

www.usmslab.com

Northern Air Flow Customer Name: Customer Address: PO Box 085595

Racine, WI 53406

(262) 639-6796 **Customer Phone:** 

PO Number: 082222 Project Name/Number:

Date of Report: August 30, 2022 Fax: Attention: T Mikulecky

The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

Sample Date:

Date Received:

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

Raw Sample Number **Sample Description Results of Microbial Analysis CTs** 

Viable Air Level: Count Below Action Level No of Personnel in Room: ISO Class 5 LAFW 214668070822 Total Microbial Count < 1 CFU/m3 of air

No growth

August 22, 2022

August 23, 2022

**Total Raw Count:** <1

Total Volume: liters of air 1000 Analytical Sensitivity: CFU/m3 of air

Pore Correction Factor

ISO Class 5 Viable Air Level: Count Below Action Level No of Personnel in Room: LAFW 214667070822 3 Total Microbial Count < 1 CFU/m3 of air

No growth

0

0

Total Raw Count: <1

Total Volume: 1000 liters of air

Analytical Sensitivity: CFU/m3 of air Pore Correction Factor 0

No of Personnel in Room:

ISO Class 7 IV Room Total Microbial Count < 1 CFU/m3 of air 5

No growth

Viable Air Level: Count Below Action Level

Total Raw Count: <1

Total Volume: liters of air 1000 Analytical Sensitivity: CFU/m3 of air 1

Pore Correction Factor

		Media: CT3P	Manufacturer:	bioMerieux
Air Sampler:	Impaction Head (# of holes)	Lot Number	:	Exp Date:
SAS	219	1009314980	)	10/12/22
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

Samples are in good condition unless otherwise noted. Results relate only to the samples tested as received. 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 & Kiska Deanna L. Kiska, Ph.D.



**Customer Phone:** 

Project Name/Number:

PO Number:

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

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Racine, WI 53406

(262) 639-6796

The Compounder

082222

Date of Report: Fax:

Sample Date:

Date Received:

August 22, 2022 August 23, 2022

August 30, 2022

Attention: T Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

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

Raw Sample Number Sample Description **Results of Microbial Analysis CTs** Viable Air Level: Count Below Action Level No of Personnel in Room:

ISO Class 8 Total Microbial Count < 1 CFU/m3 of air Ante Area

No growth

**Total Raw Count:** <1

Total Volume: liters of air 1000 Analytical Sensitivity: CFU/m3 of air 1

Pore Correction Factor

0

		Media: CT3P	Manufacturer: bioMerieux		
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:		
SAS	219	1009314980	10/12/22		
	·				
Notation for Bolded Microbes					

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PO Box 085595 Date Received: August 23, 2022 Racine, WI 53406 Date of Report: August 30, 2022

Customer Phone: (262) 639-6796 Fax:

PO Number: 082222 Attention: T Mikulecky

Project Name/Number: The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

Sample Date:

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

Sample Number Sample Description Results of Microbial Analysis Raw CTs

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

1F LAFW 214668070822 Total Microbial Count < 1 CFU/m³ of air

No growth

Total Raw Count: <1

3F

II: <1

Total Volume: 1000
Analytical Sensitivity: 1

1000 liters of air
1 CFU/m³ of air

Pore Correction Factor

orrection Factor 0

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

LAFW 214667070822 Total Microbial Count < 1 CFU/m³ of air

No growth

Total Raw Count: <1

Analytical Sensitivity:

Total Volume:

1000 liters of air

1 CFU/m³ of air

Pore Correction Factor

August 22, 2022

on Factor 0

0

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

**5F** IV Room Total Microbial 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

		Media: SDA w/Lec & Tween	Manufacturer: Hardy		
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:		
SAS	219	145522	12/11/22		
	·				
Notation for Bolded Microbes					
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod					

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Technical Manager:

Deanna L. Kiska, Ph.D.

