



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

# PERFORMANCE CERTIFICATION

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



Test Date:

November 18, 2022

## **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 #M15523; Calibrated 6/8/22

#### **Pressure Differential**

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

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial # M15523; Calibrated 6/8/22

#### **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 8/24/22

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## **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: \_\_\_\_\_

11/18/22

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

### Cleanroom Performance Test Report

Customer: Crescent Riverside  
Date: 11/18/2022  
Room ID: Class 5 Work Station 1  
Class: 5  
Dimensions: 70 square feet  
Volume: 560 cubic feet  
Test Status: Dynamic

#### Particle Count

Locations required: 6  
Particle Size >0.5 micron

Location	Readings:
1	0.0 Particle/M <sup>3</sup>
2	141.3 Particle/M <sup>3</sup>
3	0.0 Particle/M <sup>3</sup>
4	0.0 Particle/M <sup>3</sup>
5	35.3 Particle/M <sup>3</sup>
6	0.0 Particle/M <sup>3</sup>

Maximum Count- 3,520 Particle/M<sup>3</sup>  
Pass/Fail Pass

#### Air Flow

	Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Requirement: 72-108 FPM	1	94	90	92.0	7.25	667
	2	92	92	92.0	7.25	667
Avg. Velocity = 93.8	3	100	93	96.5	7.25	700
Pass/Fail : Pass	4	106	96	101.0	7.25	732
	5	97	91	94.0	7.25	682
Measured Values Avg. +/- 20%	6	94	87	90.5	7.25	656
Min. value = 75.0	7	91	90	90.5	7.25	656
Max. value = 112.5						
Pass/Fail : Pass				Total CFM =		4,760

#### Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

11/18/22

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  
Date: 11/18/2022  
Room ID: Class 5 Work Station 2  
Class: 5  
Dimensions: 28 square feet  
Volume: 224 cubic feet  
Test Status: Dynamic

#### Particle Count

Locations required: 5  
Particle Size >0.5 micron

Location	Readings:
1	0.0 Particle/M <sup>3</sup>
2	0.0 Particle/M <sup>3</sup>
3	0.0 Particle/M <sup>3</sup>
4	0.0 Particle/M <sup>3</sup>
5	0.0 Particle/M <sup>3</sup>

Maximum Count- 3,520 Particle/M<sup>3</sup>  
Pass/Fail Pass

#### Air Flow

Requirement:	72-108 FPM	Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
		8	87	97	92.0	7.25	667
		9	95	98	96.5	7.25	700
Avg. Velocity =	91.8	10	85	89	87.0	7.25	631
Pass/Fail :	Pass						

Measured Values Avg. +/- 20%  
Min. value = 73.5  
Max. value = 110.2  
Pass/Fail : Pass

Total CFM = 1,997

#### Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
8	30	<0.01%	N/R	Pass	None
9	29	<0.01%	N/R	Pass	None
10	32	<0.01%	N/R	Pass	None

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

11/18/22

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



Cleanrooms Plus  
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714-534-2770

### Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions:	325 square feet
Date:	11/18/2022	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	671.0 Particle/M <sup>3</sup>
		2	2,366.1 Particle/M <sup>3</sup>
		3	918.2 Particle/M <sup>3</sup>
		4	317.8 Particle/M <sup>3</sup>
		5	5,862.2 Particle/M <sup>3</sup>
		6	17,410.1 Particle/M <sup>3</sup>
		7	13,137.1 Particle/M <sup>3</sup>
		8	4,449.6 Particle/M <sup>3</sup>

Maximum Count- 325,000 Particle/M<sup>3</sup>  
Pass/Fail **Pass**

#### Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	99	87	93.0	7.25	674
Recommended=	30.0 /hour	2	91	87	89.0	7.25	645
Actual=	30.5 /hour						

Pass/Fail **Pass**

**Total CFM = 1,320**

#### Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

11/18/22

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

Cleanrooms Plus  
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### Cleanroom Performance Test Report

