



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

PERFORMANCE CERTIFICATION

FOR:
Option Care - Sacramento
3301 C Street, Suite 400
Sacramento, CA 95816



Test Date:

October 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.

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-2G, serial #13237; Calibrated 1/10/22

Laminar Flow Benches

Particle Count

Particle count testing was performed in accordance with the recommended practices in IEST-RP-006.

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

HEPA Filter Integrity Test

As required, HEPA filters were scanned for leaks following the recommended practices in IEST-RP-006.

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

Test Instruments:

Photometer - ATI Model TDA-2G, serial #13237; Calibrated 1/10/22

Aerosol Generator – ATI Model TDA-4BL (calibration not required)

PAO was used as the aerosol

Air Flow

Clean flow benches were measured and adjusted for airflow in accordance IEST-RP-006 and IEST-RP-002. All data collected and calculations are presented in the individual component reports submitted with this document.

Test Instruments:

Thermal Anemometer – TSI Model 9545A, serial #1615003; Calibrated 8/24/22

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 CETA Guidelines including CAG003, ISO 14644 and IEST Recommended Practices as established in this report.

Signature: _____


Arne Gjertsen
RCCP-SC #1114

Date: _____

10/18/22

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

Cleanroom Performance Test Report

Customer:	Option Care Sacramento	Dimensions:	195 square feet
Date:	10/18/2022	Volume:	1755 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5	1	565.0 particle/M ³ .
		2	211.9 particle/M ³ .
		3	988.8 particle/M ³ .
		4	529.7 particle/M ³ .
		5	0.0 particle/M ³ .
		6	0.0 particle/M ³ .
Maximum particle- Pass/Fail	352,000 particles/cu.mtr Pass		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		2	100	105	102.5	5.46	560
Required:	30.0 / hour	3	113	105	109.0	5.46	595
Actual:	76.2 / hour	4	96	109	102.5	5.46	560
		5	87	101	94.0	5.46	513
Pass/Fail	Pass						

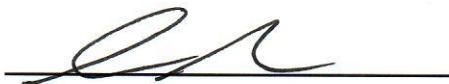
Total CFM = 2,228

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
2	36	<0.01%	N/R	Pass
3	34	<0.01%	N/R	Pass
4	36	<0.01%	N/R	Pass
5	39	<0.01%	N/R	Pass

Signature: _____



Date: _____

10/18/22

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:	Option Care Sacramento	Dimensions:	85 square feet
Date:	10/18/2022	Volume:	765 cubic feet
Room ID:	Ante room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5	Location	1	Readings:
Particle Size	>0.5		2	1,130.1 particle/M ³ .
			3	600.3 particle/M ³ .
			4	671.0 particle/M ³ .
			5	34,643.7 particle/M ³ .
				180,387.3 particle/M ³ .

Maximum particle- 352,000 particle/cu.mtr
 Pass/Fail **Pass**

Air Flow

Air Change:		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Recommended=	30.0 /hour	1	112	112	112.0	5.46	612
Actual=	48.0 /hour						
Pass/Fail	Pass						

Total CFM = 612

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	33	<0.01%	N/R	Pass

Signature: 

Date: 10/18/22

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

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

Clean Flow Hood Performance Test Report

Customer: Option Care - Sacramento
 Date: 10/18/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 185762050218
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5		1	0.0 particle/M ³ .
			2	0.0 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 particle- Pass/Fail	3,520 particle/cu.mtr Pass			

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	95	FPM Readings:			
Pass/Fail :	Pass	1- 90	9- 95	17- 89	
		2- 93	10- 96	18- 95	
		3- 93	11- 99	19- 94	
Measured Values: Avg. +/- 20%		4- 93	12- 94	20- 97	
Min. value =	76	5- 97	13- 99	21- 94	
Max. value =	114	6- 100	14- 99	22- 98	
Pass/Fail :	Pass	7- 91	15- 94	23- 93	
		8- 96	16- 97	24- 89	

Filter Integrity Test

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	23	<0.01%	N/R	Pass
Right	23	<0.01%	N/R	Pass

