



LexaMed

DESCRIPTION OF SERVICES and FEE SCHEDULE

Compliance**driven**
Education**driven**
Analysis**driven**
Client**driven**
Knowledge**driven**

LexaMed Fee Schedule

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LexaMed Fee Schedule

COMPANY HISTORY

LexaMed, Ltd. (LexaMed), headquartered in Toledo, Ohio, is a company focused on providing the pharmaceutical and medical device industries with quality, compliant, state-of-the-art services in consulting, laboratory, and packaging services. Our team of experienced, professional consultants has over two centuries of combined experience; these skill-sets allow us to address situations of any size and subject with technically competent, practical and comprehensive solutions. Our consultants are experienced in Quality Systems, Validation (product, process, equipment, methods), Sterilization (EO, steam, radiation, VHP, liquid, novel processes), Microbiology, Environmental Monitoring, Auditing, Regulatory Affairs and Engineering.

Our laboratories are ISO certified and have been in operation for more than 25 years, initially as BEC Laboratories, and now as LexaMed, providing quality services in microbiology, chemistry, and packaging. The laboratories have been expanded to include many offerings including steam BIER testing, disinfectant efficacy, D-value and z-value determinations, package integrity, container-closure studies, and stability and accelerated aging under ICH specified conditions. We also offer tests to support routine lot release such as sterility tests (product and biological indicator) and LAL endotoxin testing. We also provide testing to support sterilization cycle validations such as bioburden quantitation, sterilant resistance, ethylene oxide residues and microbial identifications.

In addition to our routine laboratory services, dedicated laboratory space and personnel for client-specific confidential R&D projects is available.

LexaMed is ISO 13485 Certified, holds a State of Ohio drug license and DEA registration, and maintains a FDA registration for both medical devices and pharmaceuticals. LexaMed is an active member of BioOhio, MichBio and PennBio, and also holds active memberships in the following associations:

AAMI • ACS • ASM • ISPE • PDA • RAPS

“LexaMed 's mission is to offer Quality, compliant value-added services and products to our clients in a courteous and expeditious manner at a fair price.”

- Robert R. Reich, LexaMed President

LexaMed manufactures BEC Growth-Chek™ Microbial Suspensions for performing USP Growth Promotion, Monograph <71>, and Bacteriostasis/Fungistasis Test and other quality control measures for growth media. Our microbial suspensions are derived from cultures traceable to a recognized culture collection identified in USP:

Aspergillus brasiliensis formerly Aspergillus niger
Bacillus subtilis
Candida albicans
Clostridium sporogenes
Escherichia coli
Geobacillus stearothermophilus
Kocuria rhizophila formerly Micrococcus luteus
Pseudomonas aeruginosa
Staphylococcus aureus

LexaMed also produces highly concentrated Bacillus subtilis "5230" suspensions for validation of heat sensitive products.

LexaMed's prices for laboratory testing and BEC Growth-Chek™ Microbial Suspensions are listed in this Description of Services and Fee Schedule brochure. This Fee Schedule lists prices for the routine tests we perform. Please inquire for any test not listed. Our scientists are prepared to respond to special testing requests to serve your custom analytical needs. Our highly competitive pricing includes the technical support you would expect to receive from your testing laboratory before, during and after completion of testing.

LexaMed Fee Schedule

GENERAL PROCEDURES

SAMPLE SUBMISSIONS

All sample submittal for testing shall be accompanied by a LexaMed Sample Submission Form containing client name, address, and name and phone number of the client contact. Sample identification shall include part number, lot number, or batch number, sterilizer load and any other identifiers deemed appropriate. The specific type of test to be conducted shall be clearly identified, along with any special instructions and purchase order number. A LexaMed Sample Submission Form is included in this brochure and can also be downloaded from our web site, www.lexamed.net. Please fill out this form and submit one with each sample submitted.

STANDARD FEES

The fees specified in this document apply to most samples and routine test methods. Samples which require special handling may incur additional charges. Prices are effective June 30, 2011 and are subject to change. The latest and up-to-date price listing can always be downloaded from our web site, www.lexamed.net.

Additional charges:

Minimum invoice fee	\$100.00
Revised reports (modification requested by client)	\$100.00
Consultation	Quote provided per project

STAT TESTING

Request for STAT, or immediate, testing can usually be accommodated, with an additional STAT fee of 1.5 x the normal fee. If the request requires scheduling changes or work outside normal work hours, the fee may be higher.

