inc.	Р	U.S. Micro-Solu hone: (724) 853-4047	tions, Inc. * 302 (Fax: (724) 853-4 <u>www.usm</u> ;	4049 All	a * Latrobe, F IA-LAP, LLC		03009		
Customer Name: Customer Address:	P.O. Bo Racine,	n Air Flow x 085595 WI 53406		Date Date	ple Date: Received: of Report:		May 5, 2021 May 10, 202 May 18, 202	21	
Customer Phone: PO Number:	(262) 63 050521	9-6796		Fax:	ntion:		Tom Mikule	ocky	
Project Name/Number:		npounder		Allei				iony	
	c	Customer sample numb	pers below are u	niquely ide	entified by pr	efixing Lab	oratory # 5	4544-21	
		Bioaerosol Sample(s) for Bacterial A	Analysis - /	Analytical Me	ethod MIC 0	5		
Sample Number			Sample Descript			Results	of Microbia	-	Ra C1
ISO Clas	s 5	Viable Air Le	vel: Count Below	Action Leve				of Personnel	
1			LAFW 6604323	33		Total Microb	ial Count <	:1 C	FU/m ³ of air
Total Raw Coun	ت <1							No growth	
Total Volume		liters of air							
Analytical Sensitivity	r: 1	CFU/m ³ of air				F	Pore Correct	tion Factor	C
ISO Clas		Viable Air Le	vel: Count Below	Action Leve	1		No	of Personnel	in Room: 1
3			LAFW 8905681	4		Total Microb	ial Count	<1 C	FU/m ³ of air
								No growth	
Total Raw Count Total Volume		liters of air							
Analytical Sensitivity		CFU/m ³ of air				F	Pore Correct	tion Factor	C
ISO Clas	s 7	Viable Air Le	vel: Count Below	Action Leve			No	of Personnel	in Room: 1
5			IV Room			Total Microb	ial Count <	:1 C	FU/m ³ of air
						·		No growth	
Total Raw Count									
Total Volume		liters of air				F	Pore Correct	tion Factor	C
Analytical Sensitivity	r: 1	CFU/m ³ of air				ſ			L. L.
				Media: TS	SA w/Lec Poly 8	80 Mar	nufacturer:	Remel	
Air Sampler:		Impaction Head (# of holes)		Lot Number:			Exp Date:	
SAS; Super 180		219			279512			07/06/21	
			Notation for Bo	Ided Microb	es				
USP<797> Phan	maceutical C	compounding-Sterile Prepara	tions states recovery	of any mold,	yeast, coagulas		ohylococcus, d	or gram-negativ	e rod
		requires im	mediate remediation a	and investigat	ion into the caus	se.			

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

Solutions Inc.	U.S. Micro-So Phone: (724) 853-4047	Dutions, Inc. * 302 Unity 7 Fax: (724) 853-4049 www.usmslab	AIHA-LAP, LLO	PA 15650 C EMLAP #103009	
Customer Name: Customer Address: Customer Phone: PO Number: Project Name/Number:	Northern Air Flow P.O. Box 085595 Racine, WI 53406 (262) 639-6796 050521 The Compounder Customer sample nut	mbers below are uniqu	Sample Date: Date Received: Date of Report: Fax: Attention: ely identified by p	May 5, 2021 May 10, 2021 May 18, 2021 Tom Mikulecky prefixing Laboratory # 54544-21	
	Bioaerosol Samp	le(s) for Bacterial Analy	/sis - Analytical M	lethod MIC 05	
Sample Number		Sample Description		Results of Microbial Analysis	CIS
ISO Class	s 8 Viable Air	Level: Count Below Actio	n Level		nel in Room: 1
7		Ante Area		Total Microbial Count < 1 No growt	CFU/m ³ of air
Total Raw Count Total Volume Analytical Sensitivity	: 1000 liters of air			Pore Correction Facto	or O

