U.S. Micro-Solutions, Inc. * 1075 South Main Street, Suite 104 * Greensburg, PA 15601
Phone: (877) 876-4276 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009
www.usmslab.com

Customer Name:	**U.S. Micro Solutions, Inc.**	**Sample Date:**	**March 30, 2018**
Customer Address:	**1075 South Main Street, Suite 104**	**Date Received:**	**March 31, 2018**
	Greensburg, PA 15601	**Date of Report:**	**April 9, 2018**
Customer Phone:	**(877) 876-4276**	**Fax:**	**(877) 876-4276**
PO Number:		**Attention:**	**John Doe**
Project Name/Number:	**USP Sample Report**		

Customer sample numbers below are uniquely identified by prefixing Laboratory # 12345-18

Bioaerosol Sample(s) for Microbial Analysis - Analytical Method USMS-G065

Sample Number	Sample Description	Results of Microbial Analysis			Raw CTs
ISO Class 7	**Viable Air Level: *Count Exceeds Action Level***				
A7	Ante - Ante Room	Total Microbial Count	38	CFU/m³ of air	
		Coagulase-negative Staphylococcus spp.			15
		Micrococcus/Kocuria spp.			2
		Escherichia coli			**1**
Total Raw Count: 19					
Total Volume: 500 liters of air					
Analytical Sensitivity: 2 CFU/m³ of air		Pore Correction Factor			1
ISO Class 7	**Viable Air Level: Count Below Action Level**				
A8	Ante - Ante Room	Total Microbial Count	4	CFU/m³ of air	
		Coagulase-negative Staphylococcus spp.			1
		Bacillus spp.			1
Total Raw Count: 2					
Total Volume: 500 liters of air					
Analytical Sensitivity: 2 CFU/m³ of air		Pore Correction Factor			0
ISO Class 7	**Viable Air Level: Count Below Action Level**				
A9	Chemo - Chemo Room	Total Microbial Count	< 2	CFU/m³ of air	
		No growth			
Total Raw Count: <1					
Total Volume: 500 liters of air					
Analytical Sensitivity: 2 CFU/m³ of air		Pore Correction Factor			0

Air Sampler:	Impaction Head (# of holes)	Media: TSA w/Lec Poly 80	
		Lot Number:	Exp Date:
SAS 180	219	287535	4/26/18
		Viable sampling was conducted while the cleanroom was in an active or dynamic state.	

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.

Technical Manager: Herbert Layman

Herbert Layman, BS, SM, CIEC

Sample Report

U.S. Micro-Solutions, Inc. * 1075 South Main Street, Suite 104 * Greensburg, PA 15601
Phone: (877) 876-4276 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009
www.usmslab.com

Customer Name:	**U.S. Micro Solutions, Inc.**	**Sample Date:**	**March 30, 2018**
Customer Address:	**1075 South Main Street, Suite 104**	**Date Received:**	**March 31, 2018**
	Greensburg, PA 15601	**Date of Report:**	**April 9, 2018**
Customer Phone:	**(877) 876-4276**	**Fax:**	**(877) 876-4276**
PO Number:		**Attention:**	**John Doe**
Project Name/Number:	**USP Sample Report**		

Customer sample numbers below are uniquely identified by prefixing Laboratory # 12345-18

Contact Plate(s) for Microbial Analysis - Analytical Method USMS-G065

Sample Number	Sample Description	Results of Microbial Analysis			Raw CTs
ISO Class 7	**Viable Surface Level: Count Below Action Level**				
S7	IV Buffer - IV Prep Room, inside of door, see map	Total Microbial Count	< 1	CFU/plate	
		No growth			
Total Raw Count:	<1				
Analytical Sensitivity:	1 CFU/plate				
ISO Class 7	**Viable Surface Level: Count Below Action Level**				
S8	Ante - Ante Room, wall, see map	Total Microbial Count	4	CFU/plate	
		Micrococcus/Kocuria spp.			3
		Coryneform bacillus			1
Total Raw Count:	4				
Analytical Sensitivity:	1 CFU/plate				
ISO Class 7	**Viable Surface Level: Count Below Action Level**				
S9	Ante - Ante Room, wall, see map	Total Microbial Count	1	CFU/plate	
		Coagulase-negative Staphylococcus spp.			1
Total Raw Count:	1				
Analytical Sensitivity:	1 CFU/plate				

NOTES:	**Media: TSA w/Lec Poly 80**	
	Lot Number:	**Exp Date:**
	287535	4/26/2018

Viable sampling was conducted while the cleanroom was in an active or dynamic state.