CLIENT VISITS & AUDITS

LexaMed recommends and encourages periodic visits and audits of the laboratories. LexaMed is an extension of your facilities and we realize that audits and visits to ensure GMP and ISO compliance are an important part of your operations. Please call or email (info@lexamed.net) to arrange an appointment.

QUALITY SYSTEMS/CERTIFICATION

LexaMed conducts testing in accordance with 21 CFR 58, 820 (US FDA, GLP/GMP regulations) and is ISO 13485 Certified. LexaMed also holds a State of Ohio drug license and DEA registration, and maintains a FDA registration for both medical devices and pharmaceuticals.

CONFIDENTIALITY

All information regarding client's samples and data is maintained in strictest confidence. Only persons authorized by the client will receive information unless directed by a regulatory agency. LexaMed will promptly notify the client if any information is requested by a regulatory or other governmental authority.

POLICIES

DISCLAIMER AND ASSUMED CLIENT RESPONSIBILITY

LexaMed will perform the services described herein in accordance with sound laboratory practice, accepted analytical procedures, and free from material defect in workmanship. LexaMed's sole obligation hereunder shall be to re-perform services which are materially deficient because of LexaMed's failure to perform said services in accordance with this Policy and the standards of the industry. Material deficiencies must be reported in writing to LexaMed within thirty (30) days after the discovery thereof, but in no event later than one (1) year from the performance of the services by LexaMed. Except as stated above, LexaMed makes no express or implied warranty of merchantability or fitness for a particular purpose of the services and/or related materials to be furnished by LexaMed. In no event shall LexaMed be liable for any direct, indirect, special or consequential damages, nor shall LexaMed be liable in any event, including its obligation to re-perform, for any losses, damages or claims in excess of the amount paid to LexaMed for the services. Results and conclusions apply only to the test article tested. No further evaluation of the results is made by LexaMed. Any extrapolation of these data to other samples is the responsibility of the client. In addition, by contracting with LexaMed, the client assumes responsibility for payment of all fees invoiced by LexaMed within thirty (30) days of receipt of the invoice. If payments are not forthcoming, the client assumes the responsibility for all legal and collection fees (including attorneys's fees) associated with the collection of the account. Extended storage or special handling must be arranged prior to sample submission.

LexaMed Fee Schedule

MICROBIOLOGY

GENERAL MICROBIOLOGY

	Price
Validation of Bioburden Method	
Exhaustive Recovery (minimum 3 samples required).....	\$500.00
Spore Inoculation and Recovery (3 samples required).....	\$360.00
Bioburden Determinations	
Total Aerobic	
Standard Plate Count (per sample).....	\$60.00
Membrane Filtration (per sample).....	\$65.00
Total Aerobic and Spores	
Standard Plate Count (per sample).....	\$75.00
Membrane Filtration (per sample).....	\$80.00
Total Aerobic and Anaerobic	
Standard Plate Count (per sample).....	\$80.00
Membrane Filtration (per sample).....	\$85.00
Total Aerobic and Fungi	
Standard Plate Count (per sample).....	\$75.00
Membrane Filtration (per sample).....	\$80.00
Total Aerobic, Anaerobic & Spores	
Standard Plate Count (per sample).....	\$85.00
Membrane Filtration (per sample).....	\$90.00
Total Aerobic, Spores & Fungi	
Standard Plate Count (per sample).....	\$85.00
Membrane Filtration (per sample).....	\$90.00
Total Aerobic, Anaerobic, Spores & Fungi	
Standard Plate Count (per sample).....	\$95.00
Membrane Filtration (per sample).....	\$100.00
Environmental Monitoring	
Settling Plate/Rodac Plate - Incubation and Enumeration (per plate).....	\$16.00
On-site (additional charge for supplies and travel, per hour).....	\$125.00
Total Plate Count	
Direct Plating.....	\$60.00
Membrane Filtration (per sample).....	\$65.00
Additional Dilutions.....	\$15.00
Enumeration of Yeasts and Molds in Food – Dilution Plating Technique per Bacteriological Analytical Manual (BAM).....	\$125.00
Minimum Inhibitory Concentration (MIC).....	Inquire
Organism Identification	
Gram Stain and Colony Morphology.....	\$50.00
Organism Identification (BIOLOG - genus & species, price per organism)	
Includes Gram Stain and Colony Morphology.....	\$120.00
Genotypic Organism Identification	Inquire
Particulate Analysis/Microscopic Count	
Solutions.....	\$245.00
Devices (extract).....	\$265.00
Water Testing	
Standard Plate Count.....	\$60.00
Fecal Coliforms.....	\$75.00
Total Coliforms.....	\$75.00
Total E. coli.....	\$75.00

