



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: Northern Air Flow
 Customer Address: PO Box 085595
 Racine, WI 53408

Sample Date: September 12, 2018
 Date Received: September 13, 2018
 Date of Report: September 19, 2018

Customer Phone: (262) 639-6796
 PO Number: 91218
 Project Name/Number: The Compounder

Fax: Attention: Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 98091-18

Bioaerosol Sample Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

Sample Description / Sample Number	Results of Microbial Analysis	Raw CTs
------------------------------------	-------------------------------	---------

LAFW 66043233	Total Microbial Count < 1 CFU/m ³ of air	
---------------	---	--

ISO Class 5	Viable Air Level:	Count Below Action Level	No of Personnel in Room: 2
-------------	-------------------	--------------------------	----------------------------

Bacteria	1	Total Bacterial Count: < 1 CFU/m ³ of air	
		No growth	
	Total Raw Count: <1	Total Volume: 1000 liters of air	Pore Correction Factor 0
	Analytical Sensitivity: 1 CFU/m ³ of air		

Fungi	1F	Total Fungal Count: < 1 CFU/m ³ of air	
		No growth	
	Total Raw Count: <1	Total Volume: 1000 liters of air	Pore Correction Factor 0
	Analytical Sensitivity: 1 CFU/m ³ of air		

LAFW 89056814	Total Microbial Count < 1 CFU/m ³ of air	
---------------	---	--

ISO Class 5	Viable Air Level:	Count Below Action Level	No of Personnel in Room: 2
-------------	-------------------	--------------------------	----------------------------

Bacteria	3	Total Bacterial Count: < 1 CFU/m ³ of air	
		No growth	
	Total Raw Count: <1	Total Volume: 1000 liters of air	Pore Correction Factor 0
	Analytical Sensitivity: 1 CFU/m ³ of air		

Fungi	3F	Total Fungal Count: < 1 CFU/m ³ of air	
		No growth	
	Total Raw Count: <1	Total Volume: 1000 liters of air	Pore Correction Factor 0
	Analytical Sensitivity: 1 CFU/m ³ of air		

Air Sampler:	Impaction Head (# of holes)	Media:	Manufacturer:	Lot Number:	Exp. Date:
SAS 180	219	TSA w/Lec Poly 80	Remel	386876	11/01/18
		SDA w/Lec Poly 80	Remel	376649	10/16/18

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 in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.

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)

When providing duplicates of this report, the document should be provided in total and not in section in accordance with AIHA-LAP, LLC. Any unauthorized or improper disclosure, copying, distribution, use, or falsification of these results is prohibited. USMS shall have no liability to the Customer or the Customer's customer for opinions stated, recommendations made, actions taken, or conduct implemented based on the test results reported.

Technical Manager: *Herbert Layman*

Herbert Layman, BS, SM, CIEC



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: Northern Air Flow
 Customer Address: PO Box 085595
 Racine, WI 53408
 Sample Date: September 12, 2018
 Date Received: September 13, 2018
 Date of Report: September 19, 2018

Customer Phone: (262) 639-6796
 PO Number: 91218
 Project Name/Number: The Compounder
 Fax: Attention: Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 98091-18

Bioaerosol Sample Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

Sample Description / Sample Number Results of Microbial Analysis Raw CTs

IV Room Total Microbial Count < 1 CFU/m³ of air

ISO Class 7 Viable Air Level: Count Below Action Level No of Personnel in Room: 2

Bacteria
 5 Total Bacterial Count: < 1 CFU/m³ of air
 No growth
 Total Raw Count: <1
 Total Volume: 1000 liters of air
 Analytical Sensitivity: 1 CFU/m³ of air
 Pore Correction Factor 0

Fungi
 5F Total Fungal Count: < 1 CFU/m³ of air
 No growth
 Total Raw Count: <1
 Total Volume: 1000 liters of air
 Analytical Sensitivity: 1 CFU/m³ of air
 Pore Correction Factor 0

Ante Area Total Microbial Count < 1 CFU/m³ of air

ISO Class 8 Viable Air Level: Count Below Action Level No of Personnel in Room: 2

Bacteria
 7 Total Bacterial Count: < 1 CFU/m³ of air
 No growth
 Total Raw Count: <1
 Total Volume: 1000 liters of air
 Analytical Sensitivity: 1 CFU/m³ of air
 Pore Correction Factor 0

Fungi
 7F Total Fungal Count: < 1 CFU/m³ of air
 No growth
 Total Raw Count: <1
 Total Volume: 1000 liters of air
 Analytical Sensitivity: 1 CFU/m³ of air
 Pore Correction Factor 0

Air Sampler:	Impaction Head (# of holes)	Media:	Manufacturer:	Lot Number:	Exp. Date:
SAS 180	219	TSA w/Lec Poly 80	Remel	386876	11/01/18
		SDA w/Lec Poly 80	Remel	376649	10/16/18

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 in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.