Signature: _____



Date: _____

10/18/22

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

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

Clean Flow Hood Performance Test Report

Customer: Option Care - Sacramento
 Date: 10/18/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 185763050218
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5		1	0.0 particle/M ³ .
			2	0.0 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 particle- 3,520 particle/cu.mtr
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	91	FPM Readings:			
Pass/Fail :	Pass	1- 96	9- 86	17- 97	
		2- 100	10- 90	18- 100	
		3- 92	11- 85	19- 99	
Measured Values: Avg. +/- 20%		4- 87	12- 81	20- 92	
Min. value =	73	5- 81	13- 86	21- 86	
Max. value =	109	6- 92	14- 94	22- 84	
Pass/Fail :	Pass	7- 92	15- 96	23- 86	
		8- 89	16- 95	24- 91	

Filter Integrity Test

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	24	<0.01%	N/R	Pass
Right	24	<0.01%	N/R	Pass

Signature: 

Date: 10/18/22

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

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

Weight Scale – Calibration Report

Customer: Option Care Sacramento

Calibration Date: 10/18/2022

Calibration Due Date: 10/18/2023

Model # Ohaus Scale Identification # CS-2000

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.

Troemner Weights calibrated on 10/4/2022. Calibration Certificate on file.

Signature:  Date: 10/18/22

Airflow Smoke Pattern Test

Option Care - Sacramento

October 18, 2022

Objective:

To perform airflow smoke pattern tests on the Laminar Flow Benches 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" from the HEPA filters and 6" in front the work area. The pattern should be uni-directional flowing outward and from the worktable and not influenced by the operators' process.

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

Smoke shall be generated above the operators' head to assure 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.


Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of workstations.
- No reflux around perimeter nor over operators' head was observed
- PEC: NuAire # 185762 Smoke study validates 1-person compounding maintains unidirectional airflow
- PEC: NuAire # 185763 Smoke study validates 1-person compounding maintains unidirectional airflow

Conclusion:

Each 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: _____


Arne Gjertsen

Date: _____

10/18/22

Viable Air and Surface Sampling

Option Care – Sacramento.

Viable air and Surface sampling was performed in accordance in with USP<797> in order to evaluate the airborne microorganisms in the controlled Class 5 Laminar Flow Benches, the Class 7 Buffer Zone and the Class 7 Ante Room as per attached plan.

Tryptic Soy Agar and Malt Extract Agar were used in each of the zones. A SAS air sampling device was used for the air sampling and 1000 liters of air was used for each of the media tests.

The test samples were taken on October 18, 2022 and delivered October 19, 2022 to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #22043291. All of the tests were within the allowable CFU and passed except air sample locations #12 & #14 as well as surface sample location #32. These locations will be retested by Option Care staff.

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

Manufacturer – Hardy Diagnostics

Air Sample:

Tryptic Soy Plates – Lot #513220; expires 12/6/22

Malt Plates – Lot #573838; expires 12/15/22

Surface Sample:

Tryptic Soy Plates – Lot #177767; expires 12/21/22

Malt Plates – Lot #514213; expires 12/22/22

Signature: _____

Arne Gjertsen

Date: _____

10/25/22

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

Date Collected: 10/18/2022
 Date Received: 10/19/2022
 Date Analyzed: 10/25/2022
 Date Reported: 10/25/2022
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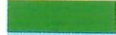


AeroMetric 797™ Results Summary Sheet

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 7 Pass Thru	7	A	Pass			
10: Class 7 Pass Thru	7	A	Pass			
11: Class 7 Buffer Zone	7	A		Acpt		
12: Class 7 Buffer Zone	7	A			O.O.C.	Presence of actionable microorganisms
13: Class 7 Ante Room	7	A		Acpt		
14: Class 7 Ante Room	7	A			O.O.C.	Presence of actionable microorganisms
15: Control/Op Handling Lot #513220 Exp: 12/6/22	NA	A				
16: Control Lot #573838P Exp: 12/15/22	NA	A				
17: Class 5 LAFW	5	S	Pass			
18: Class 5 LAFW	5	S	Pass			
19: Class 5 LAFW	5	S	Pass			
20: Class 5 LAFW	5	S	Pass			
21: Class 5 LAFW	5	S	Pass			
22: Class 5 LAFW	5	S	Pass			
23: Class 5 LAFW	5	S	Pass			
24: Class 5 LAFW	5	S	Pass			
25: Class 5 LAFW Touchscreen	5	S	Pass			
26: Class 5 LAFW Touchscreen	5	S	Pass			
27: Class 7 Buffer Zn Touchscreen	7	S	Pass			
28: Class 7 Buffer Zn Touchscreen	7	S	Pass			
29: Class 7 Buffer Zone (Cart)	7	S	Pass			
30: Class 7 Buffer Zone (Cart)	7	S	Pass			
31: Class 7 Buffer Zone (Cart)	7	S	Pass			
32: Class 7 Buffer Zone (Cart)	7	S			O.O.C.	Presence of actionable microorganisms
33: Class 7 Pass Thru	7	S	Pass			
34: Class 7 Pass Thru	7	S	Pass			
35: Class 7 Ante Room (Door)	7	S	Pass			
36: Class 7 Ante Room (Door)	7	S	Pass			
37: Class 7 Ante Room (Cart)	7	S		Acpt		
38: Class 7 Ante Room (Cart)	7	S	Pass			
39: Control Lot #147767 Exp: 12/21/22	NA	S				