		Media: TSA w/Lec Poly 80 Ma	anufacturer: Remel				
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:				
SAS; Super 180	219	279512	07/06/21				
	Notation for B	olded 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.							
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

	inc.	P	U.S. Micro-So hone: (724) 853-404	blutions, Inc. * 302 Unit 7 Fax: (724) 853-4049 <u>www.usmslab</u>	AIHA-LAP, LL	PA 15650 C EMLAP #103009	
Cus Cus PO	stomer Name: stomer Address: stomer Phone: Number: ject Name/Number:	P.O. Bo Racine, (262) 63 050521	n Air Flow x 085595 WI 53406 9-6796 npounder		Sample Date: Date Received: Date of Report: Fax: Attention:	May 5, 2021 May 10, 2021 May 18, 2021 Tom Mikulecky	
			•	mbers below are uniqu	ely identified by p	prefixing Laboratory # 54544-21	
			Bioaerosol Sam	ple(s) for Fungal Analy	sis - Analytical M	ethod MIC 05	
San	nple Number			Sample Description		Results of Microbial Analysi	s Raw CTs
	ISO Class	5	Viable Air	Level: Count Below Action	on Level	No of Person	nel in Room: 1
1F				LAFW 66043233		Total Microbial Count < 1	CFU/m ³ of air
	Total Raw Count Total Volume Analytical Sensitivity ISO Class	1000 1	liters of air CFU/m³ of air Viable Air	Level: Count Below Actic	on Level	Pore Correction Facto	or 0 Inel in Room: 1
3F				LAFW 89056814		Total Microbial Count < 1	CFU/m ³ of air
	Total Raw Count Total Volume Analytical Sensitivity	1000	liters of air CFU/m³ of air			No growt Pore Correction Facto	
	ISO Class	5 7	Viable Air	Level: Count Below Action	on Level	No of Person	inel in Room: 1
5F				IV Room		Total Microbial Count < 1	CFU/m ³ of air
	Total Raw Count Total Volume Analytical Sensitivity	1000	liters of air CFU/m³ of air			No growt Pore Correction Facto	

		Media: SDA w/Lec Poly 80 Manufa	cturer: Remel					
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:					
SAS; Super 180	219	279513	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.								

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 d Kiska

Inc.	Ρ	U.S. Micro hone: (724) 853-4	-Solutions, Inc. * 302 U 047 Fax: (724) 853-40 www.usmsl	049 AIHA-LAP, LL	PA 15650 C EMLAP #103009		
Customer Name: Customer Address: Customer Phone:	P.O. Bo Racine, (262) 63	n Air Flow x 085595 WI 53406 9-6796		Sample Date: Date Received: Date of Report: Fax:	May 18, 202	21 21	
PO Number: Project Name/Number:	050521 The Cor	npounder		Attention:	Tom Mikule	ecky	
	С	ustomer sample i	numbers below are uni	quely identified by p	prefixing Laboratory # 54	4544-21	
		Bioaerosol Sa	ample(s) for Fungal Ana	alysis - Analytical Mo	ethod MIC 05		
Sample Number			Sample Description	on	Results of Microbial	I Analysis	Raw CTs
ISO Clas	s 8	Viable	Air Level: Count Below A	ction Level			el in Room: 1
7F			Ante Area		Total Microbial Count <	: 1 No growth	CFU/m ³ of air
Total Raw Count Total Volume Analytical Sensitivity	: 1000	liters of air CFU/m³ of air			Pore Correct	tion Factor	0

		Media: SDA w/Lec Poly 80 M	anufacturer: Remel					
Air Sampler:	Impaction Head (# of holes)	Lot Number:	Exp Date:					
SAS; Super 180	219	279513	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.							