LexaMed Fee Schedule

USP Monograph <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests and USP Monograph <62> Microbial Examination of Nonsterile Products: Test for Specified Microorganisms (previously know as USP Microbial Limits)

USP specific organisms Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Salmonella enterica, Candida albicans, Clostridium sporogenes, Bile-Tolerant Gram Negative Bacteria

	Price
System Suitability, 1 organism	\$150.00
System Suitability, 2 organisms.....	\$300.00
System Suitability, 3 organisms.....	\$450.00
System Suitability, 4 organisms.....	\$600.00
System Suitability, 5 organisms.....	\$750.00
System Suitability, 6 organisms.....	\$900.00
System Suitability, 7 organisms.....	\$1050.00
Routine Screening with total plate count, 1 organism	\$60.00
Routine Screening with total plate count, 2 organisms.....	\$120.00
Routine Screening with total plate count, 3 organisms	\$180.00
Routine Screening with total plate count, 4 organisms.....	\$240.00
Routine Screening with total plate count, 5 organisms.....	\$300.00
Routine Screening with total plate count, 6 organisms.....	\$360.00
Routine Screening with total plate count, 7 organisms.....	\$420.00
USP <51> Antimicrobial Effectiveness Test, 5 organisms, 1 replicate	
7 day incubation	\$590.00
7 and 14 day incubation	\$790.00
7, 14 and 28 day incubation	\$990.00

STERILITY TESTING

BI Sterility Testing, USP/ISO Spore Strips (each).....	\$7.00
Bacteriostasis/Fungistasis	
USP, SCD and FTM (6 organisms).....	\$570.00
AAMI / ISO SCD only (3 organisms).....	\$285.00
Product Sterility Testing (Minimum Test Report Fee for Product Testing).....	\$180.00
Product Immersion Testing	
< 200 mL media (per sample).....	\$7.00
200 - 500 mL media (per sample).....	\$8.00
600 - 900 mL media (per sample).....	\$9.50
1000 mL media (per sample).....	\$12.50
Other.....	Inquire
Membrane Filtration (each).....	\$18.00
Media Fill Sterility (per sample).....	\$2.25

BACTERIAL ENDOTOXIN TEST

Limulus Amoebocyte Lysate (LAL) - Gel-Clot Method

Device.....	\$115.00
Liquid.....	\$105.00
Inhibition/Enhancement Validation (3 lots submitted at the same time).....	\$500.00
Inhibition/Enhancement Validation (per lot, submitted separately).....	\$225.00
Additional dilutions to determine endpoint (per dilution).....	\$20.00

BARRIER MATERIAL TESTING

GENERAL AND SURGICAL MASKS

Bacterial Filtration Efficiency (BFE) Testing, ASTM F2101 Method

1-4 samples (per sample).....	\$85.00
5-19 samples (per sample).....	\$75.00
20+ samples (per sample).....	Inquire

LexaMed Fee Schedule

SURGICAL DRAPES AND GOWNS

	Price
Synthetic Blood Penetration, ASTM F1670 Method	
Sample prep	Inquire
1-9 samples (per sample).....	\$75.00
10-19 samples (per sample).....	\$65.00
20+ samples (per sample).....	Inquire
Viral Penetration, ASTM F1671 Method	
Sample prep and setup.....	Inquire
1-9 samples (per sample).....	\$150.00
10-19 samples (per sample).....	\$135.00
20+ samples (per sample).....	Inquire
Hydrostatic Pressure Test, AATCC 127 Method	
1-5 samples (per sample).....	\$55.00
6-19 samples (per sample).....	\$45.00
20+ samples (per sample).....	Inquire
Spray Impact Test, AATCC 42 Method	
1-5 samples (per sample).....	\$55.00
6-19 samples (per sample).....	\$45.00
20+ samples (per sample).....	Inquire

