



U.S. Micro-Solutions, Inc. * 302 Unity Plaza * Latrobe, PA 15650
 Phone: (724) 853-4047 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009
www.usmslab.com

Customer Name: U.S. Micro-Solutions, Inc. Sample Date: November 16, 2020
 Customer Address: 302 Unity Plaza Date Received: November 17, 2020
 Latrobe, PA 15650 Date of Report: November 30, 2020
 Customer Phone: (724) 853-4047 Fax: (724) 853-4049
 PO Number: Attention:
 Project Name/Number: SPG Sample Report USP 797

Customer sample numbers below are uniquely identified by prefixing Laboratory # 12345-20

Bioaerosol Sample(s) for Bacterial & Fungal Analysis - Analytical Method MIC 05

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
C-AR-A	ISO Class 8 Viable Air Level: Count Below Action Level Ante Room / on rack	Total Microbial Count < 1 No growth No of Personnel in Room: 2 CFU/m ³ of air	
Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		Pore Correction Factor	0
C-IV-A	ISO Class 7 Viable Air Level: Count Below Action Level IV Room / on table	Total Microbial Count < 1 No growth No of Personnel in Room: 2 CFU/m ³ of air	
Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		Pore Correction Factor	0
C-HDA-A	ISO Class 7 Viable Air Level: Count Below Action Level HD Ante Rm / left of sink	Total Microbial Count 2 Micrococcus/Kocuria spp. 1 Coryneform bacillus 1 No of Personnel in Room: 2 CFU/m ³ of air	
Total Raw Count: 2 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air		Pore Correction Factor	0

Sample Report

Air Sampler:	Impaction Head (# of holes)	Media: TSA	Manufacturer: Remel
SAS 180	219	Lot Number: 147448	Exp Date: 12/22/20

Notation for Bolded Microbes

USP<797> *Pharmaceutical Compounding-Sterile Preparations* states recovery of any mold, yeast, coagulase-positive *Staphylococcus*, or gram-negative rod requires immediate remediation and investigation into the cause.

Results relate only to the samples tested. Results are reported as calculated. For biological data, the first and/or second digit should be considered significant.
 *Fungus (mold, yeast)

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Technical Manager:

Deanna L. Kiska

Deanna L. Kiska, Ph.D.



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ISO Class 7	Viability Air Level: Count Exceeds Action Level	No of Personnel in Room:	2
C-HD-A	HD Room / on table	Total Microbial Count	2 CFU/m ³ of air
		* Penicillium spp.	1
		* Cladosporium spp.	1
Total Raw Count:	2		
Total Volume:	1000 liters of air		
Analytical Sensitivity:	1 CFU/m ³ of air	Pore Correction Factor	0
ISO Class 5	Viability Air Level: Count Below Action Level	No of Personnel in Room:	2
C-98-A	#114998 / center of work area	Total Microbial Count	< 1 CFU/m ³ of air
		No growth	
<h1>Sample Report</h1>			
Total Raw Count:	<1		
Total Volume:	1000 liters of air		
Analytical Sensitivity:	1 CFU/m ³ of air	Pore Correction Factor	0
ISO Class 5	Viability Air Level: Count Below Action Level	No of Personnel in Room:	2
C-01-A	#01 / center of work area	Total Microbial Count	< 1 CFU/m ³ of air
		No growth	
Total Raw Count:	<1		
Total Volume:	1000 liters of air		
Analytical Sensitivity:	1 CFU/m ³ of air	Pore Correction Factor	0

Air Sampler:	Impaction Head (# of holes)	Media:	TSA	Manufacturer:	Remel
		Lot Number:		Exp Date:	
SAS 180	219	147448		12/22/20	

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Contact Plate(s) for Bacterial & Fungal Analysis - Analytical Method MIC 05

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
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C-AR-C	ISO Class 8	Viable Surface Level: Count Below Action Level Ante Room / center of window on door to IV room	No of Personnel in Room: 2 Total Microbial Count < 1 CFU/plate
			No growth
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			

C-IV-C	ISO Class 7	Viable Surface Level: Count Below Action Level IV Room / on window	No of Personnel in Room: 2 Total Microbial Count < 1 CFU/plate
			No growth

