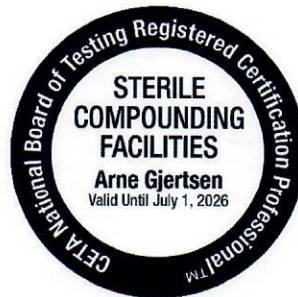




- + CONSULTING
- + CERTIFICATION
- + SERVICE SPECIALISTS
- + AIR BALANCING
- + DESIGN & COMPONENTS

PERFORMANCE CERTIFICATION

FOR
Crescent Healthcare
2010 Iowa Avenue
Suite 110
Riverside, CA 92507



Test Date:

May 24, 2022

1587 Sim Place Anaheim, CA 92802 [phone] 714-534-2770 [fax] 877-829-7921 [email] info@cleanroomsplus.com

www.cleanroomsplus.com

CERTIFICATION PROCEDURES

CLEANROOMS/CLEAN ZONES

Particle Count

Particle count testing was performed in accordance with ISO 14644 and followed the recommended practices in IEST-RP-006 and CETA Guidelines.

All data collected and calculations are presented in the individual component reports submitted with this document.

Test Instruments:

Laser Particle Counter – Climet model CI-150T, serial #131729; calibrated 3/2/22

Air Flow

All HEPA filters were measured and adjusted for airflow in accordance with ISO 14644-1, and IEST-RP-006.

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M13678; Calibrated 9/9/21

Pressure Differential

All rooms were measured for pressure differential in accordance with IEST-RP-006.

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M13678; Calibrated 9/9/21

HEPA Filter Integrity Test

As required, HEPA filters were scanned for leaks following the recommended practices in IEST-RP-0006.

All data collected and calculations are presented in the individual component reports submitted with this document.

Test Instruments:

Photometer - ATI Model TDA-2i, serial #23806; Calibrated 1/28/22

ENVIRONMENTAL COMPLIANCE

We hereby certify that the results recorded as part of this document are correct and accurate. Therefore, we certify that the subject cleanrooms/clean zones have met the requirements of ISO 14644, CETA Guidelines including CAG 003, and IEST Recommended Practices as established in this report.

Signature: _____



Arne Gjertsen
RCCP-SC #1114

Date: _____

5/24/22

Cleanrooms Plus
 1587 Sim Place
 Anaheim, CA 92802
 714-534-2770

Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions:	70 square feet
Date:	5/24/2022	Volume:	560 cubic feet
Room ID:	Class 5 Work Station 1	Test Status:	Dynamic
Class:	5		

Particle Count

Locations required:	6		
Particle Size	>0.5 micron	Location	Readings:
		1	70.6 Particle/M ³
		2	70.6 Particle/M ³
		3	0.0 Particle/M ³
		4	0.0 Particle/M ³
		5	0.0 Particle/M ³
		6	0.0 Particle/M ³

Maximum Count-	3,520 Particle/M ³
Pass/Fail	Pass

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Requirement:	72-108 FPM	1	101	91	96.0	7.25	696
		2	104	98	101.0	7.25	732
Avg. Velocity =	95.9	3	103	93	98.0	7.25	711
Pass/Fail :	Pass	4	107	108	107.5	7.25	779
		5	89	95	92.0	7.25	667
Measured Values Avg. +/- 20%		6	95	88	91.5	7.25	663
Min. value =	76.7	7	85	85	85.0	7.25	616
Max. value =	115.0						
Pass/Fail :	Pass				Total CFM =		4,865

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	29	<0.01%	N/R	Pass	None
2	28	<0.01%	N/R	Pass	None
3	29	<0.01%	N/R	Pass	None
4	26	<0.01%	N/R	Pass	None
5	30	<0.01%	N/R	Pass	None
6	31	<0.01%	N/R	Pass	None
7	33	<0.01%	N/R	Pass	None

Signature: _____



Date: _____

5/24/22

See Test Summary Sheet for instrument data & sketches for ID locations

Cleanrooms Plus
1587 Sim Place
Anaheim, CA 92802
714-534-2770

Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions:	28 square feet
Date:	5/24/2022	Volume:	224 cubic feet
Room ID:	Class 5 Work Station 2	Test Status:	Dynamic
Class:	5		