AOAC TESTING

AOAC Method 966.24 Coliform Group and E. coli Microbiological (MPN) Method.....	\$75.00
AOAC Method 966.23 Aerobic Plate Count, & MPN of coliform bacteria, E. coli and Staphylococcus.....	\$100.00
AOAC Use-Dilution Method for Testing Aqueous Based or Water Soluble Disinfectants (Based on AOAC 955.14, AOAC 955.15, AOAC 964.02)	
Neutralization Validation.....	\$1150.00
Routine Screening.....	\$700.00
AOAC Method 965.12 for Tuberculocidal Activity of Disinfectants (Routine Screening)	
Neutralization Validation.....	\$1150.00
Routine Screening.....	\$700.00
AOAC Method 965.12 for Tuberculocidal Activity of Disinfectants (Confirmative Testing).....	\$850.00

PACKAGE TESTING

Accelerated Aging of Packages, per month, up to 8ft ³	\$500.00
Transportation & Distribution Simulation Studies	Inquire
Dye Penetration, per sample	\$25.00
Seal Peel Test, per sample.....	\$30.00
Burst Test, per sample.....	\$30.00
Package Validation.....	Inquire
Package Shelf-life.....	Inquire
Container Closure Integrity Test.....	Inquire
Bacterial Microbial Aerosol Challenge Test.....	Inquire

CLEANING VALIDATIONS

LexaMed offers a full range of cleaning validation services including protocol development and associated testing services.

Reusable Device Studies per AAMI TIR12 and AAMI TIR30.....	Inquire
Disinfection of Reusable/Reprocessed Devices.....	Inquire
Sterilization of Reusables.....	Inquire

LexaMed Fee Schedule

STERILIZATION CYCLE DEVELOPMENT & VALIDATION

	Price
Radiation Sterilization Validation	
AAMI/ISO Method 1.....	Inquire
AAMI/ISO Method 1 Dose Audit.....	Inquire
AAMI/ISO Method 2.....	Inquire
AAMI/ISO Method 2 Dose Audit.....	Inquire
AAMI/ISO Substantiation of VD _{max} Method.....	Inquire
AAMI/ISO Substantiation of VD _{max} Dose Audit.....	Inquire
Ethylene Oxide Sterilization Development & Validation.....	Inquire
Moist Heat Sterilization Development & Validation.....	Inquire
Sterilization Consulting.....	Inquire

Assisting with the planning, coordination, protocols, execution and testing in association with validation of sterilization processes (including EO, VHP, moist heat, liquid, and novel processes)

BIOLOGICAL INDICATOR PERFORMANCE TESTS- POPULATION VERIFICATION

Biological Indicator Population Determination	
Paper Carrier (with heat shock), per sample.....	\$90.00
Stainless Steel Carrier (with heat shock), per sample.....	\$110.00
Additional Carriers.....	Inquire

BIOLOGICAL INDICATOR PERFORMANCE TESTS- RESISTANCE

BI/CI Resistometer	
Saturated Steam (per exposure).....	\$375.00
Performance Verification (1 Survival/1 Kill/1 Fractional) (1 Survival/1 Kill/1 Cycle 50 BI's) (1 Fractional/1 Cycle 20 BI's)	
Moist Heat.....	\$1,850.00
Sterility Test (each).....	\$7.00
D-value - Fraction Negative	
Steam Stumbo Murphy (10 strips/cycle/5 cycles).....	\$2,030.00
Steam Spearman Karber (7 exposures/10 strips/exposure).....	\$2,730.00
D-value - Survival Curve (5 point curve, 4 strips/point)	
Moist Heat.....	\$2,855.00
z-value	
Steam Stumbo Murphy (10 strips/cycle/5 cycles/3 temperatures).....	\$6,090.00
Steam Spearman Karber (7 exposures/10 strips/exposure/3 temperatures).....	\$8,190.00
Moist Heat.....	\$8,565.00
Report Generation.....	\$500.00

PRODUCT INNOCULATION (based on concentration and substrate)

