CRP
CLEANROOMS PLUS

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

PERFORMANCE CERTIFICATION

FOR
Option Care – Hawaii
550 Paiea Street # 236
Honolulu, HI 96819

Test Date:
June 29, 2022

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

CLEANROOMS/CLEAN Z0NES

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

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-2i, serial #23806; Calibrated 1/28/22
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 with 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 8/17/21

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: _____ Date: 6/29/22

Arne Gjertsen
RCCP-SC #1114

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

Cleanroom Performance Test Report

Customer:	Option Care Hawaii	Dimensions:	214 square feet
Date:	6/29/2022	Volume:	1712 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required: 6
Particle Size >0.5 micron

Location	Readings:
1	4,273.1 Particle/M³
2	3,107.7 Particle/M³
3	317.8 Particle/M³
4	70.6 Particle/M³
5	5,155.9 Particle/M³
6	2,966.4 Particle/M³

Maximum UCL = 352,000 Particle/M³
Pass/Fail **Pass**

Air Flow

Air Change:
Recommended= 30.0 /hour
Actual= 57.4 /hour

Pass/Fail **Pass**

Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
1	74	77	75.5	7.25	547
2	153	148	150.5	7.25	1091

Total CFM = 1,639

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	25	<0.01%	N/R	Pass
2	12	<0.01%	N/R	Pass

Signature: _____ Date: 6/29/22

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

Cleanrooms Plus
1587 Sim Place
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714-534-2770

Cleanroom Performance Test Report

Customer:	Option Care Hawaii	Dimensions:	79 square feet
Date:	6/29/2022	Volume:	632 cubic feet
Room ID:	Ante room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	14,302.4 Particle/M³
2	9,217.1 Particle/M³
3	3,248.9 Particle/M³
4	8,193.0 Particle/M³
5	5,862.2 Particle/M³

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

Air Flow

		Filter	Read 1	Avg. FPM	Sq. Feet	CFM
Air Change:		1	104	104.0	3.2	333
Recommended=	30.0 /hour					
Actual=	31.6 /min					

Pass/Fail **Pass**

Total CFM = 333

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	41	<0.01%	N/R	Pass	None

Signature: _____ Date: 6/29/22

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

Cleanrooms Plus
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Clean Flow Hood Performance Test Report

Customer:	Option Care Hawaii	Model #	NU-201-630
Date:	6/29/2022	Serial #	166186120114
Manufacturer:	Nuaire	Class:	5
Occupancy rate:	1	Status:	Dynamic

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	0.0 Particle/M³
2	0.0 Particle/M³
3	0.0 Particle/M³
4	0.0 Particle/M³
5	0.0 Particle/M³

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

Air Flow

Requirement: 80-100 FPM

Avg. Velocity = 92.8
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 74.2
Max. value = 111.4
Pass/Fail : **Pass**

FPM Readings:

1-	94	6-	99	11-	91
2-	96	7-	100	12-	90
3-	87	8-	93	13-	89
4-	94	9-	82	14-	91
5-	99	10-	88	15-	99

1141 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail
12	<0.01%	N/R	Pass

Signature: _____ Date: 6/24/22

See Test Summary Sheet for instrument data.

Cleanrooms Plus
1587 Sim Place
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Clean Flow Hood Performance Test Report

Customer:	Option Care Hawaii	Model #	NU-201-630
Date:	6/29/2022	Serial #	170929102715
Manufacturer:	Nuaire	Class:	5
Occupancy rate:	1	Status:	Dynamic

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	0.0 Particle/M³
2	0.0 Particle/M³
3	0.0 Particle/M³
4	0.0 Particle/M³
5	0.0 Particle/M³

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

Air Flow

Requirement: 80-100 FPM

Avg. Velocity = 88.9
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 71.1
Max. value = 106.7
Pass/Fail : **Pass**

FPM Readings:

1-	98	6-	93	11-	92
2-	92	7-	86	12-	87
3-	80	8-	83	13-	92
4-	82	9-	86	14-	95
5-	84	10-	92	15-	92

1112 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail
12	<0.01%	N/R	Pass

Signature: _____ Date: 6/29/22

See Test Summary Sheet for instrument data.