Particle Count

Locations required:	5		
Particle Size	>0.5 micron	Location	Readings:
		1	0.0 Particle/M ³
		2	70.6 Particle/M ³
		3	0.0 Particle/M ³
		4	35.3 Particle/M ³
		5	0.0 Particle/M ³

Maximum Count- 3,520 Particle/M³
 Pass/Fail **Pass**

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Requirement:	72-108 FPM	8	100	91	95.5	7.25	692
		9	98	97	97.5	7.25	707
Avg. Velocity =	94.2	10	87	92	89.5	7.25	649
Pass/Fail :	Pass						

Measured Values Avg. +/- 20%
 Min. value = 75.3
 Max. value = 113.0
 Pass/Fail : Pass

Total CFM = 2,048

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
8	29	<0.01%	N/R	Pass	None
9	29	<0.01%	N/R	Pass	None
10	31	<0.01%	N/R	Pass	None

Signature: 

Date: 5/24/22

See Test Summary Sheet for instrument data & sketches for ID locations

Cleanrooms Plus
1587 Sim Place
Anaheim, CA 92802
714-534-2770

Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions:	325 square feet
Date:	5/24/2022	Volume:	2600 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	8	Location	Readings:
Particle Size	>0.5 micron	1	31,324.1 Particle/M ³
		2	20,235.3 Particle/M ³
		3	36,409.4 Particle/M ³
		4	20,270.6 Particle/M ³
		5	10,064.7 Particle/M ³
		6	46,791.9 Particle/M ³
		7	19,811.5 Particle/M ³
		8	12,042.3 Particle/M ³

Maximum Count- 352,000 Particle/M³
 Pass/Fail **Pass**

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	88	90	89.0	7.25	645
Recommended=	30.0 /hour	2	98	90	94.0	7.25	682
Actual=	30.6 /hour						

Pass/Fail **Pass**

Total CFM = 1,327

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	31	<0.01%	N/R	Pass	None
2	30	<0.01%	N/R	Pass	None

Signature: 

Date: 5/24/22

See Test Summary Sheet for instrument data & sketches for ID locations

Cleanrooms Plus
 1587 Sim Place
 Anaheim, CA 92802
 714-534-2770

Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions	186 square feet
Date:	5/24/2022	Volume:	1488 cubic feet
Room ID:	Ante Room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5 micron	1	9,464.3 Particle/M ³
		2	11,618.5 Particle/M ³
		3	9,958.7 Particle/M ³
		4	27,192.3 Particle/M ³
		5	27,015.7 Particle/M ³
Maximum Count-	352,000 Particle/M ³	6	10,417.8 Particle/M ³
Pass/Fail	Pass		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	55	46	50.5	7.25	366
Recommended=	30.0 /hour	2	120	N/A	120.0	3.2	384
Actual=	30.2 /hour						
Pass/Fail	Pass						

Total CFM = 750

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	55	<0.01%	N/R	Pass	Yes
2	53	<0.01%	N/R	Pass	No

Signature: _____



Date: _____

5/24/22

See Test Summary Sheet for instrument data & sketches for ID locations

Airflow Smoke Pattern Test

Crescent Riverside

May 24, 2022

Objective:

To perform airflow smoke pattern tests on the Class 5 Workstations at the above mentioned Option Care facility. Smoke pattern shall be observed in both static and dynamic conditions.

Smoke shall be generated on the downstream side of the HEPA diffuser 6" above the IV barA filters and 6" in front and back of the worktable. The pattern should be unidirectional flowing down and then splitting to the front and back of the worktable and not influenced by the operators process nor equipment.

Smoke shall be generated in each of the Workstation benches to assure no reflux back up onto the work surface.

Smoke shall be generated at each door opening to verify exfiltration/infiltration as required

The smoke pattern shall be filmed and observed, with narrative, looking for unidirectional airflow, reflux, turbulence and dead spots as stated above.

A DegreeC handheld Smoke Generator shall be used.

Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- Good split of air at table was observed at each workstation.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of workstations.
- Table #1 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #2 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #3 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #4 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #5 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #6 Smoke study validates 1 person compounding maintains unidirectional airflow

Conclusion:

All of the workstations showed good unidirectional flow, good splits at table, no eddies, and no turbulence nor reflux, as shown in the attached DVD, and pass this smoke test.

Signed:  Date: 5/24/22
Arne Gjertsen

Surface and Viable Air Sampling

Surface and Viable air sampling were performed in accordance with USP<797> in order to evaluate the airborne microorganisms in the controlled Class 5 Laminar Flow workstations, the Class 7 Buffer Zone and the Class 7 Ante Room.

Tryptic Soy Agar and Malt Extract Agar Medium were used in each of the Classified zones.

A SAS 360-Duo air sampling device was used for air sampling and 1000 liters of air was sampled for each test.

The test samples were taken on May 24, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab report #22019342. All of the tests were within the allowable CFU and passed except Air Sample location #19. It will be retested and a report prepared.

A SAS 360-DUO; s/n 21-D-16717 calibrated 5/6/22 was used for all tests.

Air Sample media info:

Tryptic Soy Agar: Lot #, exp. – 6/27/22

Malt Extract Agar: Lot #503287, exp. – 6/15/22

Surface Sample media info:

Tryptic Soy Agar: Lot #144486, exp. – 7/21/22

Malt Extract Agar: Lot #502900, exp. – 6/9/22

Signature: _____

Arne Gjertsen

Date: _____

6/2/22

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **Option Care, Riverside**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
 Date Received: 5/24/2022
 Date Analyzed: 6/2/2022
 Date Reported: 6/2/2022
 Project ID: 22019342
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AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LAFW	5	A	Pass			
2: Class 5 LAFW	5	A	Pass			
3: Class 5 LAFW	5	A	Pass			
4: Class 5 LAFW	5	A	Pass			
5: Class 5 LAFW	5	A	Pass			
6: Class 5 LAFW	5	A	Pass			
7: Class 5 LAFW	5	A	Pass			
8: Class 5 LAFW	5	A	Pass			
9: Class 5 LAFW	5	A	Pass			
10: Class 5 LAFW	5	A	Pass			
11: Class 5 LAFW	5	A	Pass			
12: Class 5 LAFW	5	A	Pass			
13: Class 7 Buffer - Zone	7	A	Pass			
14: Class 7 Buffer - Zone	7	A	Pass			
15: Class 7 Buffer - Zone	7	A	Pass			
16: Class 7 Buffer - Zone	7	A	Pass			
17: Class 7 Ante Room	7	A	Pass	Acpt		
18: Class 7 Ante Room	7	A	Pass			
19: Class 7 Ante Room	7	A	Pass		O.O.C.	Presence of actionable microorganisms
20: Class 7 Ante Room	7	A	Pass			
21: Control / Operation Handler, Lot #: 5033928, Exp: 06/27/22	NA	A	Pass			
22: Control, Lot #: 503287, Exp: 06/15/22	NA	A	Pass			
23: Class 5 LAFW	5	S	Pass			
24: Class 5 LAFW	5	S	Pass			
25: Class 5 LAFW	5	S	Pass			
26: Class 5 LAFW	5	S	Pass			
27: Class 5 LAFW	5	S	Pass			
28: Class 5 LAFW	5	S	Pass			
29: Class 5 LAFW	5	S	Pass			
30: Class 5 LAFW	5	S	Pass			
31: Class 5 LAFW	5	S	Pass			
32: Class 5 LAFW	5	S	Pass			
33: Class 5 LAFW	5	S	Pass			
34: Class 5 LAFW	5	S	Pass			
35: Class 7 Buffer Zone	7	S	Pass			
36: Class 7 Buffer Zone	7	S	Pass			
37: Class 7 Buffer Zone	7	S	Pass			
38: Class 7 Buffer Zone	7	S	Pass			
39: Class 7 Buffer Zone	7	S	Pass			
40: Class 7 Buffer Zone	7	S	Pass			
41: Class 7 Ante Room	7	S	Pass			
42: Class 7 Ante Room	7	S	Pass			