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.

Technical Manager: Herbert Layman

Herbert Layman, BS, SM, CIEC

Sample Report

U.S. Micro-Solutions, Inc. * 1075 South Main Street, Suite 104 * Greensburg, PA 15601
Phone: (877) 876-4276 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009
www.usmslab.com

Customer Name:	**U.S. Micro Solutions, Inc.**	**Sample Date:**	**March 30, 2018**
Customer Address:	**1075 South Main Street, Suite 104**	**Date Received:**	**March 31, 2018**
	Greensburg, PA 15601	**Date of Report:**	**April 9, 2018**
Customer Phone:	**(877) 876-4276**	**Fax:**	**(877) 876-4276**
PO Number:		**Attention:**	**John Doe**
Project Name/Number:	**USP Sample Report**		

Customer sample numbers below are uniquely identified by prefixing Laboratory # 12345-18

Media Control for Microbial Analysis - Analytical Method USMS-G065

Sample Number	Sample Description	Results of Microbial Analysis
PC	Positive Control	*Growth of Bacillus subtilis* *Growth of Pseudomonas aeruginosa* *Growth of Staphylococcus aureus* *Growth of Aspergillus brasiliensis* *Growth of Candida albicans*
NC*	Negative Control	*No growth**

*Results are not blank corrected

NOTES:	Media: TSA w/Lec Poly 80	
	Lot Number:	**Exp Date:**
	287535	4/26/2018

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.

Technical Manager: Herbert Layman

Herbert Layman, BS, SM, CIEC

Sample Report

Coagulase-negative Staphylococcus spp.- Coagulase-negative staphylococci (CoNS) are gram-positive, spherical bacteria. The major habitats of CoNS are the skin and mucous membranes of mammals and birds. In humans, S. epidermidis is the most frequently isolated staphylococcal species colonizing the body surface. A few of the CoNS are important human pathogens and include S. epidermidis, S. haemolyticus, S. lugdunensis, and S. saprophyticus. CoNS have been increasingly recognized as health-care associated pathogens, particularly in patients with indwelling medical devices.

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.

Escherichia coli - Escherichia coli is a gram-negative, rod-shaped bacterium belonging to the Enterobacteriaceae family. It is considered a normal inhabitant of the gastrointestinal tracts of humans and animals. It is a frequent human pathogen causing urinary tract infections, bacteremia, meningitis, and diarrheal disease.

Bacillus spp. - Bacillus species are gram-positive, rod-shaped bacteria that are ubiquitous in nature. They form spores that are resistant to heat, desiccation, radiation, and disinfectants. Dissemination of spores via aerosols and dust contributes to contamination of indoor environments. Most species have little or no pathogenic potential with the exception of Bacillus cereus group, which can cause opportunistic local and systemic infections.

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.

U.S. MICRO-SOLUTIONS INC.
AN ENVIRONMENTAL MICROBIOLOGY LAB

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."

Action Level for BIOAEROSOL TESTING	
CLASSIFICATION	**TOTAL CFU/m³**
ISO Class 5	>1
ISO Class 6	>10
ISO Class 7	>10
ISO Class 8 or worse	>100

Action Level for GLOVED FINGERTIP		
	TOTAL CFU/both hands	
	Gowning	**Post Fill**
	>0	>3

Action Level for SURFACE SAMPLING	
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: 26-30°C for 5-7 days.
  - Single plate method agar plates: 30-35°C for 48-72 hours and then 26-30°C for 5-7 days.
  - Media fill vials: 20-25°C for 7 days and then 30-35°C for 7 days.
  - Cultures are examined daily (Mon – Sat).
  - Incubator temperatures are monitored 24/7 via a wireless temperature monitoring and alert system.

- **Growth Promotion -** 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* NCPF 2275

- **Accreditation**
  - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).

1075 South Main Street, Suite 104 ▲ Greensburg, PA 15601 ▲ P: 724.853.4047 ▲ F: 724.853.4049 ▲ info@usmslab.com

End of Report