

# MYCOSCIENCE INC.

*Specialists in Microbiology & Regulatory Affairs*

## LABORATORY TEST CODES

### USP STERILITY (IMMERSION)

<u>TEST #</u>	<u>DESCRIPTION</u>
M100	BI Sterility Spore Strips (10 BI's)
M101	Sterility 10 Product up to 250mL
M102	Sterility 10 Product 250-600mL
M103	Sterility 10 Product 600-1000mL
M104	Sterility 20 Product up to 250mL
M105	Sterility 20 Product 250-600mL
M106	Sterility 20 Product 600-1000mL
M107	Sterility 20 Product w/10 BI's up to 250mL
M108	Sterility 20 Product w/10 BI's 250-600mL
M109	Sterility 20 Product w/10 BI's 600-1000mL
M110	Sterility 40 Product up to 250mL
M111	Sterility 40 Product 250-600mL
M112	Sterility 40 Product 600-1000mL
M113	Sterility 40 Product w/10 BI's up to 250mL
M114	Sterility 40 Product w/10 BI's 250-600mL
M115	Sterility 40 Product w/10 BI's 600-1000mL
M116	Inoculated Products

### USP STERILITY (MEMBRANE FILTRATION)

<u>TEST #</u>	<u>DESCRIPTION</u>
M120	20 Products w/10 BI's
M121	Sterility 20 Product
M122	Sterility 40 Products w/10 BI's
M123	Sterility 40 Product

### 100 PRODUCT DOSE VERIFICATION

<u>TEST #</u>	<u>DESCRIPTION</u>
M150	100 Product Dose Verification up to 250mL
M151	100 Product Dose Verification 250-600mL
M152	100 Product Dose Verification 600-1000mL
M153	10 Product Dose VDmax Audit up to 250mL
M154	10 Product Dose VDmax Audit 250-600mL
M155	10 Product Dose VDmax Audit 600-1000mL

### BIOBURDEN TESTING (Pour Plate)

<u>TEST #</u>	<u>DESCRIPTION</u>
M200	Aerobic Bioburden 1-9 Samples
M201	10 or more Samples
M202	Aerobic & Fungal 1-9 Samples
M203	10 or more Samples
M204	Anaerobic 1-9 Samples
M205	10 or more Samples
M206	Yeast and Molds 1-9 Samples
M207	10 or more Samples
M208	Total Bioburden 1-9 Samples
M209	10 or more Samples
M210	Bioburden Recovery/Inoculated (5 samples)
M211	Bioburden Recovery/Exhaustive (5 samples)

### MICROORGANISM IDENTIFICATION

<u>TEST #</u>	<u>DESCRIPTION</u>
M250	Microbial ID-Bacteria & Fungi 1 Isolate
M251	2-5 Isolates
M252	Each additional Isolate
M254	Organism Characterization
M255	Gram Stain

### ENVIRONMENTAL SAMPLING

<u>TEST #</u>	<u>DESCRIPTION</u>
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

<u>TEST #</u>	<u>DESCRIPTION</u>
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-Phenol Coefficient
M412	Disinfectant Test-Sporocidal
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
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

<u>TEST #</u>	<u>DESCRIPTION</u>
M500	10 <sup>6</sup> 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

<u>TEST #</u>	<u>DESCRIPTION</u>
<b>Microbial Test</b>	
M600	Contact Plate Method (FDA)
M605	Microbial Aerosol Challenge
M610	Microbial Talc Challenge
M615	Vial Closure Integrity (Immersion)
<b>Physical Tests</b>	
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

<u>TEST #</u>	<u>DESCRIPTION</u>
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

<u>TEST #</u>	<u>DESCRIPTION</u>
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)