Cleanrooms Plus
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714-534-2770

Magnehelic Gauge – Calibration Report

Customer: Option Care Hawaii
Date: 6/29/2022

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: CR to Ante

Dwyer Model 605-0

Pressure readings:

Magnehelic:	Shortridge: Before adjustment	Shortridge: After adjustment *
0.50	0.510	
0.40	0.408	
0.30	0.302	
0.20	0.200	
0.10	0.097	
0.00	-0.002	

* No adjustment required

Signature: _____ Date: 6/29/22

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Magnehelic Gauge – Calibration Report

Customer: Option Care Hawaii
Date: 6/29/2022

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

Dwyer Model 605-0

Pressure readings:

Magnehelic:	Shortridge: Before adjustment	Shortridge: After adjustment *
0.50	0.505	
0.40	0.403	
0.30	0.299	
0.20	0.195	
0.10	0.093	
0.00	0.001	

* No adjustment required

Signature: _____ Date: 6/29/22

Airflow Smoke Pattern Test

Option Care – Hawaii

June 29, 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 unidirectional flowing outward and from the work table 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 work station 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.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of work stations.
- No reflux around perimeter nor over operators head was observed

Conclusion:
PEC: NuAire # 166186120114 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: NuAire # 170929102715 Smoke Study validates 1 person compounding maintains unidirectional flow.

All of the work stations showed good unidirectional flow, good splits at table, no edi-currents, and no turbulence nor reflux, as shown in the attached DVD, and pass this smoke test.

Signed: _____ Date: 6/29/22
Arne Gjertsen

Viable Air and Surface Sampling

Option Care - Hawaii

Viable air and surface sampling was performed in accordance 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 360-Duo 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 June 29, 2022. and delivered the same day to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #22025259. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics
(Air) Malt Plates – Lot #506483; expires 8/11/22
(Air) Tryptic Soy Plates – Lot #507933; expires 9/5/22
(Surface) Sabdex Plates- Lot #507439; expires 8/29/22
(Surface) Tryptic Soy Plates- Lot #145407P; expires 9/6/22

Signature: _____ Date: 7/6/22
Arne Gjertsen

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Certificate of Analysis
AIHA-LAP EMLAP# 218951

15061 Springdale St
Suite 111
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7148958401

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

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LFB	5	A				
2: Class 5 LFB	5	A				
3: Class 5 LFB	5	A				
4: Class 5 LFB	5	A				
5: Class 7 Buffer Zone	7	A				
6: Class 7 Buffer Zone	7	A				
7: Class 7 Buffer Zone	7	A				
8: Class 7 Buffer Zone	7	A				
9: Class 7 Ante Room	7	A				
10: Class 7 Ante Room	7	A				
11: Class 7 Ante Room	7	A				
12: Class 7 Ante Room	7	A				
13: Control/Op. Handling; Lot: 507933, Ex: 9/5/2022	NA	A				
14: Control; Lot: 506483P, Ex: 8/11/2022	NA	A				
15: Class 5 LFB	5	S				
16: Class 5 LFB	5	S				
17: Class 5 LFB	5	S				
18: Class 5 LFB	5	S				
19: Class 7 Buffer Zone	7	S				
20: Class 7 Buffer Zone	7	S				
21: Class 7 Buffer Zone	7	S				
22: Class 7 Buffer Zone	7	S				
23: Class 7 Ante Room	7	S				
24: Class 7 Ante Room	7	S				
25: Class 7 Ante Room	7	S				
26: Class 7 Ante Room	7	S				
27: Class 5 LFB Touchscreen	5	S				
28: Class 5 LFB Touchscreen	5	S				
29: Class 5 LFB Touchscreen	5