

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: Northern Air Flow Customer Address: P.O. Box 085595

P.O. Box 085595 Date Received: November 12, 2020 Racine, WI 53406 Date of Report: November 20, 2020

Customer Phone: (262) 369-2796 Fax:

PO Number: 111120 Attention: Tom Mikulecky

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

Sample Date:

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

Sample Number Sample Description Results of Microbial Analysis CTs

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

LAFW 89056814 Total Microbial Count < 1 CFU/m³ of air

No growth

November 11, 2020

Total Raw Count: <1

Total Volume: 1000 liters of air

Analytical Sensitivity: 1 CFU/m³ of air

Pore Correction Factor

0

0

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

LAFW 66043233 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 0

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

1 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: TSA w/Lec Poly 80 Ma	nufacturer: Remel			
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:			
SAS; Super 180	219	128680	11/17/20			
Viable sampling was conducted while the cleanroom was in an active or dynamic state.						
	Notation for Bolded Microbes					
USP<797> Pharmaceutical Co	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.

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Technical Manager:

^{*}Fungus (mold, yeast



Customer Phone:

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Customer Name: Northern Air Flow Sample Date: November 11, 2020
Customer Address: P.O. Box 085595 Date Received: November 12, 2020
Racine, WI 53406 Date of Report: November 20, 2020

(262) 369-2796 Fax:

PO Number: 111120 Attention: Tom Mikulecky

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

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

Sample Number Sample Description Results of Microbial Analysis Raw
CTs

ISO Class 8 Viable Air Level: Count Below Action Level No of Personnel in Room: 1

Ante Area Total Microbial Count 1 CFU/m³ of air

Bacillus spp.

Sample received with a split in the agar

Total Raw Count: Total Volume: 10

1000 liters of air

Analytical Sensitivity: 1 CFU/m³ of air

Pore Correction Factor

0

		Media: TSA w/Lec Poly 80 Ma	nufacturer: Remel		
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:		
SAS; Super 180	219	128680	11/17/20		
	Viable sampling was conducted while the cleanroom was in an active or dynamic state.				
	Notation for Bolded Microbes				
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PO Number: **Tom Mikulecky** 111120 Attention:

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

Sample Date:

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

Raw Sample Number **Sample Description Results of Microbial Analysis** CTs No of Personnel in Room: Viable Air Level: Count Below Action Level ISO Class 5

LAFW 89056814 1F Total Microbial Count < 1 CFU/m3 of air

No growth

Total Raw Count: <1

3F

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

Pore Correction Factor 0

November 11, 2020

Viable Air Level: Count Below Action Level ISO Class 5 No of Personnel in Room: LAFW 66043233 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

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

Total Microbial Count < 1 CFU/m3 of air 5F IV Room

No growth

0

Total Raw Count: <1

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

Pore Correction Factor

		Media: SDA w/Lec Poly 80	Manufacturer: Remel		
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:		
SAS; Super 180	219	140030	12/03/20		
	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					
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Technical Manager:

Deanna & Kiska



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Customer Phone: (262) 369-2796 Fax:

PO Number: **Tom Mikulecky** 111120 Attention:

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

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

Raw Sample Number **Sample Description Results of Microbial Analysis** CTs No of Personnel in Room: Viable Air Level: Count Below Action Level ISO Class 8

7F Ante Area Total Microbial Count < 1 CFU/m3 of air

No growth

0

Total Raw Count: <1

> Total Volume: 1000 liters of air

Pore Correction Factor Analytical Sensitivity: CFU/m3 of air

		Media: SDA w/Lec Poly 80	Manufacturer: Remel		
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:		
SAS; Super 180	219	140030	12/03/20		
	Viable sampling was conducted while the cleanroom was in an active or dynamic state.				
	Notation for Bolded Microbes				
USP<797> Pharmaceutical	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.				