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

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40: Control Lot #514213 Exp: NA S
12/22/22

-  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
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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 #: 22043291-001
 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 #: 22043291-002
 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 #: 22043291-003
 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 #: 22043291-004
 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 #: 22043291-005
 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 #: 22043291-006
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

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

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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 #: 22043291-007

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 #: 22043291-008

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

Client Sample #: 9
Sample Location: Class 7 Pass Thru
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22043291-009

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

Client Sample #: 10
Sample Location: Class 7 Pass Thru
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22043291-010

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

Client Sample #: 11
Sample Location: Class 7 Buffer Zone
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **3 CFU/m3**

Lab Sample #: 22043291-011

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Coag-negative Staphylococcus species	2	2	67	Human
Corynebacterium-like	1	1	33	Human, Environment

Comments: **Acceptable** **3** **3** **~100%**

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
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Project: **Option Care -Sacramento**
Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 12
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22043291-012

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **4 CFU/m3**

Air Volume: **1000 L**
Positive Hole: **219**

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	MRL
Aspergillus glaucus	4	4	100	1 CFU/m3
	4	4	~100%	

Comments: **O.O.C**

Client Sample #: 13
Sample Location: Class 7 Ante Room

Lab Sample #: 22043291-013

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **3 CFU/m3**

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Coag-negative Staphylococcus species	2	2	67	Human
Corynebacterium-like	1	1	33	Human, Environment
	3	3	~100%	

Comments: **Acceptable**

Client Sample #: 14
Sample Location: Class 7 Ante Room

Lab Sample #: 22043291-014

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **9 CFU/m3**

Air Volume: **1000 L**
Positive Hole: **219**

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	MRL
Aspergillus glaucus	8	8	89	1 CFU/m3
Yeast	1	1	11	1 CFU/m3
	9	9	~100%	

Comments: **O.O.C**

Client Sample #: 15
Sample Location: Control/Op Handling Lot #513220 Exp: 12/6/22

Lab Sample #: 22043291-015

Test: 1156 BACTERIAL AIR - Negative (-) Control: SOP 2.2
Results: **No Growth**

Cleanrooms Plus
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Client Sample #: 16
Sample Location: Control Lot #573838P Exp: 12/15/22
Test: 1157 FUNGAL AIR - Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22043291-016

Client Sample #: 17
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 #: 22043291-017

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 18
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 #: 22043291-018

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 19
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 #: 22043291-019

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 20
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 #: 22043291-020

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 21
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 #: 22043291-021

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 22
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 #: 22043291-022

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

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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 #: 22043291-023
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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 #: 22043291-024
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 25
 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 #: 22043291-025
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 26
 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 #: 22043291-026
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 27
 Sample Location: Class 7 Buffer Zn Touchscreen
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22043291-027
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 28
 Sample Location: Class 7 Buffer Zn Touchscreen
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22043291-028
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 29
 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 #: 22043291-029
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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

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Client Sample #: 30
 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 #: 22043291-030
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 31
 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 #: 22043291-031
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 32
 Sample Location: Class 7 Buffer Zone (Cart)
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **2 CFU/25cm²**

Lab Sample #: 22043291-032
 Area: **25 cm²**

Organism(s) Isolated:	Raw Count	CFU/25cm ²	% Total	MRL
Yeast	2	2	100	1 CFU/25cm ²
	2	2	~100%	

Comments: **O.O.C**

Client Sample #: 33
 Sample Location: Class 7 Pass Thru
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22043291-033
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 34
 Sample Location: Class 7 Pass Thru
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22043291-034
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 35
 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 #: 22043291-035
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