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **Option Care, Riverside**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
 Date Received: 5/24/2022
 Date Analyzed: 6/2/2022
 Date Reported: 6/2/2022
 Project ID: 22019342

43: Class 7 Ante Room	7	S	
44: Class 7 Ante Room	7	S	
45: Class 5 LAFW Touchscreen	5	S	
46: Class 5 LAFW Touchscreen	5	S	
47: Class 5 LAFW Touchscreen	5	S	
48: Class 5 LAFW Touchscreen	5	S	
49: Class 5 LAFW Touchscreen	5	S	
50: Class 5 LAFW Touchscreen	5	S	
51: Class 5 LAFW Touchscreen	5	S	
52: Class 5 LAFW Touchscreen	5	S	
53: Class 5 LAFW Touchscreen	5	S	
54: Class 5 LAFW Touchscreen	5	S	
55: Class 5 LAFW Touchscreen	5	S	
56: Class 5 LAFW Touchscreen	5	S	
57: Control, Lot #: 144486, Exp: 07/21/22	NA	S	
58: Control, Lot #: 502900, Exp: 06/09/22	NA	S	

-  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.

Matrix* - A: Air S: Surface

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **Option Care, Riverside**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
Date Received: 5/24/2022
Date Analyzed: 6/2/2022
Date Reported: 6/2/2022
Project ID: 22019342
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Client Sample #: 1
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-001

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 2
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-002

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 3
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-003

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 4
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-004

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 5
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-005

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 6
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-006

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **Option Care, Riverside**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
Date Received: 5/24/2022
Date Analyzed: 6/2/2022
Date Reported: 6/2/2022
Project ID: 22019342

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Client Sample #: 7
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-007

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 8
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-008

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 9
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-009

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 10
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-010

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 11
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-011

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 12
Sample Location: Class 5 LAFW

Lab Sample #: 22019342-012

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**

Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Comments: **Pass**

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **Option Care, Riverside**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
 Date Received: 5/24/2022
 Date Analyzed: 6/2/2022
 Date Reported: 6/2/2022
 Project ID: 22019342
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Client Sample #: 13
 Sample Location: Class 7 Buffer - Zone
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-013
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 14
 Sample Location: Class 7 Buffer - Zone
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-014
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 15
 Sample Location: Class 7 Buffer - Zone
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-015
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 16
 Sample Location: Class 7 Buffer - Zone
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-016
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 17
 Sample Location: Class 7 Ante Room
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **1 CFU/m3**

Lab Sample #: 22019342-017
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Micrococcus species	1	1	100	Human

Comments: **Acceptable**

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **Option Care, Riverside**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
 Date Received: 5/24/2022
 Date Analyzed: 6/2/2022
 Date Reported: 6/2/2022
 Project ID: 22019342
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Client Sample #: 18
 Sample Location: Class 7 Ante Room
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-018
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 19
 Sample Location: Class 7 Ante Room
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **1 CFU/m3**
 Comments: **O.O.C.**

Lab Sample #: 22019342-019
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Acinetobacter radioresistens	1	1	100	
	1	1	~100%	

Client Sample #: 20
 Sample Location: Class 7 Ante Room
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-020
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 21
 Sample Location: Control / Operation Handler, Lot #: 5033928, Exp: 06/27/22
 Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
 Results: **No Growth**

Lab Sample #: 22019342-021

Client Sample #: 22
 Sample Location: Control, Lot #: 503287, Exp: 06/15/22
 Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
 Results: **No Growth**

Lab Sample #: 22019342-022

Client Sample #: 23
 Sample Location: Class 5 LAFW
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-023
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **Option Care, Riverside**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 5/24/2022
Date Received: 5/24/2022
Date Analyzed: 6/2/2022
Date Reported: 6/2/2022
Project ID: 22019342

