



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



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

**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
<b>Center BSC-1</b>		<b>Total Microbial Count &lt; 1</b>		<b>CFU/plate</b>
	<b>ISO Class 5</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>15SB</b>	Total Bacterial Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Fungi</b>	<b>25SF</b>	Total Fungal Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Center BSC-2</b>		<b>Total Microbial Count &lt; 1</b>		<b>CFU/plate</b>
	<b>ISO Class 5</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>16SB</b>	Total Bacterial Count: < 1 CFU/plate <i>No growth</i>		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Fungi</b>	<b>26SF</b>	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**

<b>Lot Number:</b>	<b>Exp Date:</b>	<b>Lot Number:</b>	<b>Exp Date:</b>
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
<b>Center LF-1</b>		<b>Total Microbial Count &lt; 1</b>		<b>CFU/plate</b>
	<b>ISO Class 5</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>17SB</b>	Total Bacterial Count: < 1 CFU/plate No growth		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Fungi</b>	<b>27SF</b>	Total Fungal Count: < 1 CFU/plate No growth		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Center LF-2</b>		<b>Total Microbial Count &lt; 1</b>		<b>CFU/plate</b>
	<b>ISO Class 5</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>18SB</b>	Total Bacterial Count: < 1 CFU/plate No growth		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		
<b>Fungi</b>	<b>28SF</b>	Total Fungal Count: < 1 CFU/plate No growth		
		Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate		

**Bacterial Media: TSA w/Lec Poly 80**

**Fungal Media: SDX w/Lec Poly 80**

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

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Project Name/Number:	2014 #1		
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**Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-M002 & USMS-B002**

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

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

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

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

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

<b>Fungi</b>	<b>30SF</b>	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**

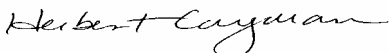
**Fungal Media: SDX w/Lec Poly 80**

<b>Lot Number:</b>	<b>Exp Date:</b>	<b>Lot Number:</b>	<b>Exp Date:</b>
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**

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

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

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

<b>PPR Counter</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/plate</b>
<b>ISO Class 7</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>

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

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

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

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<b>Sample Description / Sample Number</b>	<b>Results of Microbial Analysis</b>	<b>%</b>	<b>Raw CTs</b>
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<b>Ante East Glass Wall</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/plate</b>
<b>ISO Class 7</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>

<b>Bacteria</b>	<b>23SB</b>	<b>Total Bacterial Count: &lt; 1</b>	<b>CFU/plate</b>
		<i>No growth</i>	
	<b>Total Raw Count: &lt;1</b>		
	<b>Analytical Sensitivity: 1</b>	<b>CFU/plate</b>	

<b>Fungi</b>	<b>33SF</b>	<b>Total Fungal Count: &lt; 1</b>	<b>CFU/plate</b>
		<i>No growth</i>	
	<b>Total Raw Count: &lt;1</b>		
	<b>Analytical Sensitivity: 1</b>	<b>CFU/plate</b>	

<b>NPR Counter</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/plate</b>
<b>ISO Class 7</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>

<b>Bacteria</b>	<b>24SB</b>	<b>Total Bacterial Count: &lt; 1</b>	<b>CFU/plate</b>
		<i>No growth</i>	
	<b>Total Raw Count: &lt;1</b>		
	<b>Analytical Sensitivity: 1</b>	<b>CFU/plate</b>	

<b>Fungi</b>	<b>34SF</b>	<b>Total Fungal Count: &lt; 1</b>	<b>CFU/plate</b>
		<i>No growth</i>	
	<b>Total Raw Count: &lt;1</b>		
	<b>Analytical Sensitivity: 1</b>	<b>CFU/plate</b>	

**Bacterial Media: TSA w/Lec Poly 80**

**Fungal Media: SDX w/Lec Poly 80**

<b>Lot Number:</b>	<b>Exp Date:</b>	<b>Lot Number:</b>	<b>Exp Date:</b>
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
<b>Center BSC-1</b>	<b>Total Microbial Count &lt; 1</b>		<b>CFU/m<sup>3</sup> of air</b>
ISO Class 5	Viable Air Level:	Count Below Action Level	
<b>1AB</b>	Total Bacterial Count:	< 1	CFU/m <sup>3</sup> of air
	<i>No growth</i>		
Bacteria	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m <sup>3</sup> of air	
<b>8AF</b>	Total Fungal Count:	< 1	CFU/m <sup>3</sup> of air
	<i>No growth</i>		
Fungi	Total Raw Count:	<1	
	Total Volume:	1000 liters of air	
	Analytical Sensitivity:	1 CFU/m <sup>3</sup> of air	