Customer:	Crescent Riverside	Dimensions	186 square feet
Date:	11/18/2022	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	22,848.6 Particle/M <sup>3</sup>
		2	27,898.6 Particle/M <sup>3</sup>
		3	7,486.7 Particle/M <sup>3</sup>
		4	5,756.3 Particle/M <sup>3</sup>
		5	2,966.4 Particle/M <sup>3</sup>
		6	2,118.9 Particle/M <sup>3</sup>
Maximum Count-	352,000 Particle/M <sup>3</sup>		
Pass/Fail	<b>Pass</b>		

#### Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	57	46	51.5	7.25	373
Recommended=	30.0 /hour	2	122	N/A	122.0	3.2	390
Actual=	30.8 /hour						
Pass/Fail	<b>Pass</b>						

Total CFM = 764

#### Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	54	<0.01%	N/R	Pass	Yes
2	52	<0.01%	N/R	Pass	No

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

11/18/22

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

## **Airflow Smoke Pattern Test**

Crescent Riverside

November 18, 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 above the IV bar and 6" above the work area. The pattern should be unidirectional flowing downward and split at the worktable sweeping to the front and rear and not influenced by the operators' process.

Smoke shall be generated around the entire perimeter of the front opening of each of the workstation benches to assure no ingress back up onto the work surface.

Smoke shall be generated around the front sash to show no ingress into the workstation.

Smoke shall be generated above the operators' head to insure no ingress (reflux) back into the workstation from in front of the operator.

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


A DegreeC smoke generator shall be used with a glycol-based fog fluid. The fluid provides smoke with a density slightly lighter than air, as shown at the conclusion of the smoke study film.

**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: 11/18/22  
Arne Gjertsen



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

### Magnehelic Gauge – Calibration Report

Customer: Option Care; Riverside  
Date: 11/18/22

Test procedure:

A Shortridge ADM-860 Air Data Multimeter is used for reference readings and a Dwyer A-396A calibrating pump used to set pressure readings. The pump utilizes dual ports for comparative readings. The magnehelic gauge is pumped to mid-scale and calibrated to the Shortridge, and then confirmed at incremental readings up and down the scale.

Gauge:

Cleanroom to Ante #1

Dwyer Model 2000-00; Serial # W06T DR

Pressure readings:

Magnehelic:	Shortridge: Before adjustment	Shortridge: After adjustment *
0.25	0.259	
0.20	0.208	
0.15	0.155	
0.10	0.107	
0.05	0.052	
0.00	-0.004	

\* No adjustment required

Signature:  Date: 11/18/22

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714-534-2770

### **Magnehelic Gauge – Calibration Report**

Customer: Option Care; Riverside  
Date: 11/18/22

**Test procedure:**

A Shortridge ADM-860 Air Data Multimeter is used for reference readings and a Dwyer A-396A calibrating pump used to set pressure readings. The pump utilizes dual ports for comparative readings. The magnehelic gauge is pumped to mid-scale and calibrated to the Shortridge, and then confirmed at incremental readings up and down the scale.

**Gauge:**

Ante to Ambient #2

Dwyer Model 2000-00; Serial # W51S SW

Pressure readings:

<b>Magnehelic:</b>	<b>Shortridge: Before adjustment</b>	<b>Shortridge: After adjustment *</b>
0.25	0.259	
0.20	0.212	
0.15	0.156	
0.10	0.102	
0.05	0.050	
0.00	-0.001	

\* No adjustment required

Signature:  Date: 11/18/22

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### Weight Scale – Calibration Report

Customer: Option Care Riverside

Calibration Date: 11/18/22

Calibration Due Date: 11/18/23

Model # Ohaus CS-2000 Scale Identification # 1

Test procedure:

Using a known weight, measure and record the scales calibration weight. Confirm range of scale by using multiple smaller weights and measure and record findings.

Reading #	Master	Scale As Found	Scale As Left	Deviation	Acceptable Deviation	Pass/Fail
1	0g	0g	0g	0g	± 1 g	Pass
2	200g	200g	200g	0g	± 1 g	Pass
3	500g	500g	500g	0g	± 1 g	Pass
4	1000g	1000g	1000g	0g	± 1 g	Pass

The scale is within the manufacturers' tolerance of +/- 1 gram.

Signature:  Date: 11/18/22

### 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 November 18, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab report #22047684. All of the tests were within the allowable CFU and passed.

