



EMSL Analytical, Inc

**2500 Gateway Centre Blvd., Suite 600
Morrisville, NC 27560**

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Analytical Report - USP <797> Viable Environmental Sampling

Prepared Exclusively For:

**Contact Name
Company Name
123 Street
City, State Zipcode**

Date Sampled:	1/16/2019
Date Received:	1/17/2019
Date Analyzed:	1/24/2019
Date Reported:	1/28/2019
EMSL Order:	191900000

Sample Report

Alan Goldstein

Alan Goldstein, Lab Manager
Or Other Approved Signatory

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Samples analyzed by EMSL Analytical, Inc Morrisville, NC AIHA Accredited #173741.

Please visit our website at emsl.com for more information about our laboratory certifications and accreditations.



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EMSL Order #: 191900000
Customer ID:
Customer PO:

Attn: Contact Name
Company Name
123 Street
City, State Zipcode
Project: **Sample Report**
Phone: 800-123-1233
Fax: 800-123-1234
Collected: 1/16/2019
Received: 1/17/2019
Analyzed: 1/24/2019

Report Date: 01/28/2019 Revision: 1.00

Total Bacterial Air Count - USP <797>

Lab Sample Number	Client Sample ID & Location	ISO Class	Sample Volume (m ³)	Analytical Sensitivity (CFU / m ³)	Raw Count (CFU)	Total CFU / m ³	USP <797> Action Levels*
291900695-0009	15 - CR Left Hood Right	5	1.008	1	0	< 1	Count Below Action Level
291900695-0010	17 - CR Left Hood Left	5	1.008	1	0	< 1	Count Below Action Level
291900695-0011	19 - CR Right Hood Right	5	1.008	1	0	< 1	Count Below Action Level
291900695-0012	21 - CR Right Hood Left	5	1.008	1	0	< 1	Count Below Action Level
291900695-0013	23 - Clean Room Door	7	1.008	1	10	10	Count Below Action Level
291900695-0014	25 - Ante Room	8	1.008	1	5	5	Count Below Action Level
291900695-0015	33 - Chemo Hood Center	5	1.008	1	0	< 1	Count Below Action Level
291900695-0016	35 - Chemo Room Door	7	1.008	1	0	< 1	Count Below Action Level

TSA plates incubated at 35 ±2°C for 48-72 hours unless otherwise noted. Media Lot Number: 1832508 Expiration Date: Mar. 13, 2019
CFU=Colony forming unit NA=Not applicable

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Phone: **800-123-1233**
 Fax: **800-123-1234**

Collected: **1/16/2019**
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 Analyzed: **1/24/2019**

Report Date: 01/28/2019

Revision: 1.00

Bacterial Air Identifications - USP <797>

Lab Sample Number	Client Sample ID & Location	CFU / m3	Percentage of Total Count	Identification	Potential Pathogen*
291900695-0013	23 - Clean Room Door	5	50.0	Staphylococcus coagulase (-)	-
		5	50.0	Coryneform bacteria	-
291900695-0014	25 - Ante Room	2	40.0	Micrococcus sp.	-
		1	20.0	Coryneform bacteria	-
		1	20.0	Staphylococcus coagulase (-)	-
		1	20.0	Unidentifiable bacteria	-

CFU=Colony forming unit NA=Not applicable

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Project: Sample Report	Collected: 1/16/2019 Received: 1/17/2019 Analyzed: 1/24/2019

Report Date: 01/28/2019

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Total Fungal Air Count - USP <797>

Lab Sample Number	Client Sample ID & Location	ISO Class	Sample Volume (m ³)	Analytical Sensitivity (CFU / m ³)	Raw Count	Total CFU / m ³	USP <797> Action Levels*
291900695-0001	16 - CR Left Hood Right	5	1.008	1	0	< 1	Count Below Action Level
291900695-0002	18 - CR Left Hood Left	5	1.008	1	0	< 1	Count Below Action Level
291900695-0003	20 - CR Right Hood Right	5	1.008	1	0	< 1	Count Below Action Level
291900695-0004	22 - CR Right Hood Left	5	1.008	1	0	< 1	Count Below Action Level
291900695-0005	24 - Clean Room Door	7	1.008	1	0	< 1	Count Below Action Level
291900695-0006	26 - Ante Room	5	1.008	1	0	< 1	Count Below Action Level
291900695-0007	34 - Chemo Hood Center	5	1.008	1	0	< 1	Count Below Action Level
291900695-0008	36 - Chemo Room Door	7	1.008	1	1	1	Count Below Action Level

MEA plates incubated at 26-30°C for 5-7 days unless otherwise noted. CFU=Colony forming unit NA=Not applicable
 Media Lot Number: 1832410 Expiration Date: Mar. 12, 2019

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Project: **Sample Report**

Collected: **1/16/2019**
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Fungal Air Identifications - USP <797>

Lab Sample Number	Client Sample ID & Location	CFU / m3	Percentage of Total Count	Identification	Potential Pathogen*
291900695-0008	36 - Chemo Room Door	1	100.0	Sterile mycelium	Present

CFU=Colony forming unit NA=Not applicable

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Total Bacterial Contact Plate Count - USP <797>