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Technical Ma	nager:
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Deanna & Kiska



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Customer Phone: (262) 369-2796 Fax:

PO Number: 111120 Attention: Tom Mikulecky

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

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

Sample Num	nber	Sample Description	Results of Microb	oial Analysis	i	CTs
	ISO Class 5	Viable Surface Level: Count Below Action Level	1	No of Personr	nel in Room:	1
2		LAFW 89056814	Total Microbial Count	< 1	CFU/plate	
				No growth	ı	

Total Raw Count: <1

Analytical Sensitivity: 1 CFU/plate

	ISO Class 5	Viable Surface Level: Count Below Action Level		No of Personn	el in Room:	1
4	4	LAFW 66043233	Total Microbial Count	< 1	CFU/plate	
				No growth		

Total Raw Count: <

Analytical Sensitivity: 1 CFU/plate

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

6 IV Room 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 I	lumber:	Exp Date:	
		12	28680	11/17/20	
	Viable sampling was conducted while the cleanroom was	s 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					
I	requires immediate remediation and investiga	ation into the	Called		

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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Racine, WI 53406 Date of Report: November 20, 2020

Customer Phone: (262) 369-2796 Fax:

PO Number: 111120 Attention: Tom Mikulecky

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

			Contact Plate(s) for Bacterial Analysis - Analytic	cal Method MIC 05			
Sam	ple Number		Sample Description	Results of Micro	bial Analy	/sis	Raw CTs
	ISO Class 8		Viable Surface Level: Count Below Action Level		No of Pers	sonnel in Room:	1
8			Ante Area	Total Microbial Count	< 1	CFU/plate	
	Total Raw Count: Analytical Sensitivity:	<1 1	CFU/plate		No gro	wth	

Notes:	Media:	TSA w/Lec Poly 80	Manufacturer: Remel
	Lot Nu	ımber:	Exp Date:
	128	680	11/17/20
Viable sampling was cond	ucted while the cleanroom was in an active of	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 immed	iate remediation and investigation into the c	ause	

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*Fungus (mold, yeast)

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Deanna L. Kiska, Ph.D.	



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Customer Name: Customer Address:

Project Name/Number:

Northern Air Flow P.O. Box 085595 Racine, WI 53406 Sample Date: November 11, 2020
Date Received: November 12, 2020
Date of Report: November 20, 2020

Total Microbial Count

Customer Phone:

2F

(262) 369-2796

The Compounder Rx

PO Number: 111120

Fax: Attention:

Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
ISO Class 5	Viable Surface Level: Count Below Action Level	No of Personnel in Room:	1

LAFW 89056814

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

No growth

< 1

CFU/plate

Total Raw Count:

<1 1

<1

Analytical Sensitivity:

CFU/plate

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

4F LAFW 66043233 Total Microbial Count < 1 CFU/plate

No growth

Total Raw Count:

Analytical Sensitivity:

CFU/plate

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

 Modes:
 Media:
 SDA w/Lec Poly 80
 Manufacturer:
 Remel

 Lot Number:
 Exp Date:

 140030
 12/03/20

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

Notation for Bolded Microbes

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^{*}Fungus (mold, yeast)



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Racine, WI 53406 Date of Report: November 20, 2020

Customer Phone: (262) 369-2796 Fax:

PO Number: 111120 Attention: Tom Mikulecky

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

	Contact Plate(s) for Fungal Analysis - Analytical Method MIC 05									
Sam	mple Number Sample Description Results of Microbial Analysis Raw							Raw CTs		
	ISO Class 8		Viable St	rface Level: Count Below						
8F	ISO Class o	1	Viable St	Ante Area	ACTION LEVE		crobial Count		CFU/plate	1
JI									Or O/piato	
								No growth		
	Total Raw Count:	<1								
	Analytical Sensitivity:	1	CFU/plate							
	.,,,									
lotes	s:				Media:	SDA w/Lec Poly 80	Manufactur	er: Remel		
						Lot Number:		Exp Date		
						140030		12/03/20		
			Viable sam	oling was conducted while the			state.			
	110D 707 Dt		I Commous direction		Bolded Micro		a Ctanhul		ua rad	
	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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Technical Manager:	
Deanna L Kiska	
Deenna I Kieke Dh D	



Customer Name:	Northern Air Flow	Sample Date:	November 11, 2020
Customer Address:	P.O. Box 085595	Date Received:	November 12, 2020
	Racine, WI 53406	Date of Report:	November 20, 2020
Customer Dhane.	(202) 200 2700	Fav.	