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:

Dec	inna	ړ	Ki	ska	

Southous Jinc.			cro-Solutions, Inc. * 302 Uni i3-4047 Fax: (724) 853-404 www.usmsla	9 AIHA-LAP, LI				
Customer Name: Customer Address:	P.O. B	ern Air Flow sox 085595 e, WI 53406		Sample Date: Date Received: Date of Report:	May 5, 202 May 10, 20 May 18, 20)21		
Customer Phone: PO Number: Project Name/Number:	05052 The C	ompounder		Fax: Attention:	Tom Miku	-		
	(e numbers below are unique Plate(s) for Bacterial Analys			54544-21		
Sample Number			Sample Description		Results of Micro	bial Ana	lysis	Raw CTs
ISO Class	s 5	Viable Su	rface Level: Count Below Actio	n Level		No of Per	sonnel in Room:	1
2			LAFW 66043233		Total Microbial Count	< 1	CFU/plate	-
Total Raw Count Analytical Sensitivity ISO Class 4 Total Raw Count	: 1 s 5		rface Level: Count Below Actio LAFW 89056814	n Level	Total Microbial Count	No of Per < 1 No gr	rsonnel in Room: CFU/plate owth	1
Analytical Sensitivity		CFU/plate	feed and Denni Delan Astis					<u> </u>
ISO Class	s 7	Viable Sui	rface Level: Count Below Actio IV Room	n Level	Total Microbial Count	No of Per	rsonnel in Room: CFU/plate	1
6						No gr	·	
Total Raw Count Analytical Sensitivity		CFU/plate				9.		

Notes:	Media: TSA w/Leo	Poly 80 Manufacturer: Remel
	Lot Number:	Exp Date:
	279512	07/06/21
Notation for Bolded Micros	bes	
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold	, yeast, coagulase-positive S	taphylococcus, or gram-negative rod

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

Southous J. Inc.	U.S. Micro-Solutio Phone: (724) 853-4047		ity Plaza * Latrobe, 9 AIHA-LAP, LL ⁰ <u>b.com</u>				
Customer Name: Customer Address:	Northern Air Flow P.O. Box 085595 Racine, WI 53406		Sample Date: Date Received: Date of Report:	May 5, 202 May 10, 20 May 18, 20	21		
Customer Phone: PO Number: Project Name/Number:	(262) 639-6796 050521 The Compounder		Fax: Attention:	Tom Mikule	-		
	Customer sample numbers Contact Plate(s) fo				54544-21		
Sample Number			sis - Analytical Met		hial Anal	voie	Raw
Sample Number ISO Class		mple Description	n l evel	Results of Micro		sonnel in Room:	CTs
8	S o Viable Surface Level.	Ante Area		Total Microbial Count	< 1	CFU/plate	-
Total Raw Count Analytical Sensitivity							

Notes:	Media: TSA w/Lec Poly 8	30 Manufacturer: Remel
	Lot Number:	Exp Date:
	279512	07/06/21
Notation for Bolded Microl	bes	
USP<797> Pharmaceutical Compounding-Sterile Preparations states recovery of any mold	l, yeast, coagulase-positive Staphylc	coccus, or gram-negative rod
requires immediate remediation and investiga	ation 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

	Inc.			utions, Inc. * 302 Unity Pla Fax: (724) 853-4049 / www.usmslab.com	AIHA-LAP, LLC	PA 15650 EMLAP #103009		
	omer Name: omer Address:	P.O. B	ern Air Flow ox 085595 e, WI 53406	Date	nple Date: e Received: e of Report:	May 5, 202 May 10, 20 May 18, 20	21	
PO N	omer Phone: Jumber: ect Name/Number:	05052	639-6796 1 ompounder	Fax Atte	: intion:	Tom Mikul	ecky	
				bers below are uniquely id			54544-21	
_				s) for Fungal Analysis - Ar				Raw
Samp	Sample Number			Sample Description	1	Results of Micro	-	CTs
2F	ISO Class 5		Viable Surface Le	vel: Count Below Action Leve LAFW 66043233		otal Microbial Count	No of Personnel in Roor < 1 CFU/plat	-
4F	Total Raw Count: Analytical Sensitivity: ISO Class	1	CFU/plate Viable Surface Le	vel: Count Below Action Leve LAFW 89056814		Fotal Microbial Count	No growth No of Personnel in Roor < 1 CFU/plat	
	Total Raw Count: Analytical Sensitivity:		CFU/plate				No growth	
	ISO Class	7	Viable Surface Le	vel: Count Below Action Leve			No of Personnel in Roor	
6F		<1		IV Room		Total Microbial Count	< 1 CFU/plat	e
	Total Raw Count:		CFU/plate					
	Analytical Sensitivity:		or opiato					
	Analytical Sensitivity:			Media:	SDA w/Lec Pol	y 80 Manufactur		
	Analytical Sensitivity:			Media:	Lot Number:	y 80 Manufactur	Exp Date:	
	Analytical Sensitivity:			Media:		y 80 Manufactur		
	Analytical Sensitivity:			Media:	Lot Number: 279513	y 80 Manufactur	Exp Date:	
Notes:	Analytical Sensitivity:	1	al Compounding-Sterile Prepa		Lot Number: 279513 obes Id, yeast, coagulas	se-positive Staphylococcus	Exp Date: 07/06/21	