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Client Sample #: 24
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-024
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 25
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-025
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 26
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-026
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 27
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-027
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 28
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-028
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 29
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-029
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 30
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-030
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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 Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 31
 Sample Location: Class 5 LAFW
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-031
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 32
 Sample Location: Class 5 LAFW
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-032
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 33
 Sample Location: Class 5 LAFW
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-033
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 34
 Sample Location: Class 5 LAFW
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-034
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 35
 Sample Location: Class 7 Buffer Zone
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-035
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 36
 Sample Location: Class 7 Buffer Zone
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-036
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 37
 Sample Location: Class 7 Buffer Zone
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-037
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Client Sample #: 38
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-038
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 39
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-039
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 40
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-040
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 41
Sample Location: Class 7 Ante Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-041
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 42
Sample Location: Class 7 Ante Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-042
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 43
Sample Location: Class 7 Ante Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-043
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 44
Sample Location: Class 7 Ante Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22019342-044
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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Client Sample #: 45
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-045
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 46
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-046
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 47
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-047
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 48
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-048
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 49
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-049
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 50
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-050
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 51
 Sample Location: Class 5 LAFW Touchscreen
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22019342-051
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**



Certificate of Analysis
AIHA-LAP EMLAP# 218951

15061 Springdale St
Suite 111
Huntington Beach, CA 92649
7148958401

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Client Sample #: 52
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22019342-052
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 53
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22019342-053
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 54
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22019342-054
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 55
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22019342-055
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 56
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22019342-056
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 57
Lab Sample #: 22019342-057

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Project: **Option Care, Riverside**
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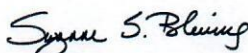
USP 797 Class and Action Levels

ISO Clean Room Classification	ISO, 0.5 u/m ³ Particulate	Viable Air Sampling 400-1000 CFU/m ³	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

Aerobiology Laboratory Associates, Inc. shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer can affect the validity of results and shall be clearly identified. Results apply to the samples as received. Aerobiology Laboratory Associates, Inc. is not responsible for the sampling activity, such as air and water volume, area, and mass unit. The report shall not be reproduced except in full without the approval of the laboratory to ensure that parts of a report are not taken out of context. Data interpretation of this report will be the client responsibility based on their sampling. Source PIC/S, 2007

Footnotes and Additional Report Information

- Regardless of the number of CFU identified, further corrective actions are required if any pathogenic organisms are identified. It is therefore suggested to identify any colonies seen on the plate to genus level to rule out pathogens such as: gram-negative rods bacteria, and coagulase positive staphylococcus spp., yeasts, and mold.
 - Regardless of ISO Class, any fungal ID from fungal media or appropriate media for single plate protocol on an air or surface plate will result in sample being Out of Compliance.
 - Positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into account multiple particles can impact on the same hole. For this reason the sum of calculated counts may be less than the positive hole corrected total.
 - TSA (Tryptic Soy Agar) for bacteria is incubated at 30-35°C for 2-4 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days. If single plate protocol is being followed, TSA or the appropriate media for bacteria is incubated at 30-35°C for 2-4 days and then the same plate is re-incubated at 26 to 30°C for 5-7 days for fungal.
 - MEDIA CONTROLS. An unexposed TSA plate or MEA plate from each sampling event/project should be submitted for quality control purposes. The lot number for controls should be the same as those plates being submitted for analysis.
 - Semi-annual monitoring for viable bacteria and fungi in air, surface contact plates, gloved fingertip and particulates is required for both Class 5 and Class 7 defined areas.
 - Viable cultures must be collected using an impaction style sampler for volumetric capture. A sufficient volume of air (400 to 1000 liters) should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
 - Standard contact plates have an area of 25 cm² or plate, unless otherwise noted in the sample area.
 - The results in this report are related to this project and these samples only.
 - MRL** Units for USP 797 Cultures are as follows: AIR is CFU/m³, SURFACE is CFU/25cm² or CFU/plate, and CONTROL is colony/sample.
MRL: Minimum Reporting Limit.
 - TARGET IDENTIFICATIONS**: Any gram-negative rod, *Staphylococcus aureus*, yeast and molds
 - Non-sporulating colony is a colony that does not produce spores and/or conidiophores. Unless distinctive spores or conidiophores are formed, fungal identification may not be possible.
 - If the final quantitative result is corrected for contamination based on the blank, the blank correction is stated in the sample comments section of the report.
- Due to rounding totals may not equal 100%.