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Client Sample #: 36
 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 #: 22043291-036
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 37
 Sample Location: Class 7 Ante Room (Cart)
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **1 CFU/25cm2**

Lab Sample #: 22043291-037
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Organism(s) Isolated:	Raw Count	CFU/25cm2	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	100	Human
	1	1	~100%	

Comments: **Acceptable**

Client Sample #: 38
 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 #: 22043291-038
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 39
 Sample Location: Control Lot #147767 Exp: 12/21/22
 Test: 1158 BACTERIAL SURFACE - Negative (-) Control: 2.2
 Results: **No Growth**

Lab Sample #: 22043291-039

Client Sample #: 40
 Sample Location: Control Lot #514213 Exp: 12/22/22
 Test: 1159 FUNGAL SURFACE - Negative (-) Control: SOP 3.2
 Results: **No Growth**

Lab Sample #: 22043291-040

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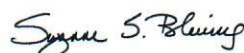
USP 797 Class and Action Levels

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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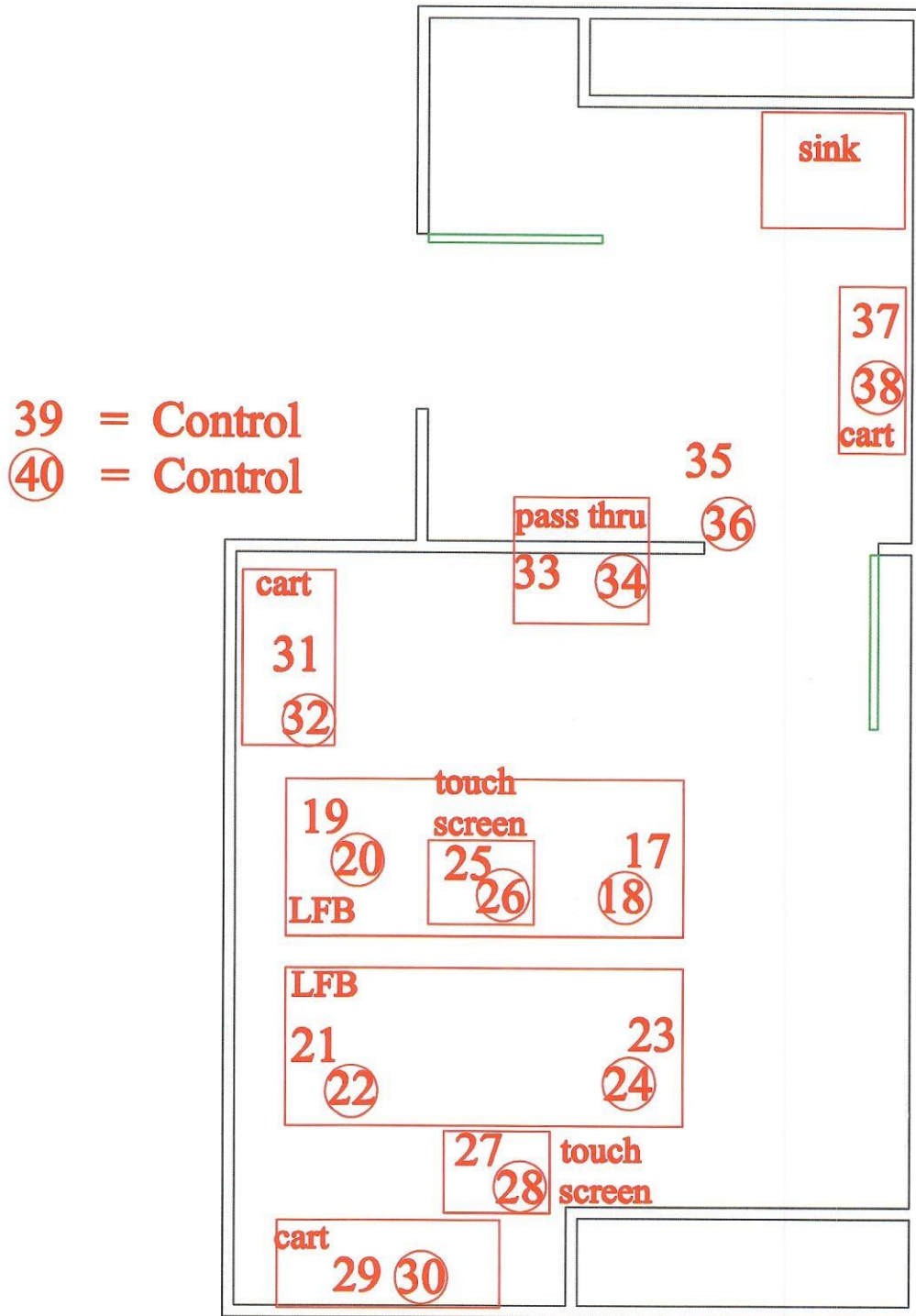
GLOSSARY