<b>Center BSC-2</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/m<sup>3</sup> of air</b>
ISO Class 5	Viable Air Level:	Count Below Action Level
<b>2AB</b>	Total Bacterial Count:	< 1 CFU/m <sup>3</sup> of air
	<i>No growth</i>	
Bacteria	Total Raw Count:	<1
	Total Volume:	1000 liters of air
	Analytical Sensitivity:	1 CFU/m <sup>3</sup> of air
<b>9AF</b>	Total Fungal Count:	< 1 CFU/m <sup>3</sup> of air
	<i>No growth</i>	
Fungi	Total Raw Count:	<1
	Total Volume:	1000 liters of air
	Analytical Sensitivity:	1 CFU/m <sup>3</sup> 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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<b>Sample Description / Sample Number</b>	<b>Results of Microbial Analysis</b>	<b>%</b>	<b>Raw CTs</b>
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**Center LF-1** **Total Microbial Count < 1** **CFU/m<sup>3</sup> of air**

<b>ISO Class 5</b>		<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>3AB</b>	Total Bacterial Count: < 1		CFU/m <sup>3</sup> of air
		<i>No growth</i>		
	Total Raw Count: <1			
	Total Volume: 1000 liters of air			
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air			
<b>Fungi</b>	<b>10AF</b>	Total Fungal Count: < 1		CFU/m <sup>3</sup> of air
		<i>No growth</i>		
	Total Raw Count: <1			
	Total Volume: 1000 liters of air			
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air			

**Center LF-2** **Total Microbial Count < 1** **CFU/m<sup>3</sup> of air**

<b>ISO Class 5</b>		<b>Viable Air Level:</b>	<b>Count Below Action Level</b>	
<b>Bacteria</b>	<b>4AB</b>	Total Bacterial Count: < 1		CFU/m <sup>3</sup> of air
		<i>No growth</i>		
	Total Raw Count: <1			
	Total Volume: 1000 liters of air			
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air			
<b>Fungi</b>	<b>11AF</b>	Total Fungal Count: < 1		CFU/m <sup>3</sup> of air
		<i>No growth</i>		
	Total Raw Count: <1			
	Total Volume: 1000 liters of air			
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air			

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

**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*

Herbert Layman, BS, SM, CIEC



U.S. Micro-Solutions, Inc. \* 475-C Willow Crossing Road \* Greensburg, PA 15601  
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 www.usmicro-solutions.com



<b>Customer Name:</b> Oncology Plus	<b>Sample Date:</b> August 12, 2014
<b>Customer Address:</b> 1070 E Brandon Blvd Brandon, FL 33511	<b>Date Received:</b> August 13, 2014
	<b>Date of Report:</b> August 18, 2014
<b>Customer Phone:</b> (813) 689-2069	<b>Fax:</b> (866) 833-0595
<b>PO Number:</b>	<b>Attention:</b> Zachary Scholl
<b>Project Name/Number:</b> 2014 #1	
<b>Customer sample numbers below are uniquely identified by prefixing Laboratory #: 83789-14</b>	

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

<b>Sample Description / Sample Number</b>	<b>Results of Microbial Analysis</b>	<b>%</b>	<b>Raw CTs</b>
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<b>Center PPR</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/m<sup>3</sup> of air</b>
<b>ISO Class 7</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>

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

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

<b>Center Ante</b>	<b>Total Microbial Count &lt; 1</b>	<b>CFU/m<sup>3</sup> of air</b>
<b>ISO Class 7</b>	<b>Viable Air Level:</b>	<b>Count Below Action Level</b>

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

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

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

**Notation for Bolded Microbes**

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Customer Name: Oncology Plus Sample Date: August 12, 2014  
 Customer Address: 1070 E Brandon Blvd Date Received: August 13, 2014  
 Brandon, FL 33511 Date of Report: August 18, 2014  
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 Project Name/Number: 2014 #1  
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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
<b>Center NPR</b>	<b>Total Microbial Count &lt; 1</b>		<b>CFU/m<sup>3</sup> of air</b>
ISO Class 7	Viable Air Level:	Count Below Action Level	
<b>Bacteria</b>	<b>7AB</b>	Total Bacterial Count: < 1	CFU/m <sup>3</sup> of air
		No growth	
	Total Raw Count: <1		
	Total Volume: 1000 liters of air		
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air		
<b>Fungi</b>	<b>14AF</b>	Total Fungal Count: < 1	CFU/m <sup>3</sup> of air
		No growth	
	Total Raw Count: <1		
	Total Volume: 1000 liters of air		
	Analytical Sensitivity: 1 CFU/m <sup>3</sup> of air		

Bacterial Media: TSA		Fungal Media: IMA	
Lot Number:	Exp Date:	Lot Number:	Exp Date:
510289	08/27/14	523602	09/29/14
<b>Notation for Bolded Microbes</b>			
USP<797> Pharmaceutical Compounding-Sterile Preparations 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.			

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*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 <sup>3</sup>	
Using an impaction sampler to collect sampling volume of 1000 liters of air	
CLASSIFICATION	TOTAL CFU/m <sup>3</sup>
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 <sup>2</sup> but no larger than 30 cm <sup>2</sup>	
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\***