Suzanne Blevins
Laboratory Director

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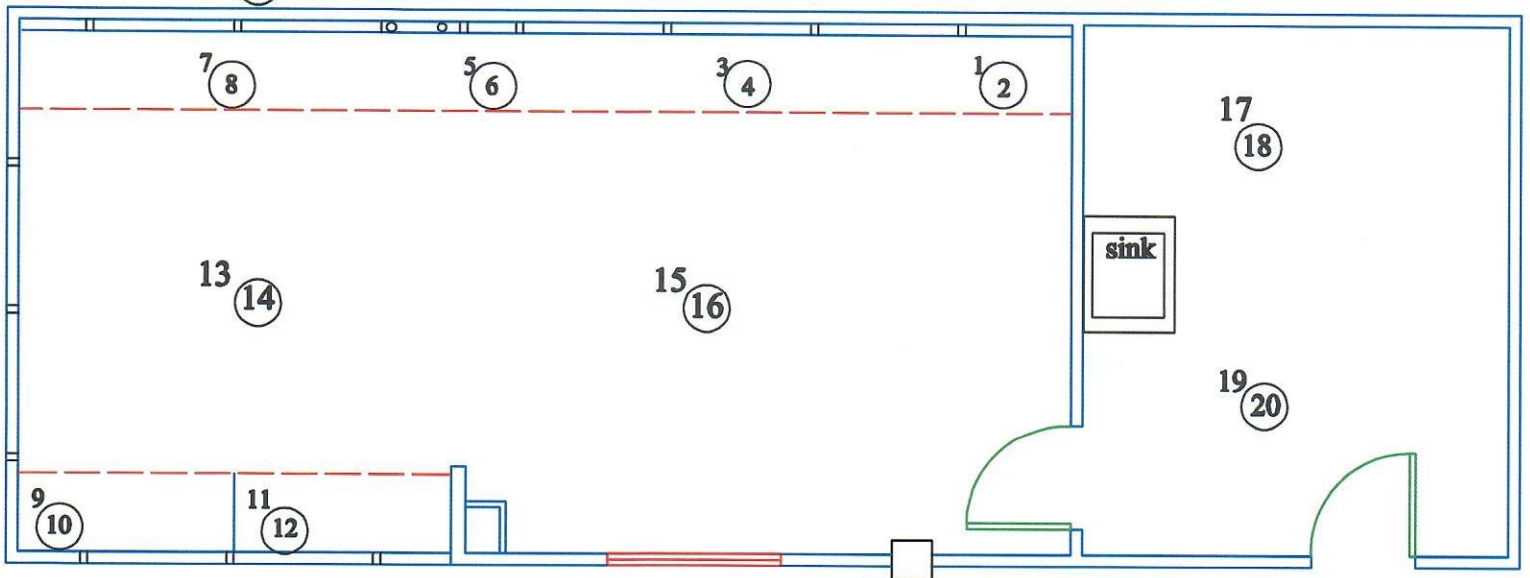
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GLOSSARY

Acinetobacter radioresistens: Acinetobacter are gram-negative, non-spore forming, strictly aerobic rods that commonly occur in pairs and in chains. Cells can become spherical in stationary phase. Acinetobacter bacteria are found in soil, water and sewage.

Micrococcus species: Micrococcus are non-spore-forming, Gram-positive cocci. They are typically non-pathogenic, and considered normal inhabitants of the human body. Micrococci are frequently isolated from air samples and are widespread in nature.

