

LABORATORY TEST CODES

STERILITY TEST (IMMERSION)

TEST # DESCRIPTION

M100	Biological Indicator (BI) Sterility
M110	USP Sterility - Immersion
M120	USP Sterility - Membrane Filtration
M150	ISO/AAMI Product Sterility (Dose Verification)

BIOBURDEN TESTING

TEST # DESCRIPTION

M200	Aerobic Bioburden
M202	Aerobic & Fungal Bioburden
M204	Anaerobic Bioburden
M206	Yeast and Molds (Fungal Bioburden)
M208	Total Bioburden (Aerobic, Anaerobic & Fungal)
M210	Bioburden Recovery/Inoculated)
M211	Bioburden Recovery/Exhaustive

MICROORGANISM IDENTIFICATION

TEST # DESCRIPTION

M250	Microbial ID-Bacteria & Fungi 1 Isolate
M251	2-5 Isolates
M252	Each additional Isolate
M254	Organism Characterization
M255	Gram Stain

ENVIRONMENTAL SAMPLING

TEST # DESCRIPTION

M300	Customized Environmental Control
M305	Air Samples-Aerobic Count
M310	Air Samples-Anaerobic Count
M315	Air Samples-Yeast & Mold Count
M316	Air Samples-Thermophilic Count
M320	Surface Samples-Aerobic Count
M325	Surface Samples-Anaerobic Count
M330	Surface Samples-Yeast & Mold Count
M331	Surface Samples-Thermophilic Count
M335	Water Analysis-Standard Plate Count
M340	Water Analysis-Coliform Count
M345	Air Samples - Particulate
M350	Settling Plates – TSA and SDA

USP & GENERAL MICROBIOLOGY

TEST # DESCRIPTION

M400	Bacteriostasis-Fungistasis Immersion (USP)
M401	B/F Test-Membrane Filtration (USP)
M402	Growth Promotion (USP)
M403A	Microbial Limits w/Prep (USP)
M403B	Microbial Limits w/Out Prep (USP)
M404	Antimicrobial Preservative Effectiveness
M405	W/14 Day Re-Challenge (USP)
M406	BP Preservative Effectiveness
M407	Bacterial Endotoxin Test (FDA LAL Method)
M408	Bacterial Endotoxin Test (USP Method)
M409	Inhibition-Enhancement FDA
M410	Antibiotic Testing (USP)
M411	Disinfectant Test- Sporocidal
M412	Disinfectant Test- Sanitizer Test
M413	Disinfectant Hard Surface Carrier Method
M414	Re-Use Device Disinfection Val.
M415	Re-Use Device Sterilization Val.
M416	Re-Use Device-Cleaning Val.
M417	AOAC Sanitizer Test
M418	Re-Use Device-Dry Time Val.
M420	D-Value, FN Method (Steam, ETO, Chemical)
M421	D-Value Evaluation (Pour Plate)
M425	USP Particulate Analysis (LVP's)
M426	Part. Analysis/Medical Devices
M430	Fungal Resistance-ASTM, TAPPI, MIL STD's
M435	Bacterial Resistance-ASTM
M440	Contact Lens Guidelines (FDA)

PRODUCT INOCULATIONS

TEST # DESCRIPTION

M500	10 ⁶ Spores/Inoculum (for ETO, Steam, Gamma) (<i>B. subtilis</i> , <i>B. stearothermophilus</i> , <i>B. pumilus</i>)
M550	BI Enumeration
M575	Biological Indicators Incubation Study (FDA Method)

PACKAGE INTEGRITY

TEST # DESCRIPTION

	Microbial Test
M600	Contact Plate Method (FDA)
M605	Microbial Aerosol Challenge
M610	Microbial Talc Challenge
M615	Vial Closure Integrity (Immersion)

Physical Tests

M625	Accelerated Aging Test
M630	ISTA Shipping Test (Vibratory & Drop Test)
M635	Drop Test (ASTM)
M640	Burst Test (ASTM)
M642	Bubble Leak Test
M645	Peel Strength (ASTM)
M650	Dye Penetration Test

TOXICOLOGY

TEST # DESCRIPTION

T100	ETO Residues (ETO, ETCH, EGLY)
T150	USP Cytotoxicity L929 MEM Elution
T151	L929 Agar Overlay
T152	ISO Cytotoxicity (Direct Contact)
T153	Hemolysis (Direct contact)
T154	(Extract)

CONSULTING SERVICES

TEST # DESCRIPTION

RC-01	FDA/ISO Regulatory Consulting
RC-02	GMP Audits
RC-03	GMP Training
RC-04	Sterilization & Environmental Control
RC-05	Laboratory Consulting
RC-10	FDA Submissions (510K, IDE, PMA)