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 #513611, exp. – 12/12/22

Malt Extract Agar: Lot #513838P, exp. – 12/15/22

Surface Sample media info:

Tryptic Soy Agar: Lot #516743, exp. – 1/31/23

Malt Extract Agar: Lot #515846, exp. – 1/17/23

Signature: \_\_\_\_\_

  
Arne Gjertsen

Date: \_\_\_\_\_

11/23/22



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

Date Collected: 11/18/2022  
Date Received: 11/18/2022  
Date Analyzed: 11/23/2022  
Date Reported: 11/23/2022  
Project ID: 22047684  
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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				
2: Class 5 LAFW	5	A				
3: Class 5 LAFW	5	A				
4: Class 5 LAFW	5	A				
5: Class 5 LAFW	5	A				
6: Class 5 LAFW	5	A				
7: Class 5 LAFW	5	A				
8: Class 5 LAFW	5	A				
9: Class 5 LAFW	5	A				
10: Class 5 LAFW	5	A				
11: Class 5 LAFW	5	A				
12: Class 5 LAFW	5	A				
13: Class 7 Buffer Zn	7	A				
14: Class 7 Buffer Zn	7	A				
15: Class 7 Buffer Zn	7	A				
16: Class 7 Buffer Zn	7	A				
17: Class 7 Ante Room	7	A				
18: Class 7 Ante Room	7	A				
19: Class 7 Ante Room	7	A				
20: Class 7 Ante Room	7	A				
21: Control/Op Handling Lot #513611 Exp: 12/12/2022	NA	A				
22: Control Lot #513838P Exp: 12/15/2022	NA	A				
23: Class 5 LAFW	5	S				
24: Class 5 LAFW	5	S				
25: Class 5 LAFW	5	S				
26: Class 5 LAFW	5	S				
27: Class 5 LAFW	5	S				
28: Class 5 LAFW	5	S				
29: Class 5 LAFW	5	S				
30: Class 5 LAFW	5	S				
31: Class 5 LAFW	5	S				

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

Date Collected: 11/18/2022  
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Date Reported: 11/23/2022  
Project ID: 22047684  
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32: Class 5 LAFW	5	S		
33: Class 5 LAFW	5	S		
34: Class 5 LAFW	5	S		
35: Class 7 Buffer Zone (Cart)	7	S		
36: Class 7 Buffer Zone (Cart)	7	S		
37: Class 7 Buffer Zone (Cart)	7	S		
38: Class 7 Buffer Zone (Cart)	7	S		
39: Class 7 Buffer Zone (Table)	7	S		
40: Class 7 Buffer Zone (Table)	7	S		
41: Class 7 Ante Room (Cart)	7	S		
42: Class 7 Ante Room (Cart)	7	S		
43: Class 7 Ante Room (Door)	7	S		
44: Class 7 Ante Room (Door)	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		

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1587 Sim Place  
Anaheim CA, 92802  
Attn: Arne Gjertsen  
Project: **O.C. Riverside**  
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 11/18/2022  
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Project ID: 22047684  
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57: Class 5 LAFW (Touchscreen)	5	S	
58: Class 5 LAFW (Touchscreen)	5	S	
59: Class 5 LAFW (Touchscreen)	5	S	
60: Class 5 LAFW (Touchscreen)	5	S	
61: Control Lot #516743 Exp: 1/31/2023	NA	S	
62: Control Lot #515846 Exp: 1/17/2023	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



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Anaheim CA, 92802  
Attn: Arne Gjertsen  
Project: **O.C. Riverside**  
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 11/18/2022  
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Date Analyzed: 11/23/2022  
Date Reported: 11/23/2022  
Project ID: 22047684  
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Client Sample #: 1  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-001

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

Client Sample #: 2  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-002

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

Client Sample #: 3  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-003

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

Client Sample #: 4  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-004

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

Client Sample #: 5  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-005

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

Client Sample #: 6  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-006

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



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

Date Collected: 11/18/2022  
Date Received: 11/18/2022  
Date Analyzed: 11/23/2022  
Date Reported: 11/23/2022  
Project ID: 22047684  
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Client Sample #: 7  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-007

