	Juc.	Phone:	U.S. Micro-Solution: (724) 853-4047 Fax	s, Inc. * 302 Unity Plaza k: (724) 853-4049 AIH www.usmslab.com	nc. * 302 Unity Plaza * Latrobe, PA 15650 724) 853-4049 AIHA-LAP, LLC EMLAP #103009 www.usmslab.com					
	Customer Name: Customer Address:	Norther PO Box Racine,	n Air Flow 085595 WI 53406		Sample Date: Date Received: Date of Report:	Novembe Novembe Novembe	r 13, 2019 r 14, 2019 r 21, 2019			
	Customer Phone: PO Number: Project Name/Number:	(262) 63 111319-	9-6796 1 Customer sample nu	imbers below are uniqu	Fax: Attention:	T Mikulec	T Mikulecky			
		Bioae	rosol Sample Set(s)	for Bacterial & Fungal	Analysis - Analyt	ical Method USMS-G065				
Sample Sa	Description / ample Number					Results of Microbia	Raw CTs			
LAFW	66043233				-	Total Microbial Count	< 1	CFU/m ³ of air		
	ISO Class	5	Viable Air L	evel: Count Be	low Action Level					
	1					Total Bacterial Count:	< 1	CFU/m ³ of air		
Bacteria	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Correc	ction Factor	0		
	1F					Total Fungal Count:	< 1	CFU/m ³ of air		
Fungi	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Correc	ction Factor	0		
LAFW	89056814				-	Total Microbial Count	< 1	CFU/m ³ of air		
	ISO Class	5	Viable Air L	evel: Count Be	low Action Level			0511/ 0 / 1		
	3					Total Bacterial Count:	< 1 No growth	CFU/m ³ of air		
Bacteria	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Correc	ction Factor	0		
	3F					Total Fungal Count:	< 1	CFU/m ³ of air		
Fungi	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Correc	No growth	0		
	Air Sampler:	lm	paction Head (# of holes)	Media:	Manufacturer:	Lot Number:		Exp. Date:		
	SAS		180	TSA w/Lec Poly 80	Remel	852611		11/26/19		
				Viable sa	mpling was conducted	while the cleanroom was in an a	active or dyna	mic state.		
				Notation for Bolded Micr	obes					
Regulto rel	USP<797> Pharmach in any a	eutical Com area is cons	pounding-Sterile Preparation	ons states recovery of any monoce and immediate remediation	old, yeast, coagulase-p on and investigation int	positive Staphylococcus, or gram to the cause must be conducted.	n-negative rod			

*Fungus (mold, yeast)

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Technical Manager: Revon Lanchalsky

Sharon Fanchalsky, AS, MLT (ASCP)

	Inc.	Phone:	U.S. Micro-Solutions (724) 853-4047 Fax	s, Inc. * 302 Unity Plaza c: (724) 853-4049 AIH www.usmslab.com	a * Latrobe, PA 15 A-LAP, LLC EML	5650 AP #103009	(Contraction of the second		
	Customer Name: Customer Address:	Norther PO Box Racine,	n Air Flow 085595 WI 53406		Sample Date: Date Received: Date of Report:	Novembe Novembe Novembe	er 13, 2019 er 14, 2019 er 21, 2019			
	Customer Phone: PO Number: Project Name/Number:	(262) 63 111319-	9-6796 1 Customor complemu	mbara balawara unia	Fax: Attention:	T Mikuleo	cky			
		Bioae	rosol Sample Set(s) f	for Bacterial & Fungal	Analysis - Analyt	ical Method USMS-G065	111470-19			
Sample	Description /					Results of Microbi	al Analysis	Raw		
						Total Microbial Count	<u> </u>	CFU/m ³ of air		
	ISO Class	7	Viable Air I	evel: Count Bel	ow Action Level	No	of Personne	el in Room 7		
	5	•				Total Bacterial Count:	< 1	CFU/m ³ of air		
Bacteria	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Corre	No growth	0		
	5F					Total Fungal Count:	< 1	CFU/m ³ of air		
Fungi	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Corre	ction Factor	0		
Ante A	Area					Total Microbial Count	Pore Correction Factor Microbial Count < 1			
	ISO Class	8	Viable Air L	evel: Count Bel	ow Action Level	No	of Personne	el in Room: 8		
Bacteria	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Correct	< 1 No growth	0		
	7F					Total Fungal Count:	< 1	CFU/m ³ of air		
Fungi	Total Raw Count: Total Volume: Analytical Sensitivity:	<1 1000 1	liters of air CFU/m³ of air			Pore Corre	No growth	0		
	Air Sampler:	lm	paction Head (# of holes)	Media:	Manufacturer:	Lot Number:		Exp. Date:		
	SAS		180	TSA w/Lec Poly 80	Remel	852611 862378		11/26/19 12/12/19		
		L		Viable sa	mpling was conducted	while the cleanroom was in an	active or dyna	mic state.		
				Notation for Bolded Micr	obes					
Posulte ro	USP<797> Pharmace in any a	eutical Com rea is cons	pounding-Sterile Preparatio idered not to be in complian	ons states recovery of any mo nee and immediate remediation	old, yeast, coagulase-p on and investigation in condidiate should be con-	positive Staphylococcus, or gran to the cause must be conducted	m-negative rod I.			