Deanna d Kiska

<sup>\*</sup>Fungus (mold, yeast)



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Customer Name: Northern Air Flow Sample Date: August 22, 2022
Customer Address: PO Box 085595 Date Received: August 23, 2022
Racine, WI 53406 Date of Report: August 30, 2022

Customer Phone: (262) 639-6796 Fax:

PO Number: 082222 Attention: T Mikulecky

Project Name/Number: The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

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

Raw Sample Description Sample Number **Results of Microbial Analysis** CTs ISO Class 8 Viable Air Level: Count Below Action Level No of Personnel in Room: 7F Ante Area Total Microbial Count < 1 CFU/m3 of air No growth Total Raw Count: <1 Total Volume: 1000 liters of air Pore Correction Factor 0 Analytical Sensitivity: CFU/m3 of air

		Media: SDA w/Lec & Tween	Manufacturer:	Hardy	
Air Sampler:	Impaction Head (# of holes)	Lot Number:		Exp Date:	
SAS	219	145522		12/11/22	
Notation for Bolded Microbes					
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Technical	Manac	aer

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Deanna L. Kiska. Ph.D.	



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Racine, WI 53406 Date of Report: August 30, 2022

Customer Phone: (262) 639-6796 Fax:

PO Number: 082222 Attention: T Mikulecky

Project Name/Number: The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

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

Sample Number	Sample Description	Results of Micro	bial Analysi	s	CTs
ISO Class	Viable Surface Level: Count Below Action Level		No of Persor	nnel in Room:	1
2	LAFW 214668070822	Total Microbial Count	< 1	CFU/plate	
			No grow	th	

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

	ISO Class 5	Viable Surface Level: Count Below Action Level		No of Person	nel in Room:	1
4		LAFW 214667070822	Total Microbial Count	< 1	CFU/plate	
				No growth	า	

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

ISO Class 7 Viable Surface Level: Count Below Action Level No of Personnel in Room: 1

IV Room Total Microbial Count < 1 CFU/plate

No growth

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

Notes:	Media:	CT3P Manufacturer: bioMerieux		
	Lot Number:	Exp Date:		
	1009314980	10/12/22		
Notation for Bolded Microbes				
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod				
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Racine, WI 53406 Date of Report: August 30, 2022

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PO Number: 082222 Attention: T Mikulecky

Project Name/Number: The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

Sam	ole Number	ISO Class 8 Viable Surface Level: Count Below Action Level	Results of Microbial Analysis	Ra CT
	ISO Class 8		No of Personnel in Roo	m: 1
8		Ante Area	Total Microbial Count < 1 CFU/pla	ate
			No growth	
	Total Raw Count:	:1		
		1 CFU/plate		

Notes:	Media:	CT3P Manufacturer: bioMerieux		
	Lot Number:	Exp Date:		
	1009314980	10/12/22		
Notation for Bolded Microbes				
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod				
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Deanna L. Kiska, Ph.D.	



U.S. Micro-Solutions, Inc. \* 302 Unity Plaza \* Latrobe, PA 15650

Phone: (724) 853-4047 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009

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Customer Name: Northern Air Flow Customer Address: PO Box 085595

PO Box 085595 Date Received: August 23, 2022 Racine, WI 53406 Date of Report: August 30, 2022

Customer Phone: (262) 639-6796

PO Number: 082222 Attention: T Mikulecky

Project Name/Number: The Compounder

Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22

Fax:

Sample Date:

August 22, 2022

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

Sample	Number	Sample Description	Results of Micro	bial Anal	ysis	Raw CTs
	ISO Class 5	Viable Surface Level: Count Below Action Level		No of Per	sonnel in Room:	1
2F		LAFW 214668070822	Total Microbial Count	< 1	CFU/plate	
				No ar	owth	

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

ISO Class 5 Viable Surface Level: Count Below Action Level No of Personnel in Room: 1

4F LAFW 214667070822 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 No of Personnel in Room: 1

6F IV Room Total Microbial Count < 1 CFU/plate

No growth

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

 Motes:
 Media:
 SDA w/Lec & Tween
 Manufacturer:
 Hardy

 Lot Number:
 Exp Date:

 145522
 12/11/22

## **Notation for Bolded Microbes**

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

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\*Fungus (mold, yeast)

