C.G. Laboratories, Inc.

1410 Southtown Drive Granbury, Texas 76048 Phone: 817-279-1945 Fax: 817-573-3304

Laboratory Testing Service Guide

Visit our website at: www.cg-labs.com

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About our Company:

C.G. Laboratories was founded in 1983 by Dr. Glenn Crum, who serves as president of our company. Dr. Crum holds a Bachelors of Science degree from Texas A&M University and a Masters and Doctorate from the University of North Texas. He worked for Johnson and Johnson at Arlington, Texas in the Microbiology Research Department. His work experience with Johnson and Johnson included microbial research on antimicrobial agents and new product development. Dr. Crum has worked with cobalt radiation sterilization, microbiology testing, chemistry testing, and ethylene oxide operations.

Initially, the Laboratory offered medical device testing that included product sterility, pre-sterilized bioburden, environmental monitoring and sterilization validations. In 1987, Dr. Crum added additional services such as on-site audits for good manufacturing practices. In 1996, C.G. Labs was relocated to Granbury, Texas. The company expanded to include packaging medical devices, sterilization and distribution of medical devices for various companies. We currently reside in Granbury, Texas and have 2 locations to better serve all of our Customer's needs.

Standards:

C.G. Laboratories, Inc. uses the following standards: AAMI, AOAC, ASTM, USI, USP, and ICH.

Company Policy:

C.G. Laboratories, Inc. accepts responsibility for the complete satisfaction of our customers. We exercise this responsibility through adequate training of our employees, adherence to proven procedures, total commitment to meeting and exceeding customer requirements, and maintaining a company culture that fosters continuous improvement. Our objective is to deliver defect free products/services on time, every time.

Registration and Certification:

C.G. Laboratories, Inc. is an FDA registered company and is ISO 13485 certified to ensure that all of our services are regulated, current and quality driven.

Additional Services:

C.G. Laboratories offers contract packaging and various decontamination services. Should you have a need for packaging or decontamination services, please contact Sherry Jacks for additional information: Sherry Jacks

Email: sjacks@cg-labs.com. Phone: 817-279-1945, ext. 2.

Laboratory Contact Information:

C.G. Laboratories personnel are available for projects of all sizes. If you would like to discuss your specific testing needs, please review the list of Contact Information listed below:

Laboratory: Quotes / Billing / TAT

Kayce Starnes, Contract Review Phone: 817-279-1945, ext. 5 Email: <u>kstarnes@cg-labs.com</u>

Billing / Mailing Address:

C.G. Laboratories, Inc. 1410 Southtown Drive Granbury, Texas 76048

Laboratory: Technical Questions

Paula Krueger, Lab Supervisor Phone: 817-279-1945, ext. 4 Email: <u>pkrueger@cg-labs.com</u>

Shipping Address:

C.G. Laboratories, Inc. Attn: Laboratory 1410 Southtown Drive Granbury, Texas 76048

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<u>Pricing Disclaimer:</u> Some prices listed below will vary from the prices that have been issued on each yearly Quote. This price variation is due to the type of product, the size of the product, and the manipulation that may occur during testing. The price given on each quote is based on these specifications.

Section 1: AGING STUDY / STABILITY STUDY SERVICES

Test Code	Test Requested
AGS-001	25°C <u>+</u> 2°C, price is per cubic foot, per month, one month intervals
AGS-002	40°C <u>+</u> 2°C, price is per cubic foot, per month, one month intervals
AGS-003	55°C <u>+</u> 2°C, price is per cubic foot, per month, one month intervals
AGS-004	55°C <u>+</u> 2°C, price is per cubic foot, per month, one month intervals
AGS-005	Special Parameters (42°C min, 68°C max, 4 cu. ft max) price is per cubic foot, per month, one month intervals
AMC-001	Minimum charge for complete Aging Study; Includes Aging Study Fees and Pull Point / Handling Fees, other testing not included
PPH-001	Pull Point / Handling Fee Instructions when shipping product to C.G. Laboratories: 1. Product should be shipped to the address listed on page 2. 2. Product should be packaged so that the shipment is ready to be placed in the incubator upon arrival. 3. If product has to be re-packaged before being placed in the incubator for testing, a pull point / handling fee will be applied. 4. When product is pulled from the chamber, a pull point / handling fee will be applied.
SHP-001	Shipping / Freight Fee (will be applied to invoice, unless Freight Account# is provided on TRF)