ted. For biological data, the first and/or second digit should be considered significant. imples tested. Results are reported as calc *Fungus (mold, yeast)

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Technical Manager: Revon Lanchelsky

Sharon Fanchalsky, AS, MLT (ASCP)

	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: Customer Address:	Northern Air Flow PO Box 085595 Racine, WI 53406		Sample Date: Date Received: Date of Report:	November 13, November 14, November 21,	2019 2019 2019						
	Customer Phone: PO Number: Project Name/Number:	(262) 639-6796 111319-1 Customer sample nur	mbers below are uniq	Fax: Attention: uely identified by pre	T Mikulecky fixing Laboratory #: 1114	70-19						
		Media Control(s) for Ba	acterial & Fungal Ana	ysis - Analytical Met	hod USMS-G065							
Sample Sa	Description / ample Number				Results of Microbial Ana	alysis						
Positive Control												
	Positive Control											
Bacteria				Gri	Growth of Staphylococcus a owth of Pseudomonas aerug Growth of Bacillus s	ureus jinosa ubtilis						
	Positive Control					11-						
Fungi					Growth of Candida alt	bicans						
Negati	ve Control											
	Negative Control*											
Bacteria	*Results a	re not blank corrected			No gi	owth*						
	Negative Control*											
Fungi	Negative Control* No growth* *Results are not blank corrected											
			Media:	Manufacturer:	Lot Number:	Exp. Date:						
			TSA w/Lec Poly 80	Remel Remel	852611 862378	11/26/19 12/12/19						
		•			0020.0							
			Notation for Bolded Micr	obes								
Reculte rol	USP<797> Pharmac in any a ate only to the samples tested. Re	eutical Compounding-Sterile Preparation area is considered not to be in compliant esults are reported as calculated. For biological	ns states recovery of any more and immediate remediation of the first and/or second states the first and/or second states and the first and/or second states and the first	ora, yeast, coagulase-positi on and investigation into the cond digit should be consider	ve <i>Stapnylococcus,</i> or gram-nega e cause must be conducted.	tive roa						

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Technical Manager: Revon Lanchaloky

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	Inc.	U.S. Micro-Sol Phone: (724) 853-4047	utions, Inc. * 302 Unity Plaza Fax: (724) 853-4049 AIH www.usmslab.com	* Latrobe, PA 15650 A-LAP, LLC EMLAP #103009	, (Carry state
	Customer Name: Customer Address:	Northern Air Flow PO Box 085595 Racine, WI 53406	Sa Da Da	mple Date: te Received: te of Report:	November 13, 2019 November 14, 2019 November 21, 2019	
	Customer Phone: PO Number: Project Name/Number:	(262) 639-6796 111319-1	Fa At	x: ention:	T Mikulecky	
		Customer sample	numbers below are unique	y identified by prefixing Lab	oratory #: 111470-19	
Sample	e Description /		sy for Baoterial & Fungar Ana	Re	sults of Microbial Analy	vsis Raw
	Sample Number			Total Miarahi	ial Count	CELI/plata
	ISO Class	5 Viable Surface	e Level: Count Below	Action Level		CF0/plate
	2			Total Bacteria	al Count: < 1	CFU/plate
	2				No gro	wth
Bacteria	Total Raw Count:	: <1				
	Analytical Sensitivity:	1 CFU/plate				
	2F			Total Funga	I Count: < 1	CFU/plate
Fungi	Total Raw Count: Analytical Sensitivity:	: <1 : 1 CFU/plate				
LAFW	V 89056814			Total Microbi	al Count < 1	CFU/plate
	ISO Class	5 Viable Surface	e Level: Count Below	Action Level		
	4			Total Bacteria	al Count: < 1	CFU/plate
Bacteria	Total Raw Count: Analytical Sensitivity:	: <1 : 1 CFU/plate			NO GIO	wu
	4F			Total Funga	I Count: < 1	CFU/plate
Fungi	Total Raw Count: Analytical Sensitivity:	: <1 : 1 CFU/plate			No gro	wth
Media: Lot Num	TSA w/Lec Poly 80 nber:	Manufacturer: Remel Exp Date:	Media: Lot Numb	SDA w/Lec Poly 80 er:	Manufacturer: Remel Exp Date:	
	852611	11/	26/19	862378		12/12/19
		Viable sampling w	ras conducted while the cleanroom v Notation for Bolded Micr	as in an active or dynamic state.		
Results r	USP<797> Pharm in ar relate only to the samples tested. R	naceutical Compounding-Sterile Pre ny area is considered not to be in co esults are reported as calculated. For	parations states recovery of any mo ompliance and immediate remediation biological data, the first and/or second	ld, yeast, coagulase-positive Staphy n and investigation into the cause n digit should be considered significant	<i>lococcus,</i> or gram-negative r nust be conducted.	od