Customer Phone: (262) 369-2796 Fax:

PO Number: 111120 Attention: **Tom Mikulecky**

Project Name/Number: The Compounder Rx

Customer sample numbers below are uniquely identified by prefixing Laboratory # 119949-20

Growth of Pseudomonas aeruginosa

	ledia Control(s) for Bacterial Analysis - Analytical Method MIC 05		
Sample Number	Sample Description	Results of Microbial Analysis	
Positive Control	Positive Control		
		Growth of Bacillus subtilis	

Growth of Staphylococcus aureus

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

	Media: TSA w/Lec Poly 80 Ma	nufacturer: Remel		
	Lot Number:	Exp Date:		
	128680	11/17/20		
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.	www.usirisi	ab.com		
Customer Name: Customer Address: Customer Phone: PO Number:	Northern Air Flow P.O. Box 085595 Racine, WI 53406 (262) 369-2796 111120	Sample Date: Date Received: Date of Report: Fax: Attention:	November 11, 2020 November 12, 2020 November 20, 2020 Tom Mikulecky	
Project Name/Number:	The Compounder Rx Customer sample numbers below are uni	quely identified by prefix	xing I aboratory # 119949-20	
	Media Control(s) for Fungal Analy			
Sample Number	Sample Description	on	Results of Microbial Analysis	
Positive Control	Positive Control			
		G	Growth of Candida albicans rowth of Aspergillus brasiliensis	
Negative Control*	Negative Control			
Results a	re not blank corrected		No growth	
	Me	edia: SDA w/Lec Poly 80	Manufacturer: Remel	
		Lot Number:	Exp Date:	

	Lot Number:	Exp Date:		
	140030	12/03/20		
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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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.



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.
- o 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:
 - o Staphylococcus aureus ATCC 25923
 - 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

OLT 02 F1 v1 DCR 20-074 Effective 02-27-20



302 Unity Plaza Latrobe, PA 15650

P: 724.853.4047 F: 724.853.4049

supplies@usmslab.com

Cleanroom Environmental Monitoring - CHAIN OF CUSTODY

Customer Information								
Customer Name: Northern Air Flow	Phone #: 262.639.6796 FAX #:			FAX#:				
Address: P.O. Box 085595		City: Racine State:			State: V	NI zip: 53406		
Attention To: Tom Mikulecky		E-Mail: tjm@northernairflow.com						
Sample Obtained By: J Mikulecky		Results:	☐ FAX	E-Mail	PO#	Proposal #		
Project Name/Number: The Compounder Rx								
comments: Please inoculate positive	controls at	the lab						
	Med	dia Info	mation	1				
Media Type	Manufactur	er		Lot #		Expiration Date		
TSA w / ROLY & LEC	Rinel			128680		11-17-20		
Sab Dex LY	Sab Dex 17 Reme			140030			12-3-20	
•				1200				
					· · · · · · · · · · · · · · · · · · ·		97	
Bioaerosol Sampler Information								
Bioaerosol Sampler	# holes in he	ead	Serial	#		Calibration Due Date		
SAS; Super 180	219	9		17-D-11913		6/2021		
		· · · · · · · · · · · · · · · · · · ·						
Relinquished By (Customer MUST sign)	20	C. Communication of the Commun			Date & Tim	ne		
Received By – Lab Use Only	and the second s	Date & T	ime 13000 00	140	Lab#	949-20		
ov 11.5-18	Manufacture Co Co. Section Co.		Name and Address of the Owner, where	ala di ancida da la bada ancida de la casa d				

Sample Code					
Α	Air Plate				
С	Contact Plate				
FT	Fingertip Plate Garbing Media Fill				
G	Garbing Plate				
S	Swab				
М	Media Fill				

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



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

Customer Name: Northern Air Flow				Project Name/Number:	Project Name/Number: The Compounder				
Sample #	Sample Date	Sample Code	Analysis Code	Sample Location & Description	Sample Volume	ISO Class	# People in Room	Static/ Dynamic (S or D)	
1115	11-11-20	Δ	BFG	LAFW 89056814	1000k	5	1	D	
2/24		L	1	и н	·	5	1	D	
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