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

Client Sample #: 8  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-008

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

Client Sample #: 9  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-009

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

Client Sample #: 10  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-010

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

Client Sample #: 11  
Sample Location: Class 5 LAFW  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-011

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

Client Sample #: 12  
Sample Location: Class 5 LAFW  
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-012

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

Cleanrooms Plus  
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Anaheim CA, 92802  
Attn: Arne Gjertsen  
Project: **O.C. Riverside**  
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 11/18/2022  
Date Received: 11/18/2022  
Date Analyzed: 11/23/2022  
Date Reported: 11/23/2022  
Project ID: 22047684  
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Client Sample #: 13  
Sample Location: Class 7 Buffer Zn  
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-013

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

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

Lab Sample #: 22047684-014

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

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

Lab Sample #: 22047684-015

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

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

Lab Sample #: 22047684-016

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 #: 22047684-017

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	100	Human

**1** **1** **~100%**

Comments: **Acceptable**

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Project: **O.C. Riverside**  
Condition of Sample(s) Upon Receipt: Acceptable

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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 #: 22047684-018

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**

Lab Sample #: 22047684-019

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

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

**1 1 ~100%**

Comments: **Acceptable**

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 #: 22047684-020

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

Client Sample #: 21  
Sample Location: Control/Op Handling Lot #513611 Exp: 12/12/2022  
Test: 1156 BACTERIAL AIR - Negative (-) Control: SOP 2.2  
Results: **No Growth**

Lab Sample #: 22047684-021

Client Sample #: 22  
Sample Location: Control Lot #513838P Exp: 12/15/2022  
Test: 1157 FUNGAL AIR - Negative (-) Control: SOP 3.2  
Results: **No Growth**

Lab Sample #: 22047684-022

Client Sample #: 23  
Sample Location: Class 5 LAFW

Lab Sample #: 22047684-023

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**



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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 #: 22047684-024

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-025

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-026

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-027

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-028

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-029

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-030

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**



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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 #: 22047684-031

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 #: 22047684-032

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 #: 22047684-033

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 #: 22047684-034

Area: **25 cm2**  
MRL: **1 CFU/25cm2**

Client Sample #: 35  
Sample Location: Class 7 Buffer Zone (Cart)  
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23  
Results: **1 CFU/25cm2**

Lab Sample #: 22047684-035

Area: **25 cm2**  
MRL: **1 CFU/25cm2**

Organism(s) Isolated:	Raw Count	CFU/25cm2	% Total	Reservoirs
Bacillus species	1	1	100	Environment
	<b>1</b>	<b>1</b>	<b>~100%</b>	

Comments: **Acceptable**

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

Lab Sample #: 22047684-036

Area: **25 cm2**  
MRL: **1 CFU/25cm2**

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Condition of Sample(s) Upon Receipt: Acceptable

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

Lab Sample #: 22047684-037

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 38  
Sample Location: Class 7 Buffer Zone (Cart)  
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-038

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 39  
Sample Location: Class 7 Buffer Zone (Table)  
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-039

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 40  
Sample Location: Class 7 Buffer Zone (Table)  
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-040

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 41  
Sample Location: Class 7 Ante Room (Cart)  
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-041

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 42  
Sample Location: Class 7 Ante Room (Cart)  
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-042

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 43  
Sample Location: Class 7 Ante Room (Door)  
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-043

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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Client Sample #: 44  
Sample Location: Class 7 Ante Room (Door)  
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9  
Results: **No Growth**  
Comments: **Pass**

Lab Sample #: 22047684-044  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-045  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-046  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-047  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-048  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-049  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

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 #: 22047684-050  
  
Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**



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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 #: 22047684-051

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 52  
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 #: 22047684-052

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 53  
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 #: 22047684-053

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 54  
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 #: 22047684-054

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 55  
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 #: 22047684-055

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 56  
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 #: 22047684-056

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 57  
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 #: 22047684-057

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**



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Client Sample #: 58  
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 #: 22047684-058

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 59  
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 #: 22047684-059

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 60  
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 #: 22047684-060