Aspergillus glaucus: Aspergillus is one of the most common fungi worldwide, occurring on a large number of substrates. A. glaucus is recovered from a wide variety of environmental sources because it can thrive in wet, dry, cold, or warm environments. Many strains produce mycotoxins. This species is considered an opportunistic pathogen in humans.

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.

Corynebacterium-like: The majority of bacteria in this group are irregularly shaped, non spore-forming, gram-positive rods. Many species are part of the normal microbiota of the skin and mucous membranes of mammals. Some species are found in the environment. Some corynebacterium cause infection, particularly Corynebacterium diphtheriae.

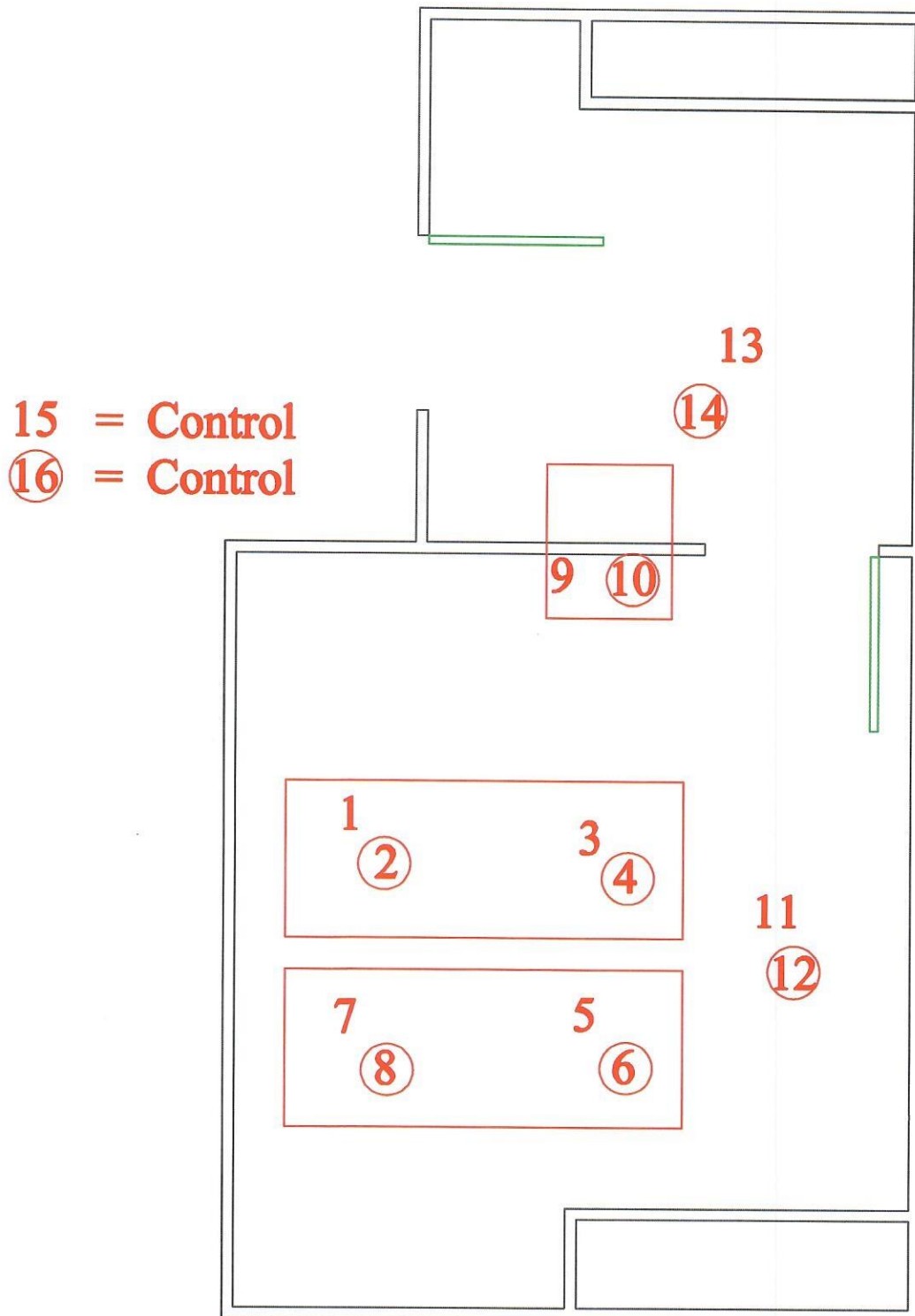
Yeast: Yeasts are fungi that are not in a single taxonomic or phylogenetic group, but are instead defined by their morphology. They are usually unicellular, oval-shaped cells that typically replicate by budding. Yeasts are found throughout nature, inhabiting soil, vegetation and aquatic ecosystems. They are also commonly found on the bodies of humans and other animals.