Section 2: AQUEOUS BIOCIDE (GB50)	
Test Code	Test Requested
GB50-001	Aqueous Biocide (GB50) Solution, shipping not included, price is per 40 mL bottle
GB50-002	Aqueous Biocide (GB50) Solution, Customer specified volume, shipping not included, price is per bottle

Section 3: BIOBURDEN SERVICES

Test Code	Test Requested
BB-100	Bioburden, aerobic bacteria only, price is per sample
BB-101	Bioburden, anaerobic bacteria only, price is per sample
BB-102	Bioburden, fungi (yeast and mold) only, price is per sample
BB-103	Bioburden, spores only, price is per sample
BB-200	Bioburden, aerobic bacteria and anaerobic bacteria only, price is per sample
BB-201	Bioburden, aerobic bacteria and fungi (yeast and mold) only, price is per sample
BB-202	Bioburden, aerobic bacteria and spores only, price is per sample
BB-203	Bioburden, anaerobic bacteria and fungi (yeast and mold) only, price is per sample
BB-204	Bioburden, anaerobic bacteria and spores only, price is per sample
BB-300	Bioburden, aerobic bacteria, anaerobic bacteria and fungi (yeast and mold) only, price is per sample
BB-301	Bioburden, aerobic bacteria, anaerobic bacteria and spores only, price is per sample
BB-302	Bioburden, aerobic bacteria, fungi (yeast and mold) and spores only, price is per sample
BB-303	Bioburden, anaerobic bacteria, fungi (yeast and mold) and spores only, price is per sample
BB-400	Bioburden, aerobic bacteria, anaerobic bacteria, fungi (yeast and mold) and spores, price is per sample
BBR-001	Bioburden Recovery (Inoculation Method), minimum of 3 samples, price is per sample
BBR-002	Bioburden Recovery (Extraction Method), minimum of 3 samples, price is per sample
BBR-003	Bioburden Recovery (Inoculation Method), each additional piece, price is per sample
BBR-004	Bioburden Recovery (Extraction Method), each additional piece, price is per sample

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Section 4: BIOLOGICAL INDICATOR SERVICES

Test Code	Test Requested
BI-001	Biological Indicator Sterility, testing only, price is per indicator
BI-002	Biological Indicator Population (Assay), price is per indicator
BI-003	Spore Suspension Preparation, includes dilution and plate counts, price is per indicator
BI-004	Biological Indicator, Purchase Only, shipping not included, price is per indicator
BI-005	Biological Indicator, Purchase and Testing, price is per indicator