Lab Sample Number	Client Sample ID & Location	ISO Class	Total CFU / Plate	USP <797> Action Levels*
291900695-0028	1 - CR Left Hood Right	5	None Detected	Count Below Action Level
291900695-0029	3 - CR Left Hood Left	5	None Detected	Count Below Action Level
291900695-0030	5 - CR Left Hood Center	5	None Detected	Count Below Action Level
291900695-0031	7 - CR Right Hood Right	5	None Detected	Count Below Action Level
291900695-0032	9 - CR Right Hood Left	5	None Detected	Count Below Action Level
291900695-0033	11 - CR Right Hood Center	5	None Detected	Count Below Action Level
291900695-0034	13 - Media Blank	N/A	None Detected	N/A
291900695-0035	29 - Chemo Hood Left Side	5	None Detected	Count Below Action Level
291900695-0036	31 - Chemo Hood Right Side	5	None Detected	Count Below Action Level
291900695-0037	39 - Cln Rm Wall	7	1	Count Below Action Level
291900695-0038	41 - Ent Ante Room Cln Room	8	None Detected	Count Below Action Level
291900695-0040	27 - Media Blank	N/A	None Detected	N/A

TSA plates incubated at 35 ±2°C for 48-72 hours unless otherwise noted. CFU=Colony forming unit NA=Not applicable

Media Lot Number: 1834401 Expiration Date: Apr. 1, 2019

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Bacterial Contact Plate Identifications - USP <797>

Lab Sample Number	Client Sample ID & Location	CFU / Plate	Percentage of Total Count	Identification	Potential Pathogen*
291900695-0037	39 - Cln Rm Wall	1	100.0	Bacillus sp.	-

CFU=Colony forming unit NA=Not applicable

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Total Fungal Contact Plate Count - USP <797>

Lab Sample Number	Client Sample ID & Location	ISO Class	Total CFU / Plate	USP <797> Action Levels*
291900695-0017	2 - CR Left Hood Right	5	None Detected	Count Below Action Level
291900695-0018	4 - CR Left Hood Left	5	None Detected	Count Below Action Level
291900695-0019	6 - CR Left Hood Center	5	None Detected	Count Below Action Level
291900695-0020	8 - CR Right Hood Right	5	None Detected	Count Below Action Level
291900695-0021	10 - CR Right Hood Left	5	None Detected	Count Below Action Level
291900695-0022	12 - CR Right Hood Center	5	None Detected	Count Below Action Level
291900695-0023	14 - Media Blank	N/A	None Detected	N/A
291900695-0024	30 - Chemo Hood Left Side	5	None Detected	Count Below Action Level
291900695-0025	32 - Chemo Hood Right Side	5	None Detected	Count Below Action Level
291900695-0026	40 - Cln Rm Wall	7	None Detected	Count Below Action Level
291900695-0027	42 - Ent Ante Room Cln Room	8	None Detected	Count Below Action Level
291900695-0039	28 - Media Blank	N/A	None Detected	N/A

MEA plates incubated at 26-30°C for 5-7 days unless otherwise noted. CFU=Colony forming unit NA=Not applicable

Media Lot Number: 1830202 Expiration Date: Feb. 18, 2019

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Received: **1/17/2019**
Analyzed: **1/24/2019**

Report Date: 01/28/2019

Revision: 1.00

Total Bacterial Glove Tip Count - USP <797>

Lab Sample Number	Client Sample ID & Location	ISO Class	Total CFU / Glove	USP <797> Action Levels* Based on Total Count per Operator
291900695-0042	37 - Glove Finger Tip	5	None Detected	-

MEA plates incubated at 35 ±2°C for 48-72 hours unless otherwise noted.

CFU=Colony forming unit NA=Not applicable

*Please reference USP <797> guidelines provided on the last page of the report. The designation of Count Above or Below Action Level is based on the total number of CFUs on both gloves and not per hand. The presence of "-" indicates that the action level for the paired gloves is on the next line of the report. Action levels are determined for qualified operators. USP <797> guidelines state that regardless of the number of CFUs recovered from the sampling location, further corrective actions will be dictated by the identification of the microorganisms recovered. Analytical procedures are based on USP <797> guidelines unless otherwise noted. EMSL maintains liability limited to cost of analysis. This report relates only to the samples reported above and may not be reproduced except in full, without written approval by EMSL. EMSL bears no responsibility for sample collection activities or analytical method limitations. Interpretation of the data contained in this report is the responsibility of the customer. Samples received in good condition unless otherwise noted.



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USP <797> Guidelines

Per USP <797> published guidelines: Action levels are determined on the basis of colony forming unit (CFU) data gathered at each sampling location and trended over time. The numbers in the following tables should be used only as guidelines. Regardless of the number of CFU identified in the pharmacy, further corrective actions will be dictated by the identification of microorganisms recovered (at least to the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a CFU using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive Staphylococcus, molds and yeasts) can be potentially fatal to patients receiving compounded sterile preparations and must be immediately remedied, regardless of CFU count.

Any CFU count that exceeds its respective action level (see Tables 1-3) should prompt a reevaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

Table 1. Recommended Air Testing Action Levels

Classification	Total CFU per cubic meter
ISO Class 5	>1
ISO Class 7	>10
ISO Class 8 or worse	>100

Table 2. Recommended Gloved Fingertip Testing Action Levels*

Classification	Limit (Qualified/Initial)
ISO Class 5	>3 / >0
ISO Class 7	Not required
ISO Class 8 or worse	Not required

*The action level for gloved hands is based on the total number of cfu on both gloves and not per hand.

Table 3. Recommended Surface Testing Action Levels

Classification	Limit (Work/Non-work Surface)
ISO Class 5	>3
ISO Class 7	>5
ISO Class 8 or worse	>100

Action limits based on approximately CFU / 25 cm² or CFU / 4 in².

For complete reference see official and current Chapter <797> at USP.org.

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