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)

When providing duplicates of this report, the document should be provided in total and not in section in accordance with AIHA-LAP, LLC. Any unauthorized or improper disclosure, copying, distribution, use, or falsification of these results is prohibited. USMS shall have no liability to the Customer or the Customer's customer for opinions stated, recommendations made, actions taken, or conduct implemented based on the test results reported.

Technical Manager: *Herbert Layman*

Herbert Layman, BS, SM, CIEC



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: Northern Air Flow
 Customer Address: PO Box 085595
 Racine, WI 53408

Sample Date: September 12, 2018
 Date Received: September 13, 2018
 Date of Report: September 19, 2018

Customer Phone: (262) 639-6796
 PO Number: 91218
 Project Name/Number: The Compounder

Fax:
 Attention: Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 98091-18

Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

Sample Description / Sample Number	Results of Microbial Analysis	Raw CTs
------------------------------------	-------------------------------	---------

LAFW 66043233	Total Microbial Count < 1	CFU/plate
ISO Class 5	Viable Surface Level: Count Below Action Level	No of Personnel in Room: 2

Bacteria	2	Total Bacterial Count: < 1	CFU/plate
	No growth		
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

Fungi	2F	Total Fungal Count: < 1	CFU/plate
	No growth		
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

LAFW 89056814	Total Microbial Count < 1	CFU/plate
ISO Class 5	Viable Surface Level: Count Below Action Level	No of Personnel in Room: 2

Bacteria	4	Total Bacterial Count: < 1	CFU/plate
	No growth		
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

Fungi	4F	Total Fungal Count: < 1	CFU/plate
	No growth		
Total Raw Count: <1			
Analytical Sensitivity: 1 CFU/plate			

Media: TSA w/Lec Poly 80	Manufacturer: Remel	Media: SDA w/Lec Poly 80	Manufacturer: Remel
Lot Number: 386876	Exp Date: 11/01/18	Lot Number: 376649	Exp Date: 10/16/18


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 in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.

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)

When providing duplicates of this report, the document should be provided in total and not in section in accordance with AIHA-LAP, LLC. Any unauthorized or improper disclosure, copying, distribution, use, or falsification of these results is prohibited. USMS shall have no liability to the Customer or the Customer's customer for opinions stated, recommendations made, actions taken, or conduct implemented based on the test results reported.

Technical Manager: 
 Herbert Layman, BS, SM, CIEC



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: Northern Air Flow
 Customer Address: PO Box 085595
 Racine, WI 53408

Sample Date: September 12, 2018
 Date Received: September 13, 2018
 Date of Report: September 19, 2018

Customer Phone: (262) 639-6796
 PO Number: 91218
 Project Name/Number: The Compounder

Fax:
 Attention: Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 98091-18

Contact Plate Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

Sample Description / Sample Number	Results of Microbial Analysis	Raw CTs
------------------------------------	-------------------------------	---------

IV Room	ISO Class 7	Viable Surface Level:	Count Below Action Level	Total Microbial Count	< 1	CFU/plate
---------	-------------	-----------------------	--------------------------	-----------------------	-----	-----------

Bacteria	6			Total Bacterial Count:	< 1	CFU/plate
					No growth	
		Total Raw Count:	<1			
		Analytical Sensitivity:	1 CFU/plate			

Fungi	6F			Total Fungal Count:	< 1	CFU/plate
					No growth	
		Total Raw Count:	<1			
		Analytical Sensitivity:	1 CFU/plate			

Ante Area	ISO Class 8	Viable Surface Level:	Count Below Action Level	Total Microbial Count	< 1	CFU/plate
-----------	-------------	-----------------------	--------------------------	-----------------------	-----	-----------

Bacteria	8			Total Bacterial Count:	< 1	CFU/plate
					No growth	
		Total Raw Count:	<1			
		Analytical Sensitivity:	1 CFU/plate			

Fungi	8F			Total Fungal Count:	< 1	CFU/plate
					No growth	
		Total Raw Count:	<1			
		Analytical Sensitivity:	1 CFU/plate			

Media: TSA w/Lec Poly 80	Manufacturer: Remel	Media: SDA w/Lec Poly 80	Manufacturer: Remel
Lot Number: 386876	Exp Date: 11/01/18	Lot Number: 376649	Exp Date: 10/16/18

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 in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.

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)

When providing duplicates of this report, the document should be provided in total and not in section in accordance with AIHA-LAP, LLC. Any unauthorized or improper disclosure, copying, distribution, use, or falsification of these results is prohibited. USMS shall have no liability to the Customer or the Customer's customer for opinions stated, recommendations made, actions taken, or conduct implemented based on the test results reported.