Test Code	Test Requested
CYT-001	Cytotoxicity Testing (Contract), shipping not included, price is per sample
PH-001	pH Testing, price is per sample
THPC-003	Product Total Heterotrophic Plate Count (THPC), Customer specific requirements, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-300	Product Total Heterotrophic Plate Count (THPC), aerobic only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-301	Product Total Heterotrophic Plate Count (THPC), anaerobic only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-302	Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-303	Product Total Heterotrophic Plate Count (THPC), spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-304	Product Total Heterotrophic Plate Count (THPC), aerobic and anaerobic only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-305	Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-306	Product Total Heterotrophic Plate Count (THPC), aerobic and spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-307	Product Total Heterotrophic Plate Count (THPC), anaerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-308	Product Total Heterotrophic Plate Count (THPC), anaerobic and spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-309	Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) and spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-310	Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-311	Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
THPC-312	Product Total Heterotrophic Plate Count (THPC), anaerobic, fungi (yeast & mold) and spores only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
USP-002	USP 51: Antimicrobial Effectiveness Testing, price is per sample Includes: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger)
USP-003	USP 51: European Method: Antimicrobial Effectiveness Testing, price is per sample Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger)
USP-004	USP 61: Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type
USP-005	USP 61: Suitability Testing for Product THPC (aerobic), 1 organism, max. 4 dilutions Choices: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Salmonella species
USP-006	USP 61: Suitability Testing for Product THPC fungi (yeast and mold), 1 organism, max. 4 dilutions Choices: Candida Albicans, Aspergillus braziliensis (niger)
USP-008	USP 62: Absence of Objectionable Organisms, 6 organisms, price is per sample Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Clostridium Species, Candida Albicans, Salmonella Species NOTE: Suitability Testing REQUIRED for each product type
USP-009	USP 62: Absence of Objectionable Organisms, Organism Specific, Customer Requested, price is per sample, per organism organism NOTE: Suitability Testing REQUIRED for each product type
USP-010	USP 62: Method Suitability Validation, price is per product, per organism, per dilution (performed only ONCE per product type)
USP-011	USP 71: Product Sterility Testing, TSB/FTM, includes daily checks, price is per sample, 10 samples per media required for Lot Release NOTE: Suitability Testing REQUIRED for each product type
BF-001	Bacteriostasis / Fungistasis Testing, price is per 5 samples (3 organisms)
BF-002	Bacteriostasis / Fungistasis Testing, each additional sample, price is per sample (3 organisms)
BF-003	Bacteriostasis / Fungistasis Suitability Testing, price is per sample, per product type, 3 organisms, (performed only ONCE per product type)

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Section 6: NUTRITIONAL / DIETARY SUPPLEMENT TESTING SERVICES Test Code **Test Requested** PH-001 pH Testing, price is per sample Product Total Heterotrophic Plate Count (THPC), Customer specific requirements, price is per sample THPC-003 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic only, price is per sample THPC-300 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic only, price is per sample THPC-301 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) only, price is per sample THPC-302 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), spores only, price is per sample THPC-303 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and anaerobic only, price is per sample THPC-304 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample THPC-305 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and spores only, price is per sample THPC-306 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic and fungi (yeast & mold) only, price is per sample THPC-307 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic and spores only, price is per sample **THPC-308** NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) and spores only, price is per sample **THPC-309** NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type THPC-310 Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and spores only, price is per sample THPC-311 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic, fungi (yeast & mold) and spores only, price is per sample THPC-312 NOTE: Suitability Testing REQUIRED for each product type USP 51: Antimicrobial Effectiveness Testing, price is per sample **USP-002** Includes: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger) USP 51: European Method: Antimicrobial Effectiveness Testing, price is per sample **USP-003** Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger) USP 61: Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample **USP-004** NOTE: Suitability Testing REQUIRED for each product type USP 61: Suitability Testing for Product THPC (aerobic), 1 organism, max. 4 dilutions **USP-005** Choices: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli USP 61: Suitability Testing for Product THPC fungi (yeast and mold), 1 organism, max. 4 dilutions **USP-006** Choices: Candida Albicans, Aspergillus braziliensis (niger) USP 62: Absence of Objectionable Organisms, 6 organisms, price is per sample Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Clostridium Species, Candida Albicans, Salmonella Species NOTE: Suitability Testing REQUIRED for each product type **USP-008** USP 62: Absence of Objectionable Organisms, Organism Specific, Customer Requested, price is per sample, per **USP-009** organism NOTE: Suitability Testing REQUIRED for each product type USP-010 USP 62: Method Suitability Validation, price is per product, per dilution, per organism (performed only ONCE per product type) USP 71: Product Sterility Testing, TSB/FTM, includes daily checks, price is per sample USP-011 10 samples per media required for Lot Release NOTE: Suitability Testing REQUIRED for each product type USP 2021/2022: Method Validation, price is per product type, 7 organisms (performed only ONCE per product type) USP-012 Includes: Staphylococcus aureus, Escherichia coli, Bacillus subtilis, Aspergillus braziliensis, Candida albicans, Salmonella typhimurium, Clostridium species USP 2021: Nutritional / Dietary Supplements, THPC Testing, Aerobic and Fungi (Y&M), includes 3 dilutions, price is per USP-014 sample NOTE: Suitability Testing REQUIRED for each product type USP 2022: Nutritional / Dietary Supplements, Absence of Objectionable Organisms, 4 organisms, 1 validated dilution, price is per sample **USP-013** Includes: Staphylococcus aureus, Salmonella typhimurium, Escherichia coli, Clostridium species NOTE: Suitability Testing REQUIRED for each product type WL-001 Weight Loss Testing: price is per sample WR-001 Water Residual Testing, Gravimetric Analysis, price is per sample SHP-001 Shipping / Freight Fee (will be applied to invoice, unless Freight Account# is provided on TRF)

