



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



Customer Name:	Oncology Plus	Sample Date:	August 12, 2014
Customer Address:	1070 E Brandon Blvd Brandon, FL 33511	Date Received:	August 13, 2014
		Date of Report:	August 18, 2014
Customer Phone:	(813) 689-2069	Fax:	(866) 833-0595
PO Number:		Attention:	Zachary Scholl
Project Name/Number:	2014 #1		

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 83789-14

Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number		Results of Microbial Analysis	%	Raw CTs
Center BSC-1		Total Microbial Count < 1		CFU/plate
	ISO Class 5	Viable Air Level:	Count Below Action Level	
Bacteria	15SB	Total Bacterial Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
Fungi	25SF	Total Fungal Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
Center BSC-2		Total Microbial Count < 1		CFU/plate
	ISO Class 5	Viable Air Level:	Count Below Action Level	
Bacteria	16SB	Total Bacterial Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
Fungi	26SF	Total Fungal Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		

Bacterial Media: TSA w/Lec Poly 80

Fungal Media: SDX w/Lec Poly 80

Lot Number:	Exp Date:	Lot Number:	Exp Date:
501364	09/02/14	529028	10/07/14

Notation for Bolded Microbes

USP<797> *Pharmaceutical Compounding-Sterile Preparations* standards state recovery of any mold, yeast, coagulase-positive *Staphylococcus* or gram-negative rod in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.

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Technical Manager:

Herbert Layman, BS, SM, CIEC



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Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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Center LF-1		Total Microbial Count < 1	CFU/plate
ISO Class 5	Viable Air Level:	Count Below Action Level	
Bacteria	17SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	
Fungi	27SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Center LF-2		Total Microbial Count < 1	CFU/plate
ISO Class 5	Viable Air Level:	Count Below Action Level	
Bacteria	18SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	
Fungi	28SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Bacterial Media: TSA w/Lec Poly 80		Fungal Media: SDX w/Lec Poly 80	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
501364	09/02/14	529028	10/07/14

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Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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PPR South Glass Wall	Total Microbial Count < 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	19SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Fungi	29SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Ante South Glass Wall	Total Microbial Count 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	20SB	Total Bacterial Count: 1	CFU/plate
		<i>Coagulase-negative Staphylococcus spp.</i>	100% 1
	Total Raw Count: 1		
	Analytical Sensitivity: 1	CFU/plate	

Fungi	30SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Bacterial Media: TSA w/Lec Poly 80

Fungal Media: SDX w/Lec Poly 80

Lot Number:	Exp Date:	Lot Number:	Exp Date:
501364	09/02/14	529028	10/07/14

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Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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NPR South Glass Wall	Total Microbial Count < 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	21SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Fungi	31SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

PPR Counter	Total Microbial Count < 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	22SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Fungi	32SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Bacterial Media: TSA w/Lec Poly 80

Fungal Media: SDX w/Lec Poly 80

Lot Number:	Exp Date:	Lot Number:	Exp Date:
501364	09/02/14	529028	10/07/14

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Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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Ante East Glass Wall		Total Microbial Count < 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level	
Bacteria	23SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	
Fungi	33SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

NPR Counter		Total Microbial Count < 1	CFU/plate
ISO Class 7	Viable Air Level:	Count Below Action Level	
Bacteria	24SB	Total Bacterial Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	
Fungi	34SF	Total Fungal Count: < 1	CFU/plate
		<i>No growth</i>	
	Total Raw Count: <1		
	Analytical Sensitivity: 1	CFU/plate	

Bacterial Media: TSA w/Lec Poly 80		Fungal Media: SDX w/Lec Poly 80	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
501364	09/02/14	529028	10/07/14

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Bioaerosol Sample Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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Center BSC-1 **Total Microbial Count < 1** **CFU/m³ of air**

ISO Class 5 **Viable Air Level:** **Count Below Action Level**

Bacteria	1AB	Total Bacterial Count:	< 1	CFU/m³ of air
				<i>No growth</i>
	Total Raw Count:	<1		
	Total Volume:	1000	liters of air	
	Analytical Sensitivity:	1	CFU/m³ of air	

Fungi	8AF	Total Fungal Count:	< 1	CFU/m³ of air
				<i>No growth</i>
	Total Raw Count:	<1		
	Total Volume:	1000	liters of air	
	Analytical Sensitivity:	1	CFU/m³ of air	

Center BSC-2 **Total Microbial Count < 1** **CFU/m³ of air**

ISO Class 5 **Viable Air Level:** **Count Below Action Level**

Bacteria	2AB	Total Bacterial Count:	< 1	CFU/m³ of air
				<i>No growth</i>
	Total Raw Count:	<1		
	Total Volume:	1000	liters of air	
	Analytical Sensitivity:	1	CFU/m³ of air	