Bacillus atrophaeus.....	Inquire
Bacillus pumilus.....	Inquire
Geobacillus stearothermophilus.....	Inquire
Aspergillus brasiliensis formerly Aspergillus niger.....	Inquire
Bacillus subtilis.....	Inquire
Candida albicans.....	Inquire
Clostridium sporogenes.....	Inquire
Kocuria rhizophila formerly Micrococcus luteus.....	Inquire
Escherichia coli.....	Inquire
Pseudomonas aeruginosa.....	Inquire
Staphylococcus aureus.....	Inquire
Other.....	Inquire

LexaMed Fee Schedule

CHEMISTRY

	Price
USP Monograph Testing	Inquire
USP Physiochemical Test- Plastics, Complete.....	\$425.00
USP Physiochemical Test- Elastometric Closures, Complete.....	\$600.00
Wet Chemistry	
Hydrogen Peroxide Titration.....	\$100.00
Hydrogen Peroxide Titration and Peracetic Acid Titration.....	\$150.00
pH Determination.....	\$45.00
Conductivity.....	\$75.00
Ethylene Oxide Residuals	
EO, EG, ECH, Simulated Use.....	\$350.00
EG and ECH.....	\$295.00
EO and ECH.....	\$295.00
EO only.....	\$235.00
EO, EG, ECH, Exhaustive Extraction (First Extraction).....	\$350.00
Each Additional Extraction.....	\$100.00
Gas Chromatography (GC) Analysis.....	Inquire
High Performance Liquid Chromatography (HPLC) Analysis.....	Inquire
Note: The price of chromatographic analysis will be based on material, method development required and system suitability needed.	

IN VITRO TOXICOLOGY

Cytotoxicity	
MEM Elution (ISO Method).....	\$215.00
MEM Elution (USP Method).....	\$200.00
Agarose Overlay (ISO Method).....	\$175.00
Agarose Overlay (USP Method).....	\$165.00

PHYSICAL TESTING

Tensile Strength of Elastic Materials, General.....	\$35.00
Puncture Resistance/Compression Testing, General.....	\$35.00
Note: Inquire about specific materials.	

ASSEMBLY AND PACKAGING

Assembly of Medical Devices.....	Inquire
Packaging	
Chevron Pouching.....	Inquire
Header Bags.....	Inquire
Pre-formed Tray Sealing.....	Inquire

STERILIZATION

3M Steri-Vac™ 5XL Gas Sterilizer (per cycle).....	\$350.00
Moist Heat (Pre-vacuum or gravity) (per cycle).....	\$225.00

ADDITIONAL TESTS AND SERVICES

Coordination of hospital simulated use and maintenance of sterility testing.....	Inquire
Coordination of sterilization exposures	
Ethylene Oxide.....	Inquire
Moist Heat.....	Inquire
Sterrad.....	Inquire
We offer dedicated lab spaces and resources for customized lab evaluations/tests.....	Inquire
Process and Method Development.....	Inquire

LexaMed Fee Schedule

BIOPHARMACEUTICAL & MEDICAL DEVICE CONSULTING

LexaMed offers consulting services in all aspects of the pharmaceutical, medical device and biotechnology industries. Our experienced consultants have over two centuries of accumulated experience and are recognized as subject-matter-experts in a variety of fields and are sought after speakers and educators at regulatory and industry conferences. They are active participants in many guideline and standard setting organizations such as AAMI, PDA, ISPE and ISO. Our consultants are, therefore, not only contemporary in our knowledge but are also influential in establishing industry practice and regulatory expectations.

“Our concept of project management involves the integration of individuals with varied skill-sets into multifunctional problem solving teams. This approach allows LexaMed to capitalize on the broad-based industrial experience of our staff and to provide the most appropriate and cost-effective practical solutions to a particular problem.”

- Robert R. Reich, LexaMed President

Our Team of Consultants has expertise in all aspects of biopharmaceutical and medical device operations, including, but not limited to:

- Process and Equipment Validation
- Sterilization – EO, Steam, VHP, Radiation, UV, Ozone, Pulsed-Light, Dry Heat
- Aseptic Processing
- Microbiology
- Chemistry - Method Development / Validation / Verification
- Environmental Monitoring
- Regulatory Compliance
- Auditing
- Quality Systems
- cGMPs – Device, Pharmaceutical, Biologics, Medical Gases
- Operational, Compliance and Post audits
- GAP analysis to regulatory standards Sterilization
- Compressed medical gases
- Aseptic operations
- CAPA and deviations/OOS
- Laboratory operations

Furthermore, LexaMed consultants routinely provide resolution to sterility issues, and have a proven record in this area. Our consultants have served as members of AAMI/ISO Biological Indicator committees for the last 20 years and do so currently. LexaMed consultants have served as co-chairs of the AAMI ISO Industrial EO Sterilization committee and remain members. They also currently serve on the Microbiological Methods, Aseptic Process, Radiation, Industrial Steam and Packaging AAMI committees.