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Section 7: ENVIRONMENTAL SERVICES

Test Code	Test Requested
ENV-001	Mileage, price is per mile, based on the current rate for the state of Texas
ENV-002	Drive Time, price is per hour
ENV-003	Sampling Time, per technician, minimum one hour, one hour interval, price is per hour
PRT-001	Preparation Time, per technician, minimum one hour, one hour interval, price is per hour
AIR-001	Air Strips - TSA, purchase/incubation/enumeration/reporting, shipping not included, price is per strip
AIR-002	Air Strips - TSA, incubation/enumeration/reporting, shipping not included, price is per strip
AIR-003	Air Strips - TSA, purchase ONLY, shipping not included, price is per strip
CTS-001	Contact Slides / Touch Plate - TSA , purchase/incubation/enumeration/reporting, shipping not included, price is per slide
CTS-002	Contact Slides / Touch Plate - TSA, incubation/enumeration/reporting, shipping not included, price is per slide
CTS-003	Contact Slides / Touch Plate - TSA, purchase ONLY, shipping not included, price is per slide
RDP-001	RODAC Plates - TSA, purchase/incubation/enumeration/reporting, shipping not included, price is per plate
RDP-002	RODAC Plates - TSA, incubation/enumeration/reporting, shipping not included, price is per plate
RDP-003	RODAC Plates - TSA, purchase ONLY, shipping not included, price is per plate
STP-001	Settling Plates - TSA, purchase/incubation/enumeration/reporting, shipping not included, price is per plate
STP-002	Settling Plates - TSA, incubation/enumeration/reporting, shipping not included, price is per plate
STP-003	Settling Plates - TSA, purchase ONLY, shipping not included, price is per plate
HF-001	Plate / RODAC / Slide Handling Fee, price is per sample (applied to invoice if sample has to be opened and removed from packaging to read results, due to excessive packaging issues)
GMS-001	Gram Stain / Morphology (includes Characterization), price is per gram stain
CHR-001	Characterization, price is per colony type
SHP-001	Shipping / Freight Fee (applied to invoice, unless Freight Account# is provided on TRF)
STR-001	Organism Re-streak Fee, price is per colony
TAB-001	Tabulation of Specific Bacteria, Mold, Spores, price is per slide/plate/RODAC
TNF-001	Transfer Fee (applied to invoice if Customer requests a transfer on weekend or holiday)
Rentals	
RNT-001	Rental of the Biotest RCS Unit, shipping not included, price is per day
RNT-002	Rental of the Biotest RCS Unit, shipping not included, price is per week
RNT-003	Rental of the Met-One Particle Counter, shipping not included, price is per day
RNT-004	Rental of the Met-One Particle Counter, shipping not included, price is per week
SHP-001	Shipping / Freight Fee (applied to invoice, unless Freight Account# is provided on TRF)
Disposal	
MD-001	Media Disposal, expired Plate / Slide / Strip, price is per sample