Fungi	9AF	Total Fungal Count:	< 1	CFU/m³ of air
				<i>No growth</i>
	Total Raw Count:	<1		
	Total Volume:	1000	liters of air	
	Analytical Sensitivity:	1	CFU/m³ of air	

Bacterial Media: TSA		Fungal Media: IMA	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
510289	08/27/14	523602	09/29/14

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Bioaerosol Sample Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
Center LF-1	Total Microbial Count < 1		CFU/m³ of air
ISO Class 5	Viable Air Level:	Count Below Action Level	
3AB	Total Bacterial Count:	< 1	CFU/m ³ of air
	No growth		
Bacteria	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m ³ of air	
10AF	Total Fungal Count:	< 1	CFU/m ³ of air
	No growth		
Fungi	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m ³ of air	

Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
Center LF-2	Total Microbial Count < 1		CFU/m³ of air
ISO Class 5	Viable Air Level:	Count Below Action Level	
4AB	Total Bacterial Count:	< 1	CFU/m ³ of air
	No growth		
Bacteria	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m ³ of air	
11AF	Total Fungal Count:	< 1	CFU/m ³ of air
	No growth		
Fungi	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m ³ of air	

Bacterial Media: TSA		Fungal Media: IMA	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
510289	08/27/14	523602	09/29/14

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Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
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Center PPR	Total Microbial Count < 1	CFU/m³ of air
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	5AB	Total Bacterial Count: < 1	CFU/m³ of air
		<i>No growth</i>	
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		

Fungi	12AF	Total Fungal Count: < 1	CFU/m³ of air
		<i>No growth</i>	
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		

Center Ante	Total Microbial Count < 1	CFU/m³ of air
ISO Class 7	Viable Air Level:	Count Below Action Level

Bacteria	6AB	Total Bacterial Count: < 1	CFU/m³ of air
		<i>No growth</i>	
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		

Fungi	13AF	Total Fungal Count: < 1	CFU/m³ of air
		<i>No growth</i>	
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		

Bacterial Media: TSA		Fungal Media: IMA	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
510289	08/27/14	523602	09/29/14

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Sample Description / Sample Number	Results of Microbial Analysis	%	Raw CTs
Center NPR	Total Microbial Count < 1		CFU/m³ of air
ISO Class 7	Viable Air Level:	Count Below Action Level	
Bacteria	7AB	Total Bacterial Count: < 1	CFU/m ³ of air
		<i>No growth</i>	
	Total Raw Count: <1		
	Total Volume: 1000 liters of air		
	Analytical Sensitivity: 1 CFU/m ³ of air		
Fungi	14AF	Total Fungal Count: < 1	CFU/m ³ of air
		<i>No growth</i>	
	Total Raw Count: <1		
	Total Volume: 1000 liters of air		
	Analytical Sensitivity: 1 CFU/m ³ of air		

Bacterial Media: TSA		Fungal Media: IMA	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
510289	08/27/14	523602	09/29/14
Notation for Bolded Microbes			
USP<797> <i>Pharmaceutical Compounding-Sterile Preparations</i> standards state recovery of any mold, yeast, coagulase-positive <i>Staphylococcus</i> or gram-negative rod in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.			

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 item tested. All internal test methods are proprietary and remain the property of U.S. Micro-Solutions, Inc (USMS). Customers are reminded that when providing duplicates of this report, the document should be provided in total and not in section in accordance with our policy. USMS shall have no liability to the customer or the customer's customer for opinions stated, recommendations made, action taken, or conduct implemented by either the customer or the customer's customer based on the test results reported. The customer will hold harmless and indemnify USMS for damages or lost profits of revenues because of results reported. In no event will USMS's liability of test results reported exceed the amount paid to USMS by the customer. USMS has provided interpretation of results in good faith using the best information at the time of the survey.

Technical Manager:

Herbert Layman, BS, SM, CIEC

Coagulase-negative Staphylococcus - The major habitats of most staphylococcal species are the skin and mucous membranes of mammals and birds. A few of the coagulase-negative *Staphylococcus* (CNS) are important human pathogens and include such species as *S. epidermis*, *S. haemolyticus*, and *S. saprophyticus* subspecies *saprophyticus*. *S. intermedius*, the recently delineated species *S. pseudintermedius*, and two clusters of *S. delphini* are closely related coagulase-positive species commonly isolated from carnivores, other mammals (e.g., horses and cats), and birds. *S. pseudintermedius* might be the predominant coagulase-positive *Staphylococcus* species recovered from normal and infected canine skin. In humans, *S. epidermidis* is the most frequently isolated staphylococcal species colonizing the body surface, where it is particularly prevalent on moist areas such as the axillae, inguinal and perineal area, anterior nares, and toe webs.

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