Sample Report

Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
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C-HDA-C	ISO Class 7	Viable Surface Level: Count Below Action Level HD Ante Rm / on wall panel to the left of door to IV	No of Personnel in Room: 2 Total Microbial Count < 1 CFU/plate
			No growth
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			

Notes:	Media: TSA w/Lec Poly 80	Manufacturer: Remel
	Lot Number: 160876	Exp Date: 01/05/21

Notation for Bolded Microbes

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Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
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C-HD-C	ISO Class 7 Viable Surface Level: Count Below Action Level HD Room / on window	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 2
No growth			
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

C-98-C	ISO Class 5 Viable Surface Level: Count Below Action Level #114998 / center of work surface	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 2
No growth			
<h1>Sample Report</h1>			
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

C-01-C	ISO Class 5 Viable Surface Level: Count Below Action Level #01 / center of work surface	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 2
No growth			
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

Notes:	Media: TSA w/Lec Poly 80	Manufacturer: Remel
	Lot Number: 160876	Exp Date: 01/05/21

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Micrococcus/Kocuria spp. - *Micrococcus* and *Kocuria* species are gram-positive, spherical bacteria which are widespread in nature and commonly found, along with coagulase-negative *Staphylococcus spp.*, as normal flora on the skin of humans and mammals. They are carried on the skin of most (~96%) people, with *M. luteus* being the predominant species. Animal and dairy products are considered secondary sources. While these organisms are generally non-pathogenic, they may act as opportunistic pathogens.

Coryneform bacillus - *Coryneform bacilli* are gram-positive, irregular, rod-shaped bacteria. Many species are part of the normal flora of the skin and mucous membranes in human and mammals. Other coryneform bacilli have been found in the inanimate environment, e.g. dairy products, plants, soil, and activated sludge. Coryneforms are a large group and include genera such as *Corynebacterium*, *Dermabacter*, *Brevibacterium*, *Microbacterium*, and *Cellulomonas*. Some species are opportunistic human pathogens.

Penicillium spp. - *Penicillium* species are fungi with worldwide distribution over a broad range of climates in soil, decaying vegetation, and foods. They are the most abundant genus of mesophilic fungi in temperate soils. About 200 species have been identified. They are indoor contaminants commonly found in carpet, wallpaper, and inside fiberglass duct insulation. High viable or spore trap air counts may be detected where water damaged materials such as drywall, wallpaper, wood, and wood products are present. Human infection with species other than *P. marneffi* are very rare.

Cladosporium spp. - *Cladosporium* species are ubiquitous with worldwide distribution and are the most common mold 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.



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." "Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase-positive *Staphylococcus*, molds, and yeasts)...must be immediately remedied, regardless of CFU count."

(Version USP 40-NF 35)

Action Level for BIOAEROSOL Samples	
CLASSIFICATION	Total CFU per 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 Samples		
Total CFU for both hands		
	Initial Garbing	Subsequent (Post Media Fill)
	>0	>3

Action Level for SURFACE Samples	
CLASSIFICATION	Total CFU per plate, swab, or area sampled
ISO Class 5	>3
ISO Class 6	>5
ISO Class 7	>5
ISO Class 8 or worse	>100

USP <797> Standard Operating Procedure

- **Incubation**
 - Samples are placed in the incubator on the day that they are received in the laboratory.
 - Bacterial agar plates: 30-35°C for 48-72 hours.
 - Fungal agar plates: 20-25°C for 5-7 days.
 - Single plate method agar plates: 30-35°C for 48-72 hours and then 20-25°C for 5-7 additional days.
 - Media fill vials: 20-25°C for 7 days and then 30-35°C for 7 days.
 - Incubator temperatures are monitored 24/7 via a wireless temperature monitoring and alert system.
- **Identification** - species identification performed by MALDI-TOF mass spectrometry.
- **Positive Controls** - performed with the following organisms when requested:
 - *Staphylococcus aureus* ATCC 25923
 - *Pseudomonas aeruginosa* ATCC 9027
 - *Bacillus subtilis* ATCC 6633
 - *Candida albicans* ATCC 10231
 - *Aspergillus brasiliensis* ATCC 16404
- **Accreditation**
 - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).

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