Section 8: IDENTIFICATION SERVICESTest CodeTest RequestedID-001Microbial Identification, price is per identificationID-002Mold Identification, price is per identificationID-003Yeast Identification, price is per identificationID-004Identification, shipped to Vendor for testing, price is per identification

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Section 9: PACKAGING INTEGRITY SERVICES

Test Code	Test Requested
BBE-001	Bubble Emission Testing, price is per seal NOTE: 1-Setup sample is required before testing begins
BBE-002	Bubble Emission Testing, testing all 4 seals, price is per pouch NOTE: 1-Setup sample is required before testing begins
BST-001	Burst Testing, price is per sample
DYE-001	Dye Penetration Testing, price is per sample
PEEL-001	Peel Strength Testing, price is per peel NOTE: PEEL-002 applies for totals less than \$100.00
PEEL-002	Peel Strength Testing, Minimum Charge
PEEL-003	Peel Strength Testing, price is per pouch (1-location on each side of pouch is tested, Customer indicates locations to be tested, if not indicated CGL will test according to Peel Strength Testing procedure)
	Each additional Peel location added to PEEL-003
SCT-001	Shipping Challenge Testing (Contract), ASTM D4169, shipping not included , price is per sample Includes: Vibration Test, Drop Impact Test, Compression Test and Concentrated Impact Test

Section 10: PRODUCT STERILITY TESTING SERVICES Test Code Test Requested

BF-001	Bacteriostasis / Fungistasis Testing, price is per max. 5 samples (3 organisms)
BF-002	Bacteriostasis / Fungistasis Testing, each additional sample, price is per sample (3 organisms)
BF-003	Bacteriostasis / Fungistasis Suitability Testing, price is per sample, per product type, 3 organisms, (performed only ONCE per product type)
PST-001	Product Sterility Testing, price is per sample

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Section 11: PRODUCT TESTING SERVICES **Test Code Test Requested** LAL-001 Endotoxin (LAL) Testing, Gel Clot Method, price is per sample LAL-002 Endotoxin (LAL) Composite Testing, Gel Clot Method, 10 samples max, price is per composite LAL-003 Chromogenic LAL Testing (Contract), shipping NOT included, price is per sample LAL-004 Endotoxin (LAL) Composite Testing, Gel Clot Method, each additional device added to composite, price is per sample LAL-005 Endotoxin (LAL) Verification Testing, Gel Clot Method, price is per positive PH-001 pH Testing, price is per sample Product Total Heterotrophic Plate Count (THPC), Customer specific requirements, price is per sample THPC-003 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic only, price is per sample THPC-300 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic only, price is per sample THPC-301 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) only, price is per sample THPC-302 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), spores only, price is per sample THPC-303 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and anaerobic only, price is per sample THPC-304 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample THPC-305 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic and spores only, price is per sample THPC-306 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic and fungi (yeast & mold) only, price is per sample **THPC-307** NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic and spores only, price is per sample **THPC-308** NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), fungi (yeast & mold) and spores only, price is per sample THPC-309 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and fungi (yeast & mold) only, price is per sample NOTE: Suitability Testing REQUIRED for each product type **THPC-310** Product Total Heterotrophic Plate Count (THPC), aerobic, anaerobic and spores only, price is per sample THPC-311 NOTE: Suitability Testing REQUIRED for each product type Product Total Heterotrophic Plate Count (THPC), anaerobic, fungi (yeast & mold) and spores only, price is per sample THPC-312 NOTE: Suitability Testing REQUIRED for each product type **USP 51:** Antimicrobial Effectiveness Testing, price is per sample USP-002 Includes: Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger) USP 51: European Method: Antimicrobial Effectiveness Testing, price is per sample **USP-003** Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans, Aspergillus braziliensis (niger) USP 61: Product Total Heterotrophic Plate Count (THPC), aerobic and fungi (yeast & mold) only, price is per sample USP-004 NOTE: Suitability Testing REQUIRED for each product type USP 61: Suitability Testing for Product THPC (aerobic), 1 organism, max. 4 dilutions **USP-005** Choices: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli USP 61: Suitability Testing for Product THPC fungi (yeast and mold), 1 organism, max. 4 dilutions **USP-006** Choices: Candida Albicans, Aspergillus braziliensis (niger) **USP-007** Suitability Testing for Product THPC, 1 organism per method, Customer specific organism, max. 4 dilutions USP 62: Absence of Objectionable Organisms, 6 organisms, price is per sample USP-008 Includes: Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Clostridium Species, Candida Albicans, Salmonella Species NOTE: Suitability Testing REQUIRED for each product type USP 62: Absence of Objectionable Organisms, Organism Specific, Customer Requested, price is per sample, per **USP-009** organism NOTE: Suitability Testing REQUIRED for each product type USP 62: Method Suitability Validation, price is per product, per dilution, per organism (performed only ONCE per product USP-010 type) USP 71: Product Sterility Testing, TSB/FTM, includes daily checks, price is per sample USP-011 10 samples per media required for Lot Release NOTE: Suitability Testing REQUIRED for each product type **USP-015** USP Monograph Testing, Customer specific Product, price is per sample type TS-001 Tensile Strength Testing, price is per sample WL-001 Weight Loss Testing: price is per sample WR-001 Water Residual Testing, Gravimetric Analysis, price is per sample Shipping / Freight Fee (will be applied to invoice, unless Freight Account# is provided on TRF) SHP-001