should be considered s *Fungus (mold, yeast)

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Technical Manager:

Deanna & Kiska

Statutes Inc.		ions, Inc. * 302 Unit Fax: (724) 853-4049 <u>www.usmslab</u>	AIHA-LAP, LL			
Customer Name: Customer Address:	Northern Air Flow P.O. Box 085595 Racine, WI 53406		Sample Date: Date Received: Date of Report:	May 5, 20: May 10, 2 May 18, 2	021	
Customer Phone: PO Number: Project Name/Number:	(262) 639-6796 050521 The Compounder		Fax: Attention:	Tom Miku	llecky	
	Customer sample numbe				54544-21	
	Contact Plate(s)	for Fungal Analysis	- Analytical Meth	nod MIC 05		Dava
Sample Number		ample Description		Results of Micro	-	Raw CTs
ISO Class 8F	s 8 Viable Surface Leve	I: Count Below Action Ante Area	Level	Total Microbial Count	No of Personnel in Room	-
					No growth	
Total Raw Count Analytical Sensitivity						
Notes:		Media:	Lot Number:	oly 80 Manufactu	Exp Date:	
			279513		07/06/21	
		Notation for Bolded				
	rmaceutical Compounding-Sterile Preparati requires imme	ediated remediation and	investigation into the o	ause.		
Samples are in good condition un should be considered significant. *Fungus (mold, yeast)	less otherwise noted. Results relate only to the	e samples tested as receiv	red. Results are reported	ed as calculated. For biologic	cal data, the first and/or second o	digit

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Technical Manager:

Deanna & Kiska

inc.	U.S. Micro-Sol Phone: (724) 853-4047	utions, Inc. * 302 Unity Fax: (724) 853-4049 <u>www.usmslab</u>	AIHA-LAP, LLC EM		
Customer Name: Customer Address: Customer Phone: PO Number: Project Name/Number:	Northern Air Flow P.O. Box 085595 Racine, WI 53406 (262) 639-6796 050521 The Compounder Customer sample num	nbers below are unique	Sample Date: Date Received: Date of Report: Fax: Attention:	May 5, 2021 May 10, 2021 May 18, 2021 Tom Mikulecky ing Laboratory # 54544-21	
	Media Co	ntrol(s) Analysis - Ana	lytical Method MIC 05		
Sample Number		Sample Description	F	esults of Microbial Analysis	
Pos Control		Positive			
				wth of Staphylococcus aureus n of Pseudomonas aeruginosa Growth of Bacillus subtilis	
Neg Control*		Negative			
Results a	re not blank corrected			No growth	

			TSA w/Lec Poly 80	Manufacturer:	Remel
			Lot Number:		Exp Date:
			279512		07/06/21
Notation for Bolded Microbes					
USP<797> Pharmaceutical Co	omnounding-Sterile Prenarations states recover	v of anv m	old veast coaquiase-positi	ve Stanbylococcus	or gram-negative rod

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.

