

Condition of Sample(s) Upon Receipt: Acceptable

Certificate of Analysis AIHA-LAP EMLAP# 102977

43760 Trade Center Place Suite 100 Sterling, Virginia 20166 (877) 648-9150 www.aerobiology.net

Aerobiology Sample Report
43760 Trade Center Place
Sterling, Virginia 20166
Attn: John Doe
Project: USP 797 Test

Date Collected: 06/14/2018
Date Received: 06/2018
Date Analyzed: 06/2018
Date Reported: 06/21/2018
Project ID: 18021265

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AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	IV Hood 1 ISO Class 5	5				
2	IV Hood 2 ISO Class 5	5				
3	Chemo Room 1 ISO Class 7	7				
4	Chemo Room 2 ISO Class 7	7				
5	Ante Room 1 ISO Class 8	8				Maximum count for Class 8 exceeded
6	Ante Room 2 ISO Class 8	8				
7	Positive Air Control	N/A				
8	Negative Air Control	N/A				
9	IV Hood 1 ISO Class 5	5				
10	IV Hood ISO Class 5	5				
11	Chemo Room 1 ISO Class 7	7				
12	Chemo Room 2 ISO Class 7	7				
13	Anteroom 1 ISO Class 8	8				
14	Anteroom 2 ISO Class 8	8				
15	Positive Surface Control	N/A				
16	Negative Surface Control	N/A				

N	No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
	Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
	O.O.C Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance with USP 797 and CAG-009 guidance documents.
	Sample results not applicable to USP 797 and CAG-009 guidance documents.



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Client Sample #: 1

Sample Location: IV Hood 1 ISO Class 5

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole Corrected Result: No Growth

Lab Sample #: 18021265-001

Positive Hole: 219
Air Volume: 1000 (L)

MRL: 1

Comments: Pass

Client Sample #: 1

Sample Location: IV Hood 1 ISO Class 5

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole Corrected Result: No Growth

Lab Sample #: 18021265-001

Positive Hole: 219
Air Volume: 1000 (L)

MRL: 1

Comments: Pass

Client Sample #: 2

Sample Location: IV Hood 2 ISO Class 5

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole Corrected Result: No Growth

Lab Sample #: 18021265-002

Positive Hole: 219
Air Volume: 1000 (L)

MRL: 1

Comments: Pass

Client Sample #: 2

Sample Location: IV Hood 2 ISO Class 5

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole Corrected Result: No Growth

Lab Sample #: 18021265-002

Positive Hole: 219 Air Volume: 1000 (L)

MRL: 1

Comments: Pass

Client Sample #: 3

Sample Location: Chemo Room 1 ISO Class 7

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole Corrected Result: 2 CFU/m³

Lab Sample #: 18021265-003

Positive Hole: 219

Air Volume: 500 (L)

MRL: **2**

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	Reservoirs
Bacillus species	1	2	100	Environment
	1	2	~100%	_
Comments: Acceptable				



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Client Sample #: 3 Lab Sample #: 18021265-003

Sample Location: Chemo Room 1 ISO Class 7

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole Corrected Result: No Growth Positiv

MRL: 2

Comments: Pass

Client Sample #: 4 Lab Sample #: 18021265-004

Sample Location: Chemo Room 2 ISO Class 7

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole Corrected Result: No Growth Positive Hole Corrected Result: No Growth Positive Hole Corrected Result: No Growth Positive Hole: 219

Air Volume: 500 (L) MRL: 2

Comments: Pass

Client Sample #: 4 Lab Sample #: 18021265-004

Sample Location: Chemo Room 2 ISO Class 7

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole Corrected Result: No Growth Positive Hole Corrected Result: No Growth Positive Hole: 219

MRL: 2

Comments: Pass

Client Sample #: 5 Lab Sample #: 18021265-005

Sample Location: Ante Room 1 ISO Class 8

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole: 219

Positive Hole Corrected Result: No Growth

Air Volume: 500 (L)

MRL: 2

Comments: Pass

Client Sample #: 5 Lab Sample #: 18021265-005

Sample Location: Ante Room 1 ISO Class 8

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole Corrected Result: 2 CFU/m³ Positive Hole Corrected Result: 2 CFU/m³

MRL: 2

Organism(s) Isolated:

Raw Count CFU/m³ % Total MRL

1 2 100 2

1 2 ~100%

Comments: 0.0.C.



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Client Sample #: 6

Sample Location: Ante Room 2 ISO Class 8

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole Corrected Result: 6 CFU/m³

Lab Sample #: 18021265-006

Positive Hole: 219
Air Volume: 500 (L)

MRL: 2

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	Reservoirs
Bacillus species	2	4	67	Environment
Micrococcus species	1	2	33	Human
Comments: Acceptable	3	6	~100%	

Client Sample #: 6

Sample Location: Ante Room 2 ISO Class 8

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole Corrected Result: No Growth

Lab Sample #: 18021265-006

Lab Sample #: 18021265-007

Lab Sample #: 18021265-007

Positive Hole: 219 Air Volume: 500 (L)

MRL: 2

Comments: Pass

Client Sample #: Control

Client Sample #: Control

Sample Location: Positive Air Control

Test: 1152, BACTERIAL AIR - USP 797 Positive (+) Control: SOP 2.2

Results: Growth

Sample Location: Positive Air Control

Test: 1153, FUNGAL AIR - USP 797 Positive (+) Control: SOP 3.2

Results: Growth

Client Sample #: Control Lab Sample #: 18021265-008

Sample Location: Negative Air Control

Test: 1156, BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2

Results: No Growth

Client Sample #: Control Lab Sample #: 18021265-008

Sample Location: Negative Air Control

Test: 1157, FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2

Results: No Growth