*Fungus (mold, yeast)

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Technical Manager: Kewn Lanchaloty Sharon Fanchalsky, AS, MLT (ASCP)

	Signature State	Solutions	Pho	U.S. Micro ne: (724) 853-4	-Solutions, Inc. 047 Fax: (724 www	* 302 Unity P) 853-4049 /.usmslab.cc	laza * Latrobe, P AIHA-LAP, LLC <u>m</u>	PA 15650 EMLAP #10300	9	(Cean a stand
	Customer Nar Customer Ado	ne: dress:	Norther PO Box Racine,	n Air Flow 085595 WI 53406			Sample Date: Date Received: Date of Report	:	November November November	13, 2019 14, 2019 21, 2019	
	Customer Pho PO Number: Project Name/	one: /Number:	(262) 63 111319-	9-6796 1			Fax: Attention:		T Mikuleck	у	
				Customer sar	nple numbers b Set(s) for Bacter	elow are unio	quely identified Analysis - Analy	by prefixing Lat	boratory #: 1	111470-19	
Sample	e Description /							Re	esults of Mic	robial Analy	/sis Raw
E E E E E E E E E E E E E E E E E E E	Sample Numbe	r						Total Microh	ial Count	. 1	CELI/plate
	om	ISO Class	7	Viable Sur	face Level:	Count Be	ow Action Leve			< I No of Pers	onnel in Room: 7
	c		•			oount Bo		Total Bacter	ial Count:	< 1	CFU/plate
	0									No gro	wth
Bacteria	Total Analytica	Raw Count: I Sensitivity:	<1 1	CFU/plate							
	6F							Total Funga	al Count:	< 1	CFU/plate
Fungi	Total Analytica	Raw Count: I Sensitivity:	<1 1	CFU/plate							
Ante	Area							Total Microb	ial Count	< 1	CFU/plate
		ISO Class	8	Viable Sur	face Level:	Count Be	ow Action Leve			No of Pers	onnel in Room: 8
	8							Total Bacter	ial Count:	< 1	CFU/plate
Bacteria	Total Analytica	Raw Count: I Sensitivity:	<1 1	CFU/plate						No gro	wth
	8F							Total Funga	al Count:	< 1	CFU/plate
Fungi	Total Analytica	Raw Count: I Sensitivity:	<1 1	CFU/plate						No gro	wth
Media: Lot Num	TSA w/Lec	Poly 80	Manuf	acturer: Remel		Media Lot N	umber: SDA v	w/Lec Poly 80	Manufactu	rer: Remel	
Lot Hull	8526	611		inp Duto.	11/26/19	LOUN	1	862378			12/12/19
				Viable sampl	ing was conducted v	while the cleanro	om was in an active	or dynamic state.			
	USF	P<797> Pharm in ar	aceutical C ny area is c	Compounding-Steril onsidered not to be	e Preparations state	es recovery of an immediate reme	y mold, yeast, coagu diation and investiga	Ilase-positive Staph tion into the cause I	nylococcus, or g must be conduc	gram-negative r sted.	od

*Fungus (mold, yeast)

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Technical Manager: Kewn Lanchaloty Sharon Fanchalsky, AS, MLT (ASCP)

Contact Plate Set(s) for Bacterial and Fungal Analysis Page 5 of 6



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 CFL	J 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
 - o 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).