LexaMed Fee Schedule

LexaMed manufactures



Microbial suspensions specially prepared for simplifying the performance of USP Growth Promotion, Monograph <71>, Bacteriostasis/Fungistasis testing, and other Quality Control Measures for Growth Media are available for sale. LexaMed has over 20 years of proven performance history in the manufacturing of these microbial suspensions. They are shipped ready-to-use; they require no additional preparation or dilution prior to use. Each lot is derived from cultures traceable to a recognized culture collection identified in USP, and certified for purity and population (<100 organisms per dose). LexaMed can also produce special, made-to-order microbial suspensions. The organisms listed below can be manufactured in various concentrations.

ORGANISM	SHELF LIFE	100 DOSE VIAL	20 DOSE VIAL
Bacillus subtilis	365 Days	\$114.00/Vial P/N 6633-100	\$42.00/Vial P/N 6633-20
Candida albicans	60 Days	\$145.00/Vial P/N 10231-100	\$50.00/Vial P/N 10231-20
Clostridium sporogenes	365 Days	\$114.00/Vial P/N 11437-100	\$42.00/Vial P/N 11437-20
Aspergillus brasiliensis formerly Aspergillus niger	180 Days	\$200.00/Vial P/N 16404-100	\$57.00/Vial P/N 16404-20
Kocuria rhizophila formerly Micrococcus luteus	60 Days	\$145.00/Vial P/N 9341-100	\$50.00/Vial P/N 9341-20
Escherichia coli	90 Days	\$145.00/Vial P/N 8739-100	\$50.00/Vial P/N 8739-20
Geobacillus stearothermophilus	365 Days	\$145.00/Vial P/N 7953-100	\$54.00/Vial P/N 7953-20
Staphylococcus aureus	90 Days	\$160.00/Vial P/N 6538-100	\$56.00/Vial P/N 6538-20
Pseudomonas aeruginosa	90 Days	\$190.00/Vial P/N 9027-100	\$57.00/Vial P/N 9027-20

100 Dose Vial - 10 mL Volume, < 100 Organisms per 0.1 mL
 20 Dose Vial - 10 mL Volume, < 100 Organisms per 0.5 mL



TO BE USED BY MICROBIOLOGIST TRAINED TO WORK WITH LIVE MICROORGANISMS

All orders incur a \$15.00 handling fee. All rush orders (placed after 12:00 noon EST, requiring same day shipping) will incur an additional \$25.00 handling fee. International orders (including Puerto Rico) will incur a \$25.00 handling fee and must be charged to a credit card.

SAVE TIME & MONEY

- No Culture Preparation
- No Need to Standardize and Dilute Suspensions
- No Extra Media to Prepare
- No Repeat Test Due to Dilution Error

EASY TO USE

- Inoculate Appropriate Test Organism(s) into Medium
- Verify Population by Plate Count
- Incubate Cultures at Appropriate Temperatures
- Read Results

LexaMed produces highly concentrated Bacillus subtilis "5230" suspensions for validation of heat sensitive products.

Organism	Sterilization Validation Use	Cost
Bacillus subtilis "5230"	Validation of heat sensitive materials	\$2000.00/Vial 10 mL @ 10 ⁷ population
Other BEC Growth-Chek™ Organisms in Various Concentrations	INQUIRE	INQUIRE

To place a BEC Growth-Chek™ order, call the office toll-free @ (888) 232-5227



LexaMed, Ltd.
705 Front Street
Toledo, Ohio 43605
Email: info@lexamed.net

Phone: 419-693-5307
Fax: 419-691-0418
Toll Free: 888-232-5227
Website: www.lexamed.net

Sample Submission Form (Use one form per sample-Use latest copy from www.lexamed.net)

Upon completion, attach file to email and send to info@lexamed.net or fax to 419-691-0418.