21 = Control/ Op. Handling
22 = Control

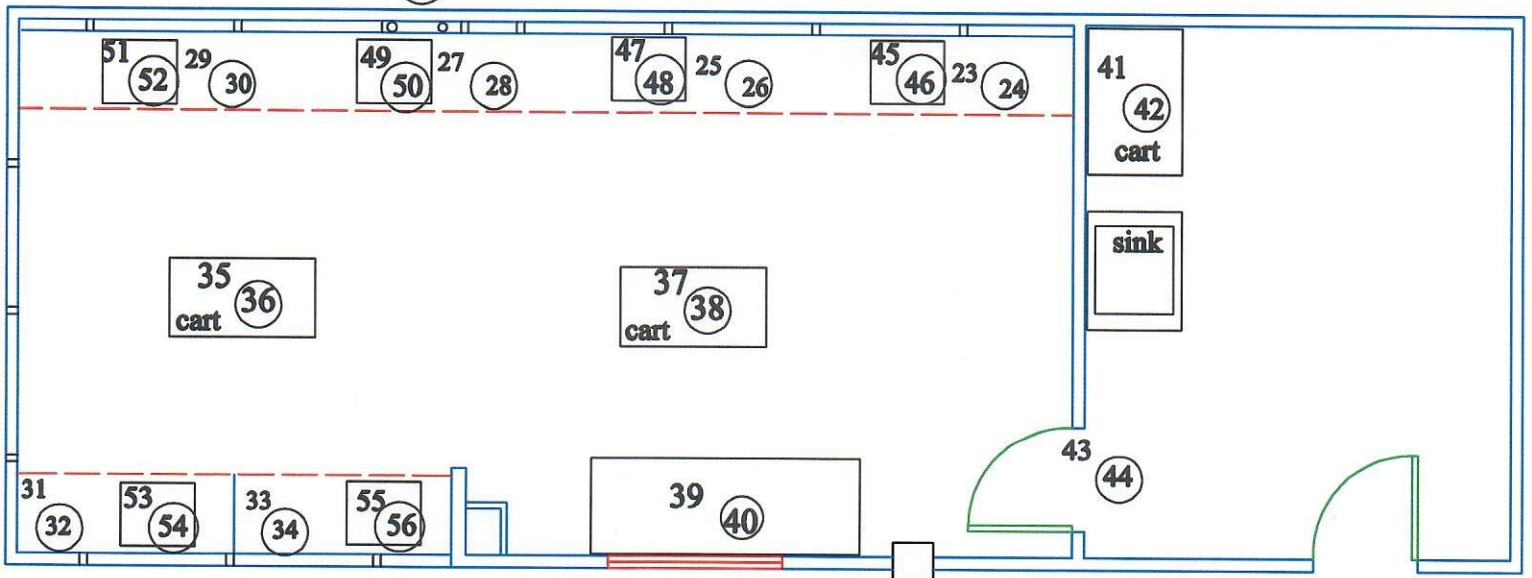


Crescent - Riverside
Viable Air Sample Locations

= Bacterial
○ = Fungal

57 = Control

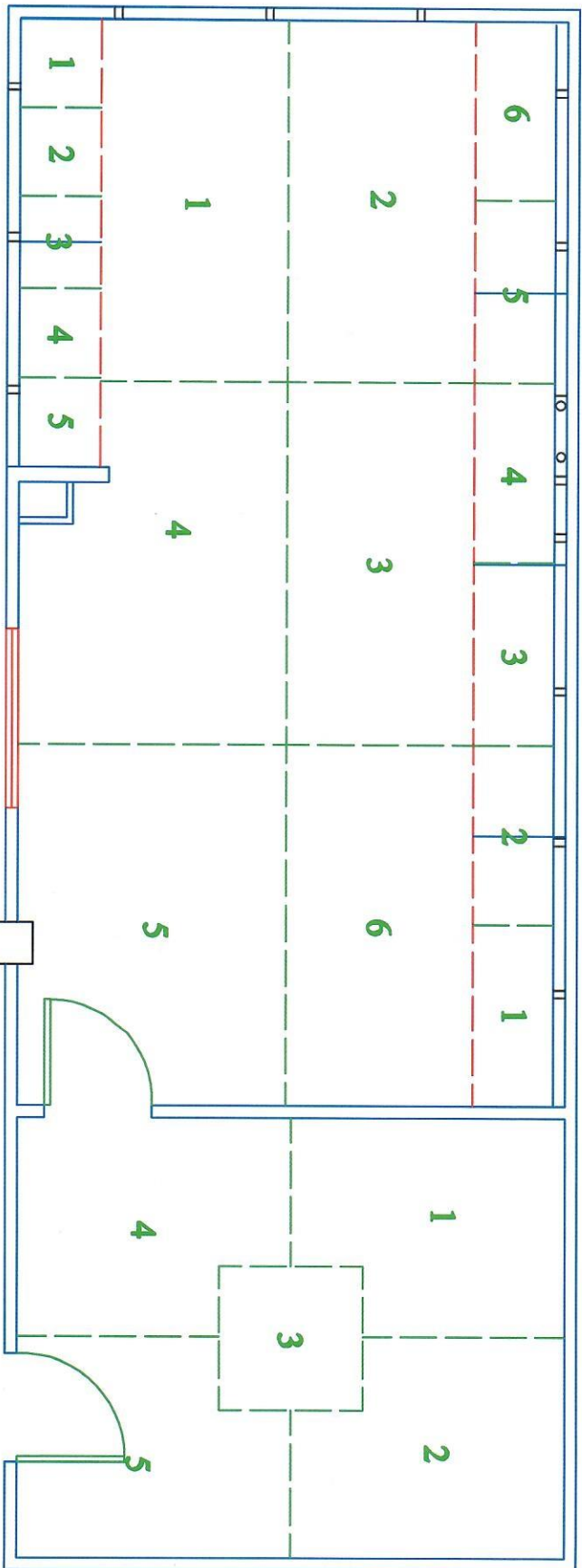