Technical Manager:

Herbert Layman

Herbert Layman, BS, SM, CIEC



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:	Northern Air Flow	Sample Date:	September 12, 2018
Customer Address:	PO Box 085595 Racine, WI 53408	Date Received:	September 13, 2018
		Date of Report:	September 19, 2018
Customer Phone:	(262) 639-6796	Fax:	
PO Number:	91218	Attention:	Tom Mikulecky
Project Name/Number:	The Compounder		

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 98091-18

Media Control(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

Sample Description / Sample Number	Results of Microbial Analysis
------------------------------------	-------------------------------

Positive Control

Bacteria	Positive Control	Growth of Staphylococcus aureus Growth of Pseudomonas aeruginosa Growth of Bacillus subtilis
-----------------	-------------------------	--

Fungi	Positive Control	Growth of Aspergillus brasiliensis Growth of Candida albicans
--------------	-------------------------	--

Negative Control

Bacteria	Negative Control*	No growth*
	*Results are not blank corrected	

Fungi	Negative Control*	No growth*
	*Results are not blank corrected	


Media:	Manufacturer:	Lot Number:	Exp. Date:
TSA w/Lec Poly 80	Remel	386876	11/01/18
SDA w/Lec Poly 80	Remel	376649	10/16/18

Notation for Bolded Microbes

USP<797> *Pharmaceutical Compounding-Sterile Preparations* states 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.

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.

When providing duplicates of this report, the document should be provided in total and not in section in accordance with AIHA-LAP, LLC. Any unauthorized or improper disclosure, copying, distribution, use, or falsification of these results is prohibited. USMS shall have no liability to the Customer or the Customer's customer for opinions stated, recommendations made, actions taken, or conduct implemented based on the test results reported.

Technical Manager: 

 Herbert Layman, BS, SM, CIEC



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 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		
	Gowning	Post 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: 26-30°C for 5-7 days.
 - Single plate method agar plates: 30-35°C for 48-72 hours (bacteria) and then 26-30°C for 5-7 days (fungi).
 - 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



U.S. Micro-Solutions, Inc.

1075 S Main Street, Suite 104
Greensburg, PA 15601
PH: 724-853-4047 FAX: 724-853-4049

supplies@usmslab.com



USP 797 TEST REQUEST - CHAIN OF CUSTODY

Media Lot # / Exp. Date *Remel*

TSA air:

SDA air:

TSA contact w/ L&P: *386 876 / 11-1-18*

SDA contact w/ L&P: *376 649 / 10-16-18*

Other: Sampler: SAS 180; 219 holes

Customer Name: **Northern Air Flow**

Phone #: **262.639.6796**

FAX #:

Address: **P.O. Box 095595**

City: **Racine**

State: **WI**

Zip: **53408**

Attention To: **Tom Mikulecky**

E-Mail: **tjm@northernairflow.com**

Sample Obtained By: **J Mikulecky**

Results: FAX E-Mail PO# *91218* Proposal #

Project Name/Number: **The Compounder**

Comments: **Please inoculate positive controls at lab.**

Sample #	Sample Date	Sample Code	Analysis Code	Sample Location & Description	Sample Volume	ISO Class	# People in Room	Static/Dynamic (S or D)
1 / 1F	9-12-18	A	BFG	LAFW 66043233	1000/c	5	2	D
2 / 2F	↓	C		" "		5	2	D
3 / 3F		A		LAFW 89056814	1000/c	5	2	D
4 / 4F		C		" "		5	2	D
5 / 5F		A		IV Room	1000/c	7	2	D
6 / 6F		C		" "		7	2	D
7 / 7F		A		Antic Area	1000/c	8	2	D
8 / 8F		C		" "		8	2	D
<i>Positive control negative control</i>								

Relinquished By (Customer MUST sign)

JMK 9-12-18

Date & Time

Received By - Lab Use Only

Amor Mar

Date & Time

9-13-18 0945

Lab #

98091-18

Rev. 12-14-17

Sample Code	
A	Air Plate
C	Contact Plate
FT	Fingerip Plate <input type="checkbox"/> Gowning <input type="checkbox"/> Post Fill
	S
M	Media Fill
O	Other

Analysis Code					
Dual Plate Method	BFG	Bacteria & Fungi - Counts w/ Genus ID	Bacterial Culture	BG	Bacteria - Counts w/ Genus ID
	BFS	Bacteria & Fungi - Counts w/ Species ID		BS	Bacteria-Counts w/ Species ID
	BFC	Bacteria & Fungi - Counts only		BC	Bacteria - Counts only
Single Plate Method	SPG	Bacteria & Fungi - Counts w/ Genus ID	Fungal Culture	FG	Fungi - Counts w/ Genus ID
	SPS	Bacteria & Fungi - Counts w/ Species ID		FC	Fungi - Counts only
Pre-incubated Plate	IDG	Bacteria & Fungi - Counts w/ Genus ID	Media Fill pre-incubated	STER PRE	Subculture & ID of Positive Vial
	IDS	Bacteria & Fungi - Counts w/ Species ID	Other	MISC	

AMENDED added controls to match samples received.

11/11 9-12-18