



U.S. Micro-Solutions, Inc. * 475-C Willow Crossing Road * Greensburg, PA 15601
 Phone: (724) 853-4047 Fax: (724) 853-4049 AIHA EMLAP # 103009
 www.usmicro-solutions.com



Customer Name: Sample Cleanroom Report Sample Date: July 18, 2011
 Customer Address: Date Received: July 20, 2011
 Date of Report: July 25, 2011
 Customer Phone: Fax:
 PO Number: Attention:
 Project Name/Number:

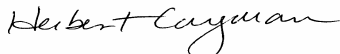
Customer sample numbers below are uniquely identified by prefixing Laboratory #

SAS Air Plate Sample(s) (Bacteria) - Analytical Method USMS-B002

Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 5 Viable Surface Level: Count Below Action Level					
B-1	TSA	Center of Chemo Hood	Total Bacterial Count < 1	CFU/m ³ of air	
No growth					
Total Raw Count: <1					
Total Volume: 1000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 8 Viable Surface Level: Count Below Action Level					
B-2	TSA	Anteroom Entrance Side	Total Bacterial Count 1	CFU/m ³ of air	
Coagulase-negative Staphylococcus spp. 100% 1					
Total Raw Count: 1					
Total Volume: 1000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 7 Viable Surface Level: Count Below Action Level					
B-3	TSA	Center of Chemo Room	Total Bacterial Count 2	CFU/m ³ of air	
Micrococcus luteus 50% 1					
Coagulase-negative Staphylococcus spp. 50% 1					
Total Raw Count: 2					
Total Volume: 1000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					

Note: Results are reported as calculated. For interpreted purposes of biological data, the first and/or second digit generally should be considered significant. Note: Total percentages may not equal 100% due to rounding. Results relate only to the items tested.

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Technical Manager: 

Herbert Layman, BS, SM, CIEC



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Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 8 Viable Surface Level: Count Below Action Level					
B-4	TSA	Anteroom Gown Side	Total Bacterial Count	1	CFU/m ³ of air
				<i>Micrococcus luteus</i>	100% 1
Total Raw Count: 1 Total Volume: 1000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 7 Viable Surface Level: Count Below Action Level					
B-5	TSA	Center of Compound Room	Total Bacterial Count	< 1	CFU/m ³ of air
				<i>No growth</i>	
Total Raw Count: <1 Total Volume: 1000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 5 Viable Surface Level: Count Below Action Level					
B-6	TSA	Center of Compounding BSC	Total Bacterial Count	< 1	CFU/m ³ of air
				<i>No growth</i>	
Total Raw Count: <1 Total Volume: 1000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					

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SAS Air Plate Sample(s) (Fungi) - Analytical Method USMS-M002

Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 5 Viable Surface Level: Count Below Action Level					
F-7	IMA	Center of Chemo Hood	Total Fungal Count < 1	CFU/m ³ of air	
<i>No growth</i>					
Total Raw Count: <1					
Total Volume: 1,000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 7 Viable Surface Level: Count Below Action Level					
F-8	IMA	Center of Chemo Room	Total Fungal Count 2	CFU/m ³ of air	
<i>Cladosporium spp.</i> 100% 2					
Total Raw Count: 2					
Total Volume: 1,000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 8 Viable Surface Level: Count Below Action Level					
F-9	IMA	Anteroom Entrance Side	Total Fungal Count 2	CFU/m ³ of air	
<i>Pithomyces spp.</i> 100% 2					
Total Raw Count: 2					
Total Volume: 1,000.00 liters of air					
Analytical Sensitivity: 1 CFU/m ³ of air					

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SAS Air Plate Sample(s) (Fungi) - Analytical Method USMS-M002

Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 8 Viable Surface Level: Count Below Action Level					
F-10	IMA	Anteroom Gown Side	Total Fungal Count 2	CFU/m ³ of air	
			<i>Pithomyces spp.</i>	100%	2
Total Raw Count: 2 Total Volume: 1,000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 7 Viable Surface Level: Count Below Action Level					
F-11	IMA	Center of Compound Room	Total Fungal Count < 1	CFU/m ³ of air	
No growth					
Total Raw Count: <1 Total Volume: 1,000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					
ISO Class 5 Viable Surface Level: Count Below Action Level					
F-12	IMA	Center of Compounding BSC	Total Fungal Count < 1	CFU/m ³ of air	
No growth					
Total Raw Count: <1 Total Volume: 1,000.00 liters of air Analytical Sensitivity: 1 CFU/m ³ of air					

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Culturable Contact Agar Plate(s) (Bacteria) - Analytical Method USMS-B002

Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 5 Viable Surface Level: Count Below Action Level					
S-13	TSA w/Lec Poly 80	Center of Chemo Hood	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-14	TSA w/Lec Poly 80	Center of Chemo Left Counter	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-15	TSA w/Lec Poly 80	Center of Chemo Right Counter	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					

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Culturable Contact Agar Plate(s) (Bacteria) - Analytical Method USMS-B002

Sample Number	Media	Sample Description	Results of Microbial Analysis	%	Raw CTs
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-16	TSA w/Lec Poly 80	Room B93A Pass Through	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-17	TSA w/Lec Poly 80	Room B93S Pass Through	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-18	TSA w/Lec Poly 80	Compound Room Center of Left Counter	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					

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ISO Class 5 Viable Surface Level: Count Below Action Level					
S-19	TSA w/Lec Poly 80	Center of Compounding BSC	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 7 Viable Surface Level: Count Below Action Level					
S-20	TSA w/Lec Poly 80	Compounding Center of Right Counter	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					
ISO Class 8 Viable Surface Level: Count Below Action Level					
S-21	TSA w/Lec Poly 80	Center of Gowning Cabinet	Total Bacterial Count < 1		CFU/plate
<i>No growth</i>					
Total Raw Count: <1					
Analytical Sensitivity: 1 CFU/plate					

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Laboratory Report

Micrococcus spp. and other gram-positive bacteria are widespread in nature and are commonly found along with coagulase-negative *Staphylococcus* spp. on the skin of humans and mammals. Examples of gram-positive bacilli are *Corynebacterium* spp.

Cladosporium spp. - *Cladosporium* species are ubiquitous with worldwide distribution and are the most common mould on dead organic matter and in the air. The highest concentrations outdoors of *Cladosporium* species occur in summer and early fall in temperate areas. *Cladosporium* species are common in indoor environments and often isolated from the surface of fiberglass duct liners around return and supply ducts, shower walls & curtains, and basement walls. They are usually found indoors in numbers less than outdoor numbers.

Pithomyces spp. - The cosmopolitan fungus *Pithomyces* is often found in decaying wood, plant material, and the soil. A dematiaceous fungus that is distinguished from *Alternaria* and *Ulocladium* species by its scarcely differentiated conidiophores and its conidia which retain an annular frill at the base upon liberation.

USP 797 GUIDELINES

USP 797 refers to chapter 797 "Pharmaceutical Compounding – Sterile Preparations," in the USP National Formulary. It sets practice standards to help ensure that compounded sterile preparations are of high quality. USP 797 describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded.

RISK LEVEL FOR CSP (COMPOUNDED STERILE PREPARATIONS)

There are three risk levels for CSPs: low, medium and high. Each category is assigned based on the potential for microbial contamination. The high-risk level is assigned based on the potential for not achieving sterility of the CSP.

CLASSIFICATION	RISK OF NOT ACHIEVING STERILITY
ISO Class 5	Low Risk
ISO Class 6	Medium Risk
ISO Class 7	Medium Risk
ISO Class 8	High Risk

RECOMMENDED ACTION LEVELS FOR MICROBIAL CONTAMINATION

USP 797 states that the tables of recommended action levels are intended to be used as guidelines only, and "Action levels are determined on the basis of CFU data gathered at each sampling location and trended over time."

ACTION LEVEL FOR AIR TESTING - SAS BIOAEROSOL - CFU/m ³	
Using an impaction sampler to collect sampling volume of 1000 liters of air	
CLASSIFICATION	TOTAL CFU/m ³
ISO Class 5	>1
ISO Class 6	>10
ISO Class 7	>10
ISO Class 8 or worse	>100

ACTION LEVEL FOR GLOVED FINGERTIP - CFU/Plate	
TSA plates should be used to sample gloved fingertips after compounding - Immediately after exiting the ISO Class 5 environment	
CLASSIFICATION	TOTAL CFU/Plate
ISO Class 5	>3
ISO Class 6	Not Required
ISO Class 7	Not Required
ISO Class 8 or worse	Not Required

ACTION LEVEL FOR SURFACE SAMPLING - CONTACT PLATES - CFU/Plate	
Surface sampling can be accomplished using contact plates and/or swabs. The area covered should be at least 24 cm ² but no larger than 30 cm ²	
CLASSIFICATION	TOTAL CFU/Plate
ISO Class 5	>3
ISO Class 6	>5
ISO Class 7	>5
ISO Class 8 or worse	>100

REFERENCES

USP797.Org, Inc. (2011, March 4). Retrieved from <http://www.usp797.org/index.html>

End of Report