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Surface Sample Locations

- # = TSA Media
- # = MEA Media

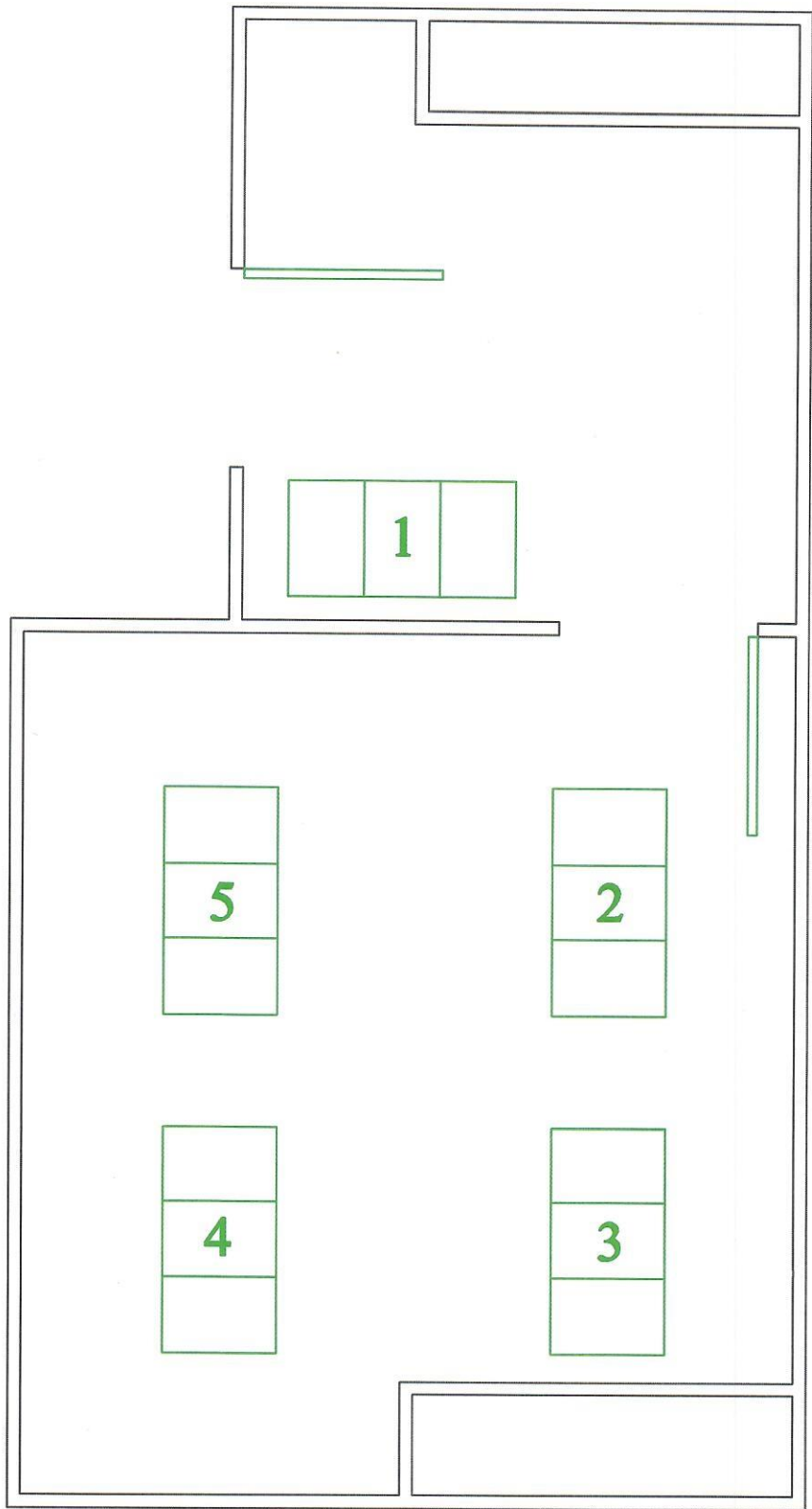