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Section 12: VALIDATION SERVICES

Test Oads	Tech Democrad
Test Code	Test Requested
VAL-001	VDMax Dose Determination Validation Includes: 30-Bioburden, 5-Bioburden Recovery, 10-Sterility, 9-Bacteriostasis/Fungistasis (3-samples, 3-organisms each), Sterilization Fee,
	shipping not included
VAL-002	VDMax Dose Audit, ANSI/AAMI/ISO 11137-2:2006, single lot Includes: 10-Bioburden, 10-Sterility, Sterilization Fee, shipping not included
	Method 1 Validation
VAL-003	Includes: 30-Bioburden, 5-Bioburden Recovery, 100-Sterility, 9-Bacteriostasis/Fungistasis (3-samples, 3-organisms each), Sterilization
	Fee, shipping not included
	Method 1 Dose Audit, single Lot
VAL-004	Price includes: 10-Bioburden, 100-Sterility, Sterilization Fee, shipping not included
	ANSI/AAMI/ISO 11137-2:2006
VAL-005	ETO Decontamination Validation, price is per product type
VAL-006	Validation, Customer specified, price is per product type
VAL-007	EBeam Dose Determination Validation
VAL-008	EBeam Dose Audit
VAL-009	Endotoxin (LAL) Validation
VAL-010	Steam Decontamination Validation
VAL-011	Autoclave Qualification
PRG-001	Validation Protocol and Report Generation, price is per protocol
PRG-002	Validation Protocol Generation ONLY, price is per protocol
PRG-003	Validation Report Generation ONLY, price is per report
EXP-001	Expedite Fee