Client #	Sample Description: (This I.D. will be typed on the final report)		
Company			
Address	Part #	Lot #	
Contact Person (Authorized to receive final report)	Batch#	PO#	
Phone	Date test results are requested		
Fax	Preliminary Results: <input type="checkbox"/> STAT (extra fee) <input type="checkbox"/> Phone		
Email	<input type="checkbox"/> Fax <input type="checkbox"/> Email		
Sample Qty. <input type="checkbox"/> Sterile <input type="checkbox"/> Non-Sterile	Extraction Time	Temp	(if applicable)
Storage Condition: <input type="checkbox"/> Room Temp <input type="checkbox"/> Refrigerated <input type="checkbox"/> Other _____	Product will be destroyed after testing unless otherwise requested.		
Samples Received on: <input type="checkbox"/> Cold Packs <input type="checkbox"/> Ice <input type="checkbox"/> Room Temp			

Please perform the following tests:

General Microbiology

- Validation of Bioburden Method–Exhaustive
- Validation of Bioburden Method–Spore Inoculation
- Environmental Monitoring–Settling Plate/Rodac Plate
- Total Plate Count–Direct Plating
- Total Plate Count–Membrane Filtration
- Organism Identification–Gram Stain/Colony Morphology
- Organism Identification–Genus & Species
- Organism Identification–Genotypic
- Particulate Analysis/Microscopic Count–Solutions
- Particulate Analysis/Microscopic Count–Devices
- Water Testing–Standard Plate Count
- Water Testing–Fecal Coliforms
- Water Testing–Total Coliforms
- Water Testing–Total E. coli
- Antimicrobial Preservative Effectiveness USP
- USP<61>&<62> Aerobic Bacteria & Yeast & Mold Suitability Test
- USP<61>&<62> Aerobic Bacteria & Yeast & Mold Routine Screening

Sterility Testing

- Bacteriostasis/Fungistasis
- Membrane Filtration
- Biological Indicators–Spore Strips–Qty _____
- Product Immersion–Qty _____
- Media Fill Sterility Evaluation
- Aseptic SIP Preparation

Other Tests Requested/Special Instructions:

Authorization Signature _____

For Laboratory Use Only – Sample Acknowledgment

LexaMed Lab # _____

Date Received _____

Logged in by _____

Bioburden Determinations

- Total Aerobic
- Total Aerobic Spore
- Total Anaerobic
- Total Yeast and Mold

Biological Indicator Performance Tests

- BI/CI Resistometer–Saturated Steam
- BI/CI Resistometer–EO
- BI Population Determination
- Performance Verification–Moist Heat
- Performance Verification–EO
- Performance Verification–Sterility Test- Qty _____
- D-value – FN –Steam Stumbo Murphy
- D-value – FN –Steam Spearman Karber
- D-value – FN –EO Stumbo Murphy
- D-value – FN –EO Spearman Karber
- D-value – Survival Curve –Moist Heat
- D-value – Survival Curve –EO
- z-value – Steam Stumbo Murphy
- z-value – Steam Spearman Karber
- z-value – Moist Heat

In Vitro Toxicology

- Cytotoxicity – ISO Method
- Cytotoxicity – USP Method
- Cytotoxicity – ISO Agar Overlay
- Cytotoxicity – USP Agar Overlay

Chemistry

- USP Physiochemical –Plastics
- USP Physiochemical –Elastomeric Closures
- Hydrogen Peroxide Titration
- Hydrogen Peroxide/Peracetic Acid Ti
- tration
- pH Determination
- Conductivity
- LAL – Device
- LAL – Liquid
- LAL – Inhibition/Enhancement Validation

AOAC Testing

- Method 966.23
- Method 966.24
- Use-Dilution Aqueous or Water Soluble Disinfectants-Presumptive
- Use-Dilution Aqueous or Water Soluble Disinfectants-Confirmatory
- Tuberculocidal Activity of Disinfectants-Presumptive
- Tuberculocidal Activity of Disinfectants- Confirmatory

Ethylene Oxide Residuals

- Ethylene Oxide (EO)
- Ethylene Chlorohydrin (EC)
- Ethylene Glycol (EG)

Extraction Method:

- Simulated Use Extraction
- Exhaustive Extraction (24hr intervals)

TCL Required?: Yes No

Surface Area of Device: _____

Date _____