Area: **25 cm<sup>2</sup>**  
MRL: **1 CFU/25cm<sup>2</sup>**

Client Sample #: 61  
Sample Location: Control Lot #516743 Exp: 1/31/2023  
Test: 1158 BACTERIAL SURFACE - Negative (-) Control: 2.2  
Results: **No Growth**

Lab Sample #: 22047684-061

Client Sample #: 62  
Sample Location: Control Lot #515846 Exp: 1/17/2023  
Test: 1159 FUNGAL SURFACE - Negative (-) Control: SOP 3.2  
Results: **No Growth**

Lab Sample #: 22047684-062

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### USP 797 Class and Action Levels

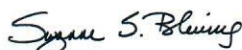
ISO Clean Room Classification	ISO, 0.5 u/m <sup>3</sup> Particulate	Viable Air Sampling 400-1000 CFU/m <sup>3</sup>	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>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 cm<sup>2</sup> 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/m<sup>3</sup>, SURFACE is CFU/25cm<sup>2</sup> 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%.



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Laboratory Director

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Project: **O.C. Riverside**  
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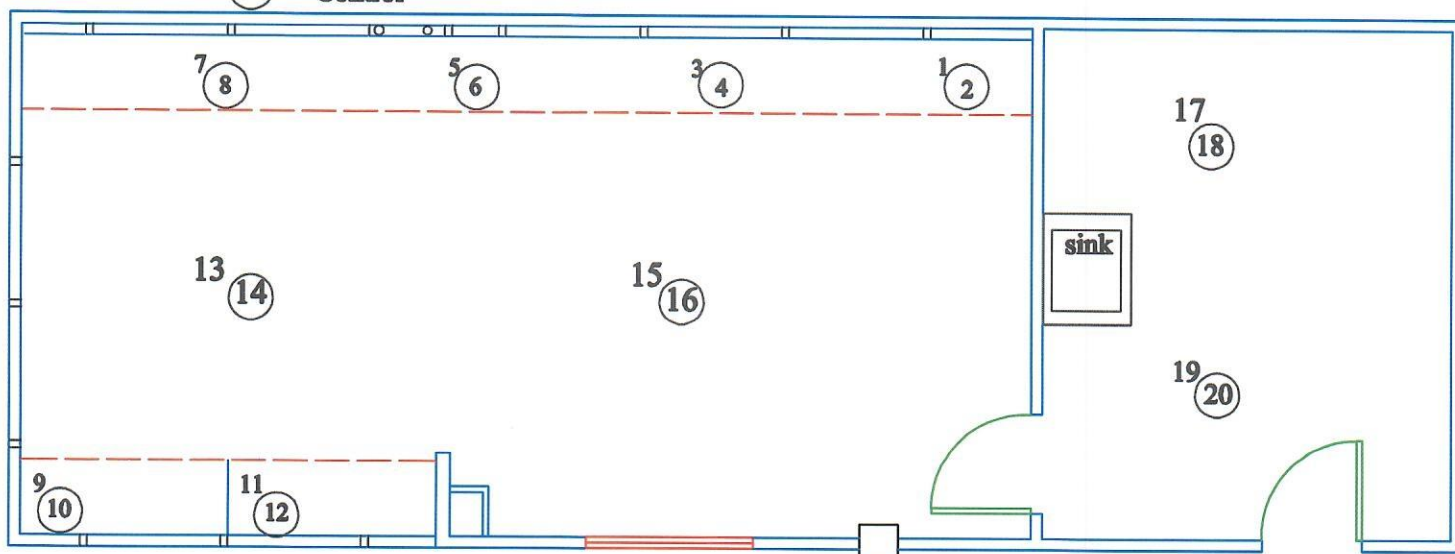
## GLOSSARY

**Bacillus species:** Bacillus are aerobic, endospore-forming, gram-positive, rod-shaped bacteria. Some species are harmful to humans and animals, but the majority of these species are not pathogenic and are recovered from a wide variety of natural habitats.

**Coag-negative Staphylococcus species:** Staphylococcus are non spore-forming, gram-positive cocci. Coagulase Negative Staphylococcus species constitute a major part of the normal microbiota of humans.