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Customer Name:	Northern Air Flow	Sample Date:	August 22, 2022
Customer Address:	PO Box 085595	Date Received:	August 23, 2022
	Racine, WI 53406	Date of Report:	August 30, 2022

**Customer Phone:** (262) 639-6796 Fax:

PO Number: 082222 Attention: T Mikulecky

The Compounder Project Name/Number:

	Customer sample numbers below are uniquely identified by prefixing Laboratory # 88697-22  Contact Plate(s) for Fungal Analysis - Analytical Method MIC 05									
Samı	ple Number			Sample Descri			Results of Micr	obial Analy	sis	Raw CTs
	ISO Class 8		Viable Surfa	ace Level: Count Belov	w Action Leve	el		No of Pers	onnel in Room:	
8F				Ante Area	1	To	tal Microbial Count	< 1	CFU/plate	
	Total Raw Count: Analytical Sensitivity:	<1 1	CFU/plate					No grov	vth	
Notes					Modio	SDA will on ° To	Manufactor	War day		
Notes	:				Media:	SDA w/Lec & Two Lot Number:	een Manufacti	urer: Hardy Exp D	)ato:	
						145522		12/11		
							<u>-</u>			
					r Bolded Micr					
	USP<797> Pharma	aceutica		Preparations states reco				us, or gram-ne	gative rod	

requires immediated remediation and investigation into the cause.

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\*Fungus (mold, yeast)

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Technical Manager:	
Deanna L Kiska	
Dogna I Kieka Ph D	-



Customer Name:	Northern Air Flow		Sample Date:	August 22, 2022	
Customer Address:	PO Box 085595		Date Received:	August 23, 2022	
	Racine, WI 53406		Date of Report:	August 30, 2022	
Customer Phone:	(262) 639-6796		Fax:		
PO Number:	082222		Attention:	T Mikulecky	
Project Name/Number:	The Compounder				
	Customer sample	e numbers below are unique	ely identified by prefix	ng Laboratory # 88697-22	
	Med	ia Control(s) Analysis - Ana	lytical Method MIC 05		
Sample Number		Sample Description	R	esults of Microbial Analysis	
9		Positive			
				Growth of Bacillus subtilis	
				n of Pseudomonas aeruginosa	
			Gro	wth of Staphylococcus aureus	
10		Negative			
				No growth*	
*Results a	are not blank corrected				

	Media: CT3P Ma	nufacturer: bioMerieux		
	Lot Number:	Exp Date:		
	1009314980	10/12/22		
Notation for Bolded Microbes				
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod				

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Inc.		<u>www.usmsian</u>	<u>.com</u>				
Customer Name: Customer Address: Customer Phone: PO Number: Project Name/Number:	Northern Air Flow PO Box 085595 Racine, WI 53406 (262) 639-6796 082222 The Compounder Customer sampl	e numbers below are uniqu	Sample Date: Date Received: Date of Report: Fax: Attention:	August 22, 2022 August 23, 2022 August 30, 2022 T Mikulecky king Laboratory # 88697-22			
Media Control(s) Analysis - Analytical Method MIC 05							
Sample Number		Sample Description		Results of Microbial Analysis			
9F		Positive					
			Gı	Growth of Candida albicans rowth of Aspergillus brasiliensis			
10F		Negative					
*Results a	re not blank corrected			No growth*			
		Media	a: SDA w/Lec & Tween	Manufacturer: Hardy			

	Media: SDA w/Lec & Tween Ma	nufacturer: Hardy			
	Lot Number:	Exp Date:			
	145522	12/11/22			
Notation for Bolded Microbes					
USP<797> Pharmaceutical Compounding-Sterile Preparations states recove	USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod				

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#### 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 <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 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

- o 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.
- o 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 6538
  - Pseudomonas aeruginosa ATCC 9027
  - o Bacillus subtilis ATCC 6633
  - o 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).