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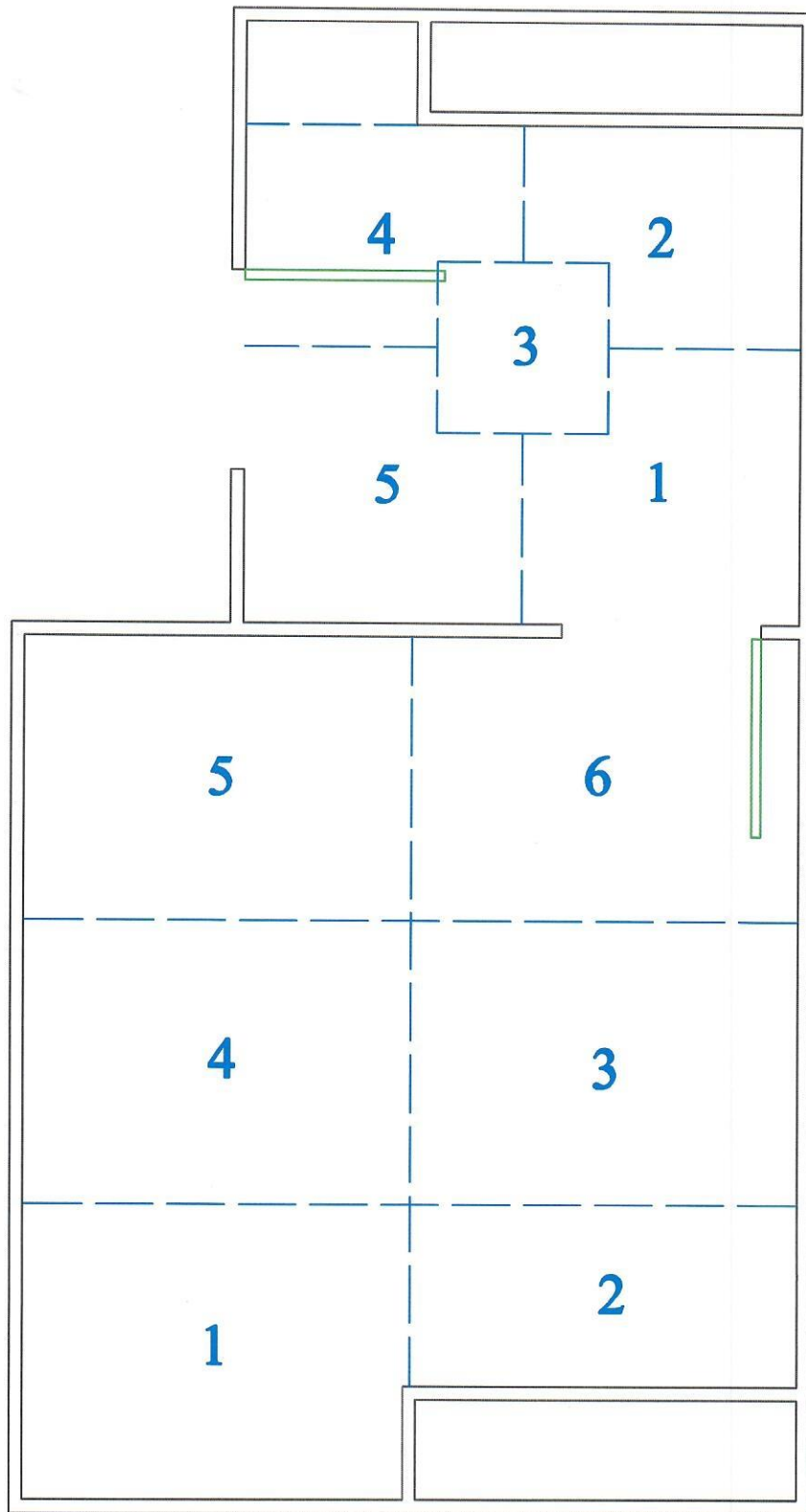
Viable Sample Locations