21 = Control/ Op. Handling  
22 = Control



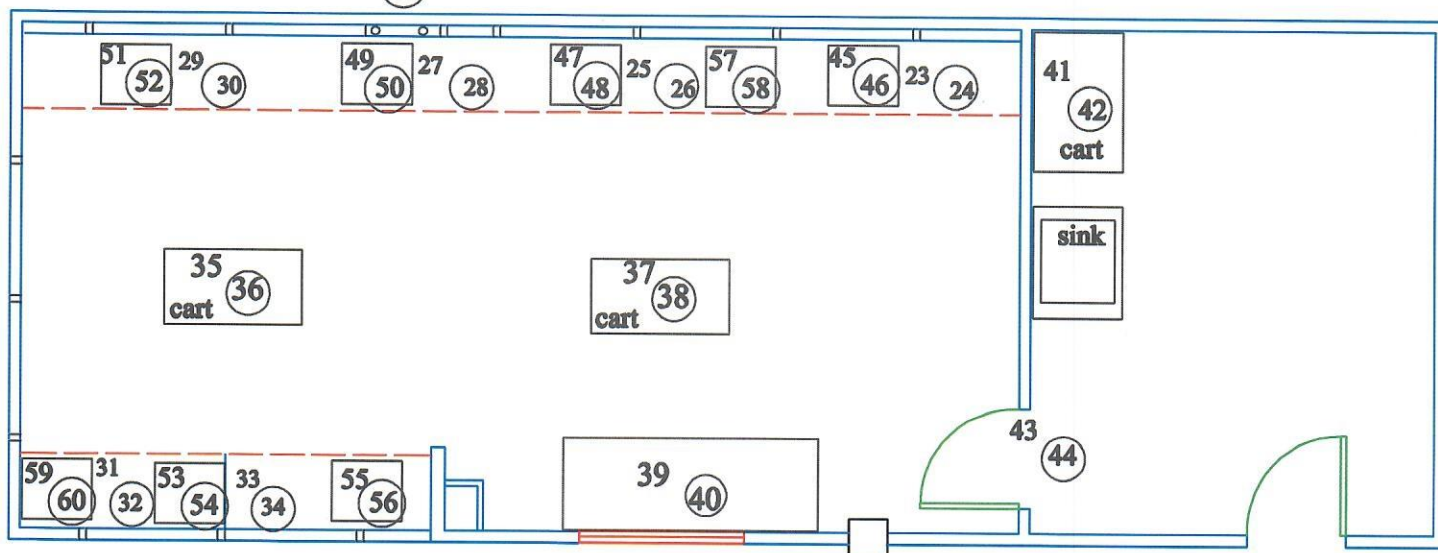
**Crescent - Riverside**  
**Viable Air Sample Locations**

