



Customer Name:	Northern Air Flow	Sample Date:	November 13, 2019
Customer Address:	PO Box 085595 Racine, WI 53406	Date Received:	November 14, 2019
		Date of Report:	November 21, 2019
Customer Phone:	(262) 639-6796	Fax:	
PO Number:	111319-1	Attention:	T Mikulecky
Project Name/Number:			

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 111470-19

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

Sample Description / Sample Number	Results of Microbial Analysis	Raw CTs
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LAFW 66043233 Total Microbial Count < 1 CFU/m³ of air

ISO Class 5 Viable Air Level: Count Below Action Level

Bacteria	1	Total Bacterial 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

Fungi	1F	Total Fungal 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

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

ISO Class 5 Viable Air Level: Count Below Action Level

Bacteria	3	Total Bacterial 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

Fungi	3F	Total Fungal 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:	Manufacturer:	Lot Number:	Exp. Date:
SAS	180	TSA w/Lec Poly 80	Remel	852611	11/26/19
		SDA w/Lec Poly 80	Remel	862378	12/12/19

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)

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Technical Manager:

Sharon Fanchalsky

Sharon Fanchalsky, AS, MLT (ASCP)



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Sample Description / Sample Number	Results of Microbial Analysis	Raw CTs
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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: 7

Bacteria	5	Total Bacterial 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

Fungi	5F	Total Fungal 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

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: 8

Bacteria	7	Total Bacterial 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

Fungi	7F	Total Fungal 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:	Manufacturer:	Lot Number:	Exp. Date:
SAS	180	TSA w/Lec Poly 80	Remel	852611	11/26/19
		SDA w/Lec Poly 80	Remel	862378	12/12/19

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Customer Name: Northern Air Flow
 Customer Address: PO Box 085595
 Racine, WI 53406
 Customer Phone: (262) 639-6796
 PO Number: 111319-1
 Project Name/Number:

Sample Date: November 13, 2019
 Date Received: November 14, 2019
 Date of Report: November 21, 2019
 Fax:
 Attention: T Mikulecky

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 111470-19
 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	

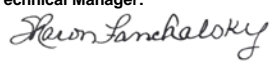
Fungi	Negative Control*	No growth*
	*Results are not blank corrected	

Media:	Manufacturer:	Lot Number:	Exp. Date:
TSA w/Lec Poly 80	Remel	852611	11/26/19
SDA w/Lec Poly 80	Remel	862378	12/12/19

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Customer sample numbers below are uniquely identified by prefixing Laboratory #: 111470-19

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				
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				
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:	852611	Exp Date:	11/26/19	Lot Number:	862378	Exp Date:	12/12/19

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Sample Description / Sample Number		Results of Microbial Analysis		Raw CTs
IV Room		Total Microbial Count	< 1	CFU/plate
	ISO Class 7	Viable Surface Level:	Count Below Action Level	No of Personnel in Room: 7
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		Total Microbial Count	< 1	CFU/plate
	ISO Class 8	Viable Surface Level:	Count Below Action Level	No of Personnel in Room: 8
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:	852611	Exp Date:	11/26/19	Lot Number:	862378	Exp Date:	12/12/19

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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 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* NCPF 2275
- **Accreditation**
 - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).

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