302 Unity Plaza 🛕 Latrobe, PA 15650 🛕 P: 724.853.4047 🛕 F: 724-853-4049 🛕 info@usmslab.com

QLT 02 F1 v2 DCR 22-071 Effective 03-08-22



302 Unity Plaza Latrobe, PA 15650

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supplies@usmslab.com

# Cleanroom Environmental Monitoring - CHAIN OF CUSTODY

Customer Information								
Customer Name: Northern Air Flow	Phone #: 262.639.6796 FA			FAX#:	FAX #:			
Address: P.O. Box 085595		city: Racine			State: WI	zip: 53406		
			E-Mail: tjm@northernairflowcom					
Sample Obtained By: Jared Mikulecky	Results:	☐ FAX	E-Mail	PO# 082222	Proposal#			
Project Name/Number: The Comp	ounder	<u> </u>		**************************************				
	not 797	Other - pleas	e specify:					
comments: Please inoculate positive	controls at	lab						
	Me	dia Infor	mation	)				
Media Type	Manufactur	er	Lot #			Expiration Date		
TSA CT3P	BioMerie	/χ		100931499	10-12-22			
Sabo w/LT	Hardy			145522	12-11-22			
Bioaerosol Sampler Information								
Bioaerosol Sampler	# holes in he				Calib	ration Due Date		
SAS	219	17-D-11913			9/2022			
Relinquished By (Customer MUST sign)  **The sign of the sign of th					Date &	Date & Time		
Received By – Lab Use Only	X		Date & Ti	me	Lab#	u-0-1 20		
v. 12-5-18			LXDE	State Off	2 188	5697-22		

S	Sample Code					
Α	Air Plate					
С	Contact Plate					
F	Fingertip Plate Garbing Media Fill					
G	Garbing Plate					
S	Swab					
M	Media Fill					

Analysis Code							
	BFG	Bacteria & Fungi – Counts w/ Genus ID		BG	Bacteria – Counts w/ Genus ID		
Dual Plate Method	BFS	Bacteria & Fungi – Counts w/ Species ID	Bacterial Culture	BS	Bacteria – Counts w/ Species II		
	BFC	Bacteria & Fungi – Counts only		ВС	Bacteria – Counts only		
Sinale	SPG	Bacteria & Fungi – Counts w/ Genus ID		FG	Fungi – Counts w/ Genus ID		
Plate Method	SPS	Bacteria & Fungi – Counts w/ Species ID	Fungal Culture	FS	Fungi – Counts w/ Species ID		
Wethou	SPC	Bacteria & Fungí – Counts only		FC	Fungi – Counts only		
Pre-	IDG	Bacteria & Fungi – Counts w/ Genus ID	Media Fill	STER	Presence/Absence of Growth		
incubated Plate	IDS	Bacteria & Fungi – Counts w/ Species ID	Media Fill pre-incubated	STER PRE	Subculture & ID of Positive Unit		

Rev. 11-14-18



302 Unity Plaza Latrobe, PA 15650

P: 724.853.4047 F: 724.853.4049

supplies@usmslab.com

# Cleanroom Environmental Monitoring - CHAIN OF CUSTODY - Additional Samples

	A 1 1	A : F						•	
ustomer Name	∍: Norther	n Air F	low		Project Name/Number:	The Comp	ocunds.	,	
Sample #	Sample Date	Sample Code	Analysis Code	Sample Loc	cation & Description	Sample Volume	ISO Class	# People in Room	Station Dynam (S or I
1/15	8-22-22	A	BFG	LAFW 211	1000/L	5	•	D	
2/24	1	د		14	l (		5	į	D
3/34		Α		LAFW 21	4667070822	1000 4	5	Ĭ	D
4/44		c	district of the second	31	l.		5	i	D
5 5F		A	Section 1	IV R	-66 M	1000 4	7	Ì	D
le   ipF		ı		16	11		7	i	P
7/7	SO CONTRACTOR OF SOME	A		Ante	Area	1000 \	8	î	D
8/8f		c		1,	1.1		8	i	D
9/98		X	17.700	+ Control	(2)				
10 lief	V X		V	- Contro	1 (2)				······
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				A					
			1	1/					
eived By – La	b Use Only			the state of the s	Date & Time	0945 S	# \$100	7-22	)