 mL  
(For each microbiological analysis, fill one cup to capacity.)
- 1383 TOC Sample Vials, 40 mL  
(For each TOC test, fill 2 vials to capacity.)
- 1384 Test Tubes, Sterile, Non-pyrogenic, 15 mL  
(For each LAL test, fill one tube to capacity.)

## **TOXICOLOGY SERVICES**

### **OECD (Organisation for Economic Co-Operation and Development) Guidelines**

- Skin Corrosivity (6 rabbits)
- 7244 Acute Oral Toxicity
  - Limit Test (5000 mg/kg, 10 rats)
  - LD50, Up and Down Test (5 – 15 rats)
- 7240 Acute Dermal Toxicity
- 7242 Acute Inhalation Toxicity
- 7246 Acute Dermal Irritation
  - 3 rabbits, observations at 1, 24, 48 and 72 hours
  - 3 rabbits, sequential test
- 7243 Acute Oral Toxicity (5 rats)
- 7252 Acute Eye Irritation/Corrosion
  - 3 rabbits, observations at 1, 24, 48 and 72 hours

### **EPA Guidelines (OPPTS/FIFRA and TSCA)**

- Acute Oral Toxicity
- 7256 – Limit Test (5000 mg/kg or 2000 mg/kg, 3 – 5 rats, sequential dosing)
- 7257 – LD50, Up and Down Test (5 – 15 rats)
- Acute Dermal Toxicity
- 7250 – Limit Test (2000 mg/kg, 10 rabbits)
- Dermal LD50, (5 – 10 rabbits)
- 7264 Acute Dermal Irritation
  - 3 rabbits, observations at 1, 24, 48 and 72 hours
  - 3 rabbits, sequential test
- 7260 Acute Eye Irritation
  - 3 rabbits, observations at 1, 24, 48 and 72 hours
- 7254 Acute Inhalation Toxicity

*Studies performed following EPA guidelines include GLP treatment.*

### **FHSA Guidelines**

- 7276 Acute Oral Toxicity
  - Limit Test (5000 mg/kg, 10 rats, no necropsies)
  - Each additional dose level (for LD50 determination)
  - necropsies
- 7270 Acute Dermal Toxicity
  - Limit Test (2000 mg/kg, 12 rabbits)
  - Each additional dose level
- 7284 Primary Skin Irritation
  - 6 rabbits, 24 and 72 hour observations
  - Second sample, same rabbits
- 7282 Primary Eye Irritation
  - 6 rabbits, 24, 48, and 72 hour observations
- 7274 Acute Inhalation Toxicity

*Additional observation days will incur extra charges.*

### **ISO Guidelines**

- 7285 Ocular Irritation Test
  - 3 rabbits, 1, 24, 48, and 72 hour observations
- 7286 Skin Irritation Test
  - 3 rabbits, 1, 24, 48, and 72 hour observations

### **Skin Sensitization Studies**

- 7501 Closed Patch Test (ISO)
- 7502 Buehler Method (EPA)
- 7507 Dose Level Determination
- 7503 Maximization Test – Magnusson Kligman Method (12 test guinea pigs)\*\*
- 7505 Maximization Test – Magnusson Kligman Method (11 test guinea pigs)\*\*
  - Each additional guinea pig
- 7510 Re-challenge (including 5 naive controls)
- 7508 Positive Controls (historical validation)
- 7509 Positive Controls (concurrent)
- 7512 Murine Local Lymph Node Assay (LLNA) (includes positive control)

*\* These test fees include historical positive controls. A positive control group is a group treated with a known sensitizing agent. A positive control group must be included with a sensitization test to demonstrate that a sensitization response can be elicited under the conditions of the test. There are two types of positive controls. A concurrent positive control group is one conducted at the same time as a particular test. Alternatively, Pacific BioLabs runs a historical positive control group at least once a year. Any test performed during the year under the same conditions can be compared to this control. The historical control minimizes cost and the use of animals.*

*\*\* The Maximization Test using 12 test animals is recommended for all critical sensitization determinations. The larger test group size allows for a more accurate assessment of sensitization potential and has a lower incidence of false positives.*

### **Toxicity Screening Tests**

- 7401 Acute Oral Toxicity (5 rats)
- 7403 Acute Dermal Toxicity (4 rabbits)
- 7405 Primary Eye Irritation (3 rabbits)
- 7407 Primary Skin Irritation
  - 3 rabbits
  - Second sample, same rabbits
- 7410 Complete Screening Profile
  - Includes acute oral and dermal toxicity and primary skin and eye irritation studies.

*These screening tests use a reduced number of animals than standard FHSA protocols. They are suitable for consumer and specialty chemical products other than those requiring EPA or FDA registration.*