



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
Racine, WI 53406
Customer Phone: (262) 639-6796
PO Number: 050521
Project Name/Number: The Compounder

Sample Date: May 5, 2021
Date Received: May 10, 2021
Date of Report: May 18, 2021
Fax:
Attention: Tom Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory # 54544-21

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
1	ISO Class 5 Viable Air Level: Count Below Action Level LAFW 66043233	No of Personnel in Room: 1 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	
3	ISO Class 5 Viable Air Level: Count Below Action Level LAFW 89056814	No of Personnel in Room: 1 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	
5	ISO Class 7 Viable Air Level: Count Below Action Level IV Room	No of Personnel in Room: 1 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 w/Lec Poly 80	Manufacturer: Remel
SAS; Super 180	219	Lot Number:	Exp Date:
		279512	07/06/21

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.

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*Fungus (mold, yeast)

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Technical Manager:

Deanna L. Kiska

Deanna L. Kiska, Ph.D.



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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
7	ISO Class 8 Viable Air Level: Count Below Action Level Ante Area	No of Personnel in Room: 1 Total Microbial Count < 1 CFU/m ³ of air No growth	1
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 w/Lec Poly 80	Manufacturer: Remel
SAS; Super 180	219	Lot Number:	Exp Date:
		279512	07/06/21

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
1F	ISO Class 5 Viable Air Level: Count Below Action Level LAFW 66043233	No of Personnel in Room: 1 Total Microbial Count < 1 CFU/m ³ of air No growth	1
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air	Pore Correction Factor	0
3F	ISO Class 5 Viable Air Level: Count Below Action Level LAFW 89056814	No of Personnel in Room: 1 Total Microbial Count < 1 CFU/m ³ of air No growth	1
	Total Raw Count: <1 Total Volume: 1000 liters of air Analytical Sensitivity: 1 CFU/m ³ of air	Pore Correction Factor	0
5F	ISO Class 7 Viable Air Level: Count Below Action Level IV Room	No of Personnel in Room: 1 Total Microbial Count < 1 CFU/m ³ of air No growth	1
	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: SDA w/Lec Poly 80	Manufacturer: Remel
SAS: Super 180	219	Lot Number:	Exp Date:
		279513	07/06/21

Notation for Bolded Microbes

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
7F	ISO Class 8 Viable Air Level: Count Below Action Level Ante Area	No of Personnel in Room: 1 Total Microbial Count < 1 CFU/m ³ of air No growth	1
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: SDA w/Lec Poly 80	Manufacturer: Remel
SAS: Super 180	219	Lot Number: 279513	Exp Date: 07/06/21

Notation for Bolded Microbes

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
2	ISO Class 5 Viable Surface Level: Count Below Action Level LAFW 66043233	Total Microbial Count < 1 CFU/plate No growth	No of Personnel in Room: 1
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
4	ISO Class 5 Viable Surface Level: Count Below Action Level LAFW 89056814	Total Microbial Count < 1 CFU/plate No growth	No of Personnel in Room: 1
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
6	ISO Class 7 Viable Surface Level: Count Below Action Level IV Room	Total Microbial Count < 1 CFU/plate No growth	No of Personnel in Room: 1
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			

Notes:	Media: TSA w/Lec Poly 80	Manufacturer: Remel
	Lot Number:	Exp Date:
	279512	07/06/21

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
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8	ISO Class 8 Viable Surface Level: Count Below Action Level Ante Area	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 1
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No growth

Total Raw Count: <1
Analytical Sensitivity: 1 CFU/plate

Notes:	Media: TSA w/Lec Poly 80	Manufacturer: Remel
	Lot Number:	Exp Date:
	279512	07/06/21

Notation for Bolded Microbes

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
2F	ISO Class 5 Viable Surface Level: Count Below Action Level LAFW 66043233	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 1
No growth			
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
4F	ISO Class 5 Viable Surface Level: Count Below Action Level LAFW 89056814	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 1
No growth			
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
6F	ISO Class 7 Viable Surface Level: Count Below Action Level IV Room	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 1
No growth			
Total Raw Count: <1 Analytical Sensitivity: 1 CFU/plate			
Notes:	Media:	SDA w/Lec Poly 80	Manufacturer: Remel
	Lot Number:	279513	Exp Date: 07/06/21

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

Sample Number	Sample Description	Results of Microbial Analysis	Raw CTs
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8F	ISO Class 8 Viable Surface Level: Count Below Action Level Ante Area	Total Microbial Count < 1 CFU/plate	No of Personnel in Room: 1
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No growth

Total Raw Count: <1
Analytical Sensitivity: 1 CFU/plate

Notes:	Media: SDA w/Lec Poly 80	Manufacturer: Remel
	Lot Number: 279513	Exp Date: 07/06/21

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*Fungus (mold, yeast)

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Media Control(s) Analysis - Analytical Method MIC 05

Sample Number	Sample Description	Results of Microbial Analysis
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Pos Control

Positive

Growth of Staphylococcus aureus
Growth of Pseudomonas aeruginosa
Growth of Bacillus subtilis

Neg Control*

Negative

No growth*

*Results are not blank corrected

Notation for Bolded Microbes

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Media Control(s) Analysis - Analytical Method MIC 05

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

Pos Control

Positive

Growth of Candida albicans
Growth of Aspergillus brasiliensis

Neg Control*

Negative

No growth*

*Results are not blank corrected

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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."

(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).

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

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



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AN ENVIRONMENTAL MICROBIOLOGY LAB

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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	FAX #:
Address: P.O. Box 085595	City: Racine	State: WI Zip: 53406
Attention To: Tom Mikulecky	E-Mail: tjm@northernairflow.com	
Sample Obtained By: J Mikulecky	Results: <input type="checkbox"/> FAX <input checked="" type="checkbox"/> E-Mail	PO# 050521 Proposal #
Project Name/Number: The Compounder		
Type of Project: <input checked="" type="checkbox"/> USP 797 <input type="checkbox"/> USP not 797 <input type="checkbox"/> Other - please specify:		
Comments: Please inoculate positive controls at the lab		

Media Information

Media Type	Manufacturer	Lot #	Expiration Date
TSA LBP	Remel	279512	7-6-21
Sab Dex LBP	Remel	279513	7-6-21

Bioaerosol Sampler Information

Bioaerosol Sampler	# holes in head	Serial #	Calibration Due Date
SAS; Super 180	219	17-D-11913	6/2021
Relinquished By (Customer MUST sign)			Date & Time
Received By - Lab Use Only			Lab #

5/5/21
05/10/21 0930
54544-21

Rev. 11-5-18

Sample Code	
A	Air Plate
C	Contact Plate
FT	Fingertip Plate <input type="checkbox"/> Garbing <input type="checkbox"/> Media Fill
G	Garbing Plate
S	Swab
M	Media Fill

Rev. 11-14-18

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		FS	Fungi – Counts w/ Species ID
	SPC	Bacteria & Fungi – 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

Cleanroom Environmental Monitoring – CHAIN OF CUSTODY – Additional Samples

Customer Name:

NAF

Project Name/Number:

The Compounder

[illegible]

Received By – Lab Use Only

Date & Time

05/10/21 0930

Lab #

54/544-21