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Technical Manager:

Deanna & Kiska Deanna L. Kiska, Ph.D.

inc.	U.S. Micro-Sol Phone: (724) 853-4047	utions, Inc. * 302 Unity Fax: (724) 853-4049 <u>www.usmslab</u>	AIHA-LAP, LLC EI		
Customer Name: Customer Address: Customer Phone: PO Number: Project Name/Number:				May 5, 2021 May 10, 2021 May 18, 2021 Tom Mikulecky xing Laboratory # 54544-21	
Sample Number		ntrol(s) Analysis - Ana		Results of Microbial Analysis	
Pos Control		Positive		Growth of Candida albicans	
			G	rowth of Aspergillus brasiliensis	
Neg Control*		Negative			
Results a	re not blank corrected			No growth	

	Media: SDA w/Lec Poly 80 Ma	nufacturer: Remel
	Lot Number:	Exp Date:
	279513	07/06/21
Notation for B	olded Microbes	
USP<797> Pharmaceutical Compounding-Sterile Preparations states recover	v of any mold yeast coaquilase-positive Sta	inhylococcus or gram-negative rod

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Technical Manager:

Deanna & Kiska Deanna L. Kiska, Ph.D.



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
 - 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 25923
 - Pseudomonas aeruginosa ATCC 9027
 - Bacillus subtilis ATCC 6633
 - o Candida albicans ATCC 10231
 - o 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



302 Unity Plaza Latrobe, PA 15650

P: 724.853.4047 F: 724.853.4049

supplies@usmslab.com

Cleanroom Environmental Monitoring – CHAIN OF CUSTODY

	Custo	omer Inf	formation	on		
Customer Name: Northern Air Flow		Phone #: 2	62.639	.6796	FAX #:	
Address: P.O. Box 085595		City: Rac	ine		State: WI	Zip: 53406
Attention To: Tom Mikulecky		E-Mail: tjn	n@north	nernairflow.c	om	- t
Sample Obtained By: J Mikulecky		Results:	☐ FAX	🔳 E-Mail	PO# 050521	Proposal #
Project Name/Number: The Comp	ounder				03072	-1
	presently.	Other - pleas	e specify:			
Comments: Please inoculate positive					an the second	
		lia Info	mation			
Media Type	Manufacture	er		Lot #		Expiration Date
TSA LOP	Remel	1		27951	2	7-6-21
Sab Dex L6P	Reme	el		27951		7.6.21
		•				
					· · · · · · · · · · · · · · · · · · ·	
······						
			1.6			
E	Bioaerosol S	Sample	r Intorn	nation		
Bioaerosol Sampler	# holes in he	ead Serial #		Calit	pration Due Date	
SAS; Super 180	219		17-D-11913			6/2021
				an a		
Relinquished By (Customer MUST sign)					Date 8	& Time
	5/5/	21	•			
Received By - Lab/Use Only	A		Date & Ti	법입 것 같아요. 그렇게 잘 사람이 가지 않니?	Lab#	4544-21

Rev. 11-5-18

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

Г

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 ID	
	BFÇ	Bacteria & Fungi – Counts only		BC	Bacteria – Counts only	
Single	SPG	Bacteria & Fungi – Counts w/ Genus ID		FG	Fungi – Counts w/ Genus ID	
Plate	SPS	Bacteria & Fungi – Counts w/ Species ID	Fungal Culture	FS	Fungi – Counts w/ Species ID	
Method	SPC	Bacteria & Fungi – 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

Page: 1 of ____



302 Unity Plaza Latrobe, PA 15650

P: 724.853,4047 F: 724.853.4049

AN ENVIRONMENTAL MICROBIOLOGY LAB

supplies@usmslab.com

Cleanroom Environmental Monitoring - CHAIN OF CUSTODY - Additional Samples

Sample #	Sample Date	Sample Code	Analysis Code	Sample Location & Description	Sample Volume	ISO Class	# People in Room	Static Dynam (S or D
1/14	5-5-21	A	BFG	LAFW 66043233	1000/1	5	I	D
2/24		i		ч I _I	•	5	1	D
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