58 = Control



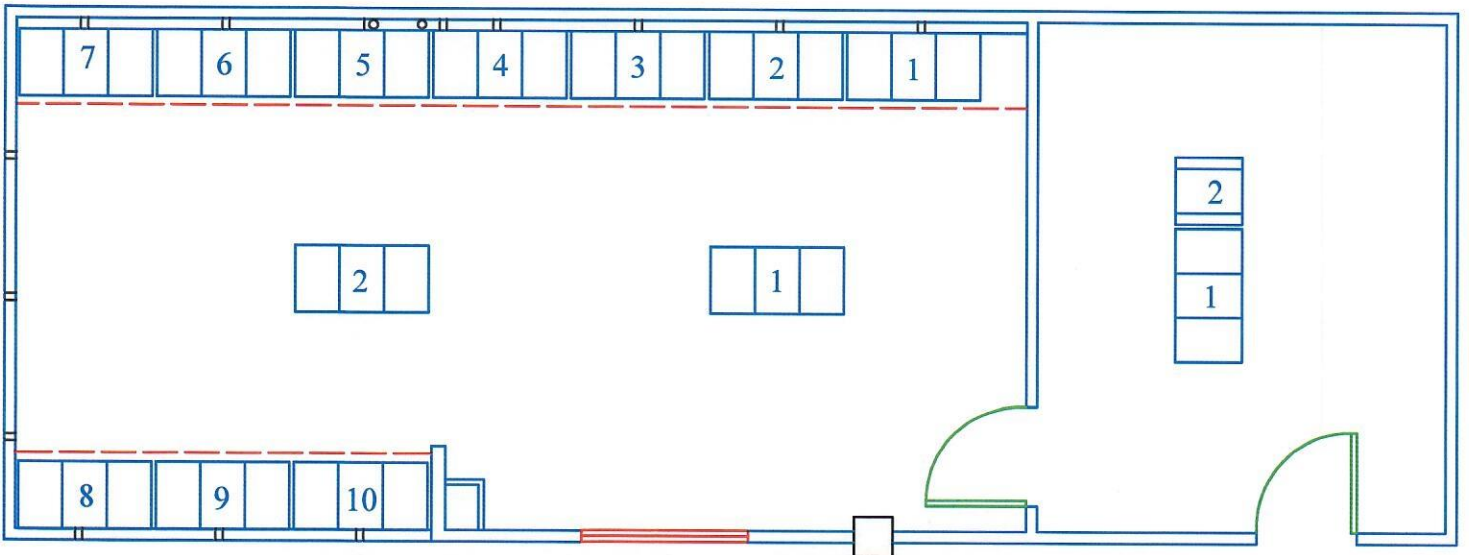
Crescent - Riverside
Surface Sample Locations

= Bacterial

○ = Fungal



Crescent - Riverside
Particle Count Locations



Crescent - Riverside
HEPA Filter Locations