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Section 1	Section 13: WATER TESTING SERVICES	
Test Code	Test Requested	
ALG-001	Algae Count Testing, Count ONLY, price is per sample	
ALG-002	Algae Speciation Testing, Algae count included, price is per sample	
CHL-001	Chlorine Testing, price is per sample	
COL-001	Coliform Testing, price is per sample	
COND-001	Conductivity Testing, price is per sample	
PH-001	pH Testing, price is per sample	
SRB-001	Sulfate Reducing Bacteria Testing, price is per sample	
THPC-001	Water Total Heterotrophic Plate Count (THPC), Customer specific requirements, price is per sample	
THPC-002	Water Total Heterotrophic Plate Count (THPC), Duplicate sample sent to Vendor, price is per sample	
THPC-100	USP Total Heterotrophic Plate Count (THPC), aerobic only, price is per sample	
THPC-101	USP Total Heterotrophic Plate Count (THPC), anaerobic only, price is per sample	
THPC-102	USP Total Heterotrophic Plate Count (THPC), aerobic and anaerobic only, price is per sample	
THPC-200	Well Water Total Heterotrophic Plate Count (THPC), aerobic only, price is per sample	
THPC-201	Well Water Total Heterotrophic Plate Count (THPC), anaerobic only, price is per sample	
THPC-202	Well Water Total Heterotrophic Plate Count (THPC), aerobic and anaerobic only, price is per sample	
TOC-001	Total Organic Carbon (Contract-Lan), shipping not included, price is per sample	
TOC-002	Total Organic Carbon (Contract-CTL), shipping not included, price is per sample	
TOC-003	Total Organic Carbon (Contract-CTL), screening included, shipping not included, price is per sample	
USP-001	USP Monograph Testing, price is per sample site, shipping not included , price is per sample set Includes: 1-Total Organic Carbon (Contract-Lan), 1-Conductivity, 1-LAL, 1-THPC (aerobic)	
WWS-001	Well Water Suitability Testing (Contract), shipping included, price is per sample	
SHP-001	Shipping / Freight Fee (will be applied to invoice, unless Freight Account# is provided on TRF)	

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Section 14: MISCELLANEOUS TESTING

Test Code	Test Requested
CON-001	Consultation by Russell Crum, price is per hour
CTG-001	Culture Growth
CYC-001	Autoclave Cycle, Customer specified parameters, price is per cycle
CYC-002	ETO Bier Vessel Cycle, Customer specified parameters, price is per cycle
CYT-001	Cytotoxicity Testing (Contract), shipping not included, price is per sample
DE-001	D/E Broth Purchase, includes D/E Broth containers and swabs, shipping not included , price is per D/E Broth container
EO-001	Ethylene Oxide and Ethylene Chlorohydrin Residual Testing (Contract), shipping not included, price is per sample
GP-001	Growth Promotion Testing, price is per lot, price is per 6 organisms Includes: pH, Sterility, Volume Check (liquid only), Indicator Organisms (inoculation, incubation, enumeration, in duplicate) Organisms: Pseudomonas aeruginosa (ATCC 9027), Staphylococcus aureus (ATCC 6538), Escherichia coli (ATCC 8739), Aspergillus brasiliensis (ATCC 16404), Candida Albicans (ATCC 10237), Bacillus subtilis (ATCC 6633)
GP-002	Growth Promotion Testing, Customer specific organism, price is per lot, price is per organism Includes: pH, Sterility, Volume Check (liquid only), Indicator Organisms (inoculation, incubation, enumeration, in duplicate)
ISF-001	Isolation Fee, price is per isolation
MIC-001	Minimal Inhibitory Concentration (MIC) Testing, price is per sample
ORG-001	Ordering Organisms, Customer specified organism, shipping not included, price is per organism
PA-001	Particulate Analysis, Gravimetric Method, Vendor: AFL, price is per sample Includes: PNOR, Total – Tared, PVC Filter (Tared) +/- 10u (PVC, Tare)
RPT-001	Vendor Reporting Fee
SPL-001	Supplies for Testing, Customer specific, shipping included
SPR-001	Spray Testing, price is per sample
TKT-001	Time Kill Testing, Max 3 time pulls, 1 organism, 1 Concentration/Formulation, price is per sample
TRV-001	Travel Expenses, Includes overnight stay and all travel expenses
VT-001	Visual / Color / Odor / Thickness Testing, price is per sample
VT-002	Visual / Form / Color / Odor / Clarity Testing, price is per sample
VT-003	Visual / Functionality Testing, price is per sample
VOC-001	Volatile Compound Testing, EPA TO-15, GC/MS, price includes 6L Summa Can Rental for 3 days, price is per sample (Armstrong)
ZOI-001	Zone of Inhibition Testing, price is per sample