# = Bacterial  
O = Fungal



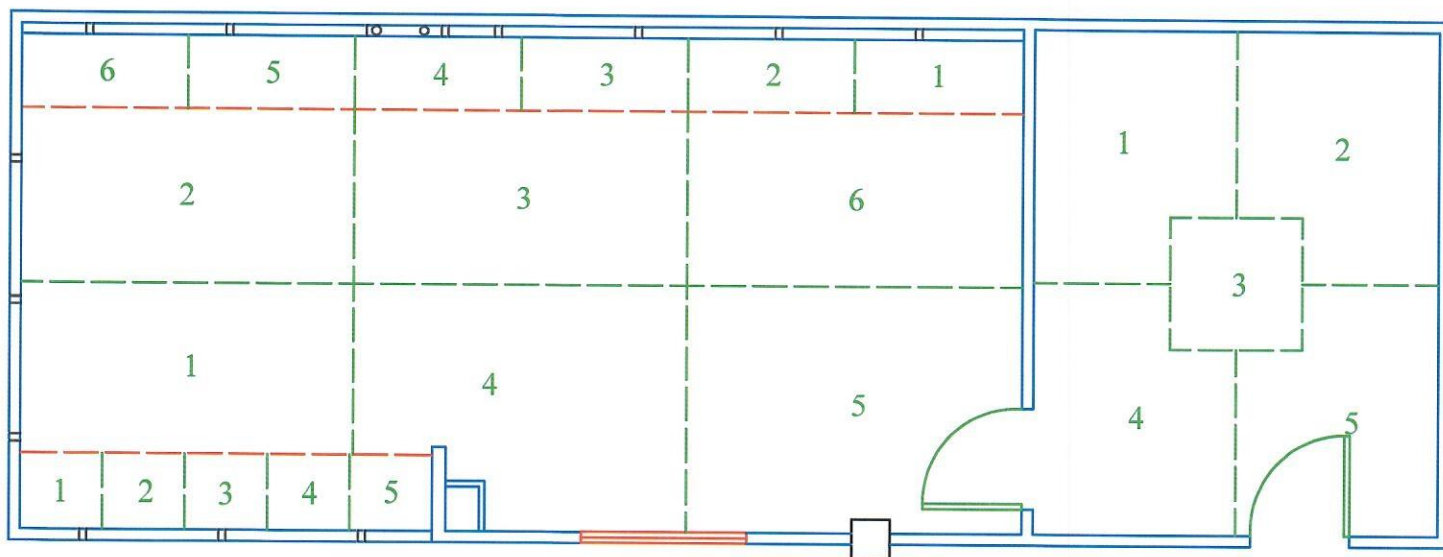
61 = Control

62 = Control

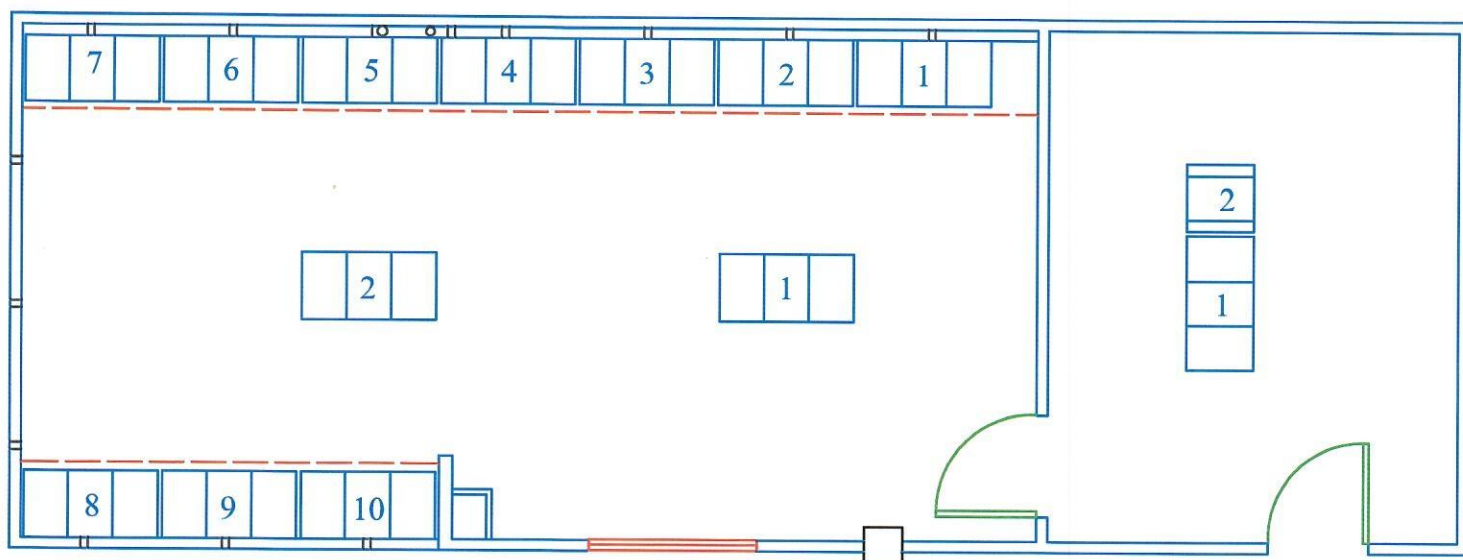


**Crescent - Riverside**  
**Surface Sample Locations**

# = Bacterial  
○ = Fungal



Crescent - Riverside  
Particle Count Locations



Crescent - Riverside  
HEPA Filter Locations