= TSA Media

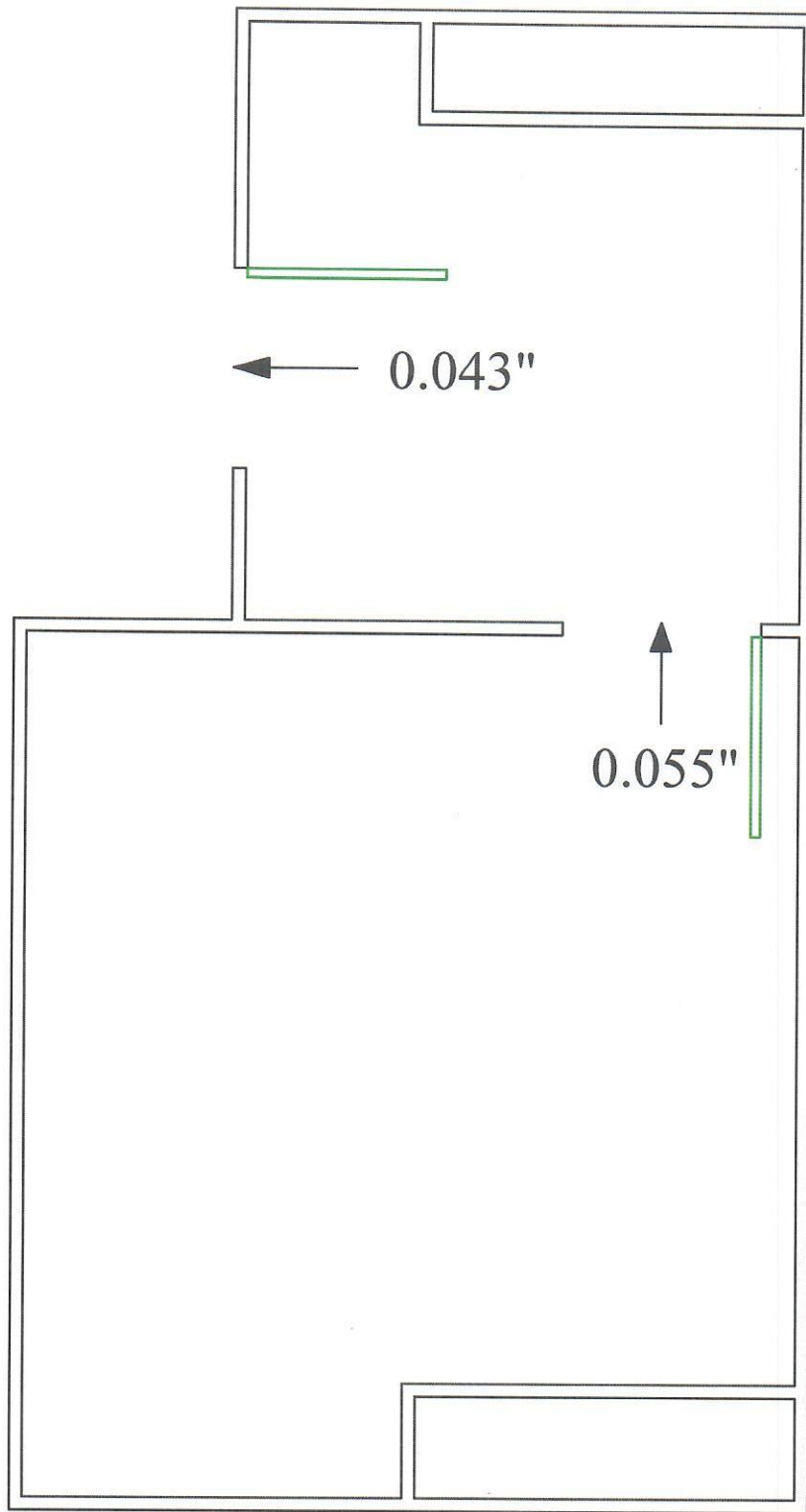
Ⓝ = MEA Media



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HEPA Filter Locations



Option Care - Sacramento
Particle Count Locations



Option Care - Sacramento
Pressure Gradients