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

	U S	.S. OL			D S INC.	YEN Code	IDE inged	Dan	natch.	S (U) 724.85	mp() 53.404	302 Latrobe,	Jnity Plaza PA 15650 4.853.4049		
Cleanroom Environmental Monitoring – CHAIN OF CUSTODY															
Customer Information															
Customer Name: Northern Air Flow Phone #: 262.639.6796 FAX #:															
Addres	s: P.O. Box 08	8559	95			_{City:} Rac	ine			State: V	VI	Zip: 534	106		
Attentio	on To: T Mikule	cky				_{E-Mail:} tjm	@north	nern	airflowcon	n					
Sample	e Obtained By: Jar	ed N	likulecky			Results:	☐ FAX		🔳 E-Mail	PO#	9-1	Proposal	# .		
Project	Name/Number:														
Type of Project: USP 797 USP not 797 Other - please specify: Comments: Please inoculate positive controls at lab															
Media Information															
Medi	а Туре	1		Γ	Manufactu	rer		Lot	:#			Expiration Date			
	TSIA W	poly	+ LEC		Reme	(852 WI			N	26 19		
	Seh D)ex	Lip		Rem		-		842378			12	12/19		
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····.	· · · · ·			Bi	aarosol	Sample	r Inforr	nati	on		• }				
Piezo	racal Sampler				holes in h	ead	Serial	#			Calib	ration D	ue Date		
DIUde	SAS	S	· · · · · · · · · · · · · · · · · · ·		18	0	1	17-	D-11913		1.1.	6/20	19-		
			<u></u>								4/20	22			
Relinqu	ished By (Customer	MUST	sign)		Rih	11	13/16				Date &	Time			
Dhahim	d By - 1 sh Lisa Oh	IV A	٨	(Date & T	īme			Lab #				
Receive	By - Lab Use Off	Ń	li_			5	11114	19	0950).	-111	170	19		
	V	1					A '		Code	<u>.</u>		• • •			
Sa	mple Code						Ana	iysis	Loae		Bast				
А	Air Plate		Dual Plate	BFG	Bacteria & F	-ungi – Count	s w/ Genus		Bacterial	BG	Bacte	eria - Coun	ts w/ Species ID		
С	Contact Plate		Method	BFS	Bacteria & F	-ungi – Count	s w Specie	SID	Culture		Dacle				

Air Plate			BFG	Bacteria & Fungi – Counts w/ Genus ID		BG	Bacteria - Counts w/ Gerlus ID
	Contact Plate		BFS	Bacteria & Fungi – Counts w/ Species ID	Bacterial Culture	BS	Bacteria – Counts w/ Species ID
			BFC	Bacteria & Fungi – Counts only		BC	Bacteria – Counts only
Fingertip Plate			SPG	Bacteria & Fungi – Counts w/ Genus ID		FG	Fungi – Counts w/ Genus ID
Media Fill		Single Plate	SPS	Bacteria & Fungi – Counts w/ Species ID	Fungal Culture	FS	Fungi – Counts w/ Species ID
Garbing Plate		Method	SPC	Bacteria & Fungi – Counts only		FC	Fungi – Counts only
Swab		Pre-	IDG	Bacteria & Fungi – Counts w/ Genus ID	Media Fill	STER	Presence/Absence of Growth
Media Fill		incubated Plate	IDS	Bacteria & Fungi – Counts w/ Species ID	Media Fill pre-incubated	STER PRE	Subculture & ID of Positive Unit

Rev. 11-14-18

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302 Unity Plaza Latrobe, PA 15650

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supplies@usmslab.com

Cleanroom Environmental Monitoring – CHAIN OF CUSTODY – Additional Samples

Customer Name	Norther	h Air Fl	ow		Project Name/Number:	The Cou	npou.	nder	
Sample #	Sample Date	Sample Code	Analysis Code	Sample Loc	cation & Description	Sample Volume	ISO Class	# People in Room	Static/ Dynamic (S or D)
1/15	11-13-19	A	BFG	LAFW let	043233	1000/2	5	NA	\mathcal{D}
2 25	1	ĩ	BFE	ja	9.		5	NA	\mathcal{D}
3 3F		A	BFG	LAFW 8	905 4814	1000/0	5	MA	D
4 48		C	BFG	и	21		5	NA	D
5 54		β	BFh	τv	Room	1000/1	7	7	D
4 44		С	BR	· }ı	'1		7	7	D
7/78		Ą	BFG	Ante	Area	1000/1	8	8	D
8/86		i	BRE	ц	ι <u>.</u>		8	8	\mathcal{D}
				positive	control (2)				
	. V			negotiv	c control (2)				
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-									
					14				
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Received By - La	b Use Only	101			Date & Time	950 Lat	14	10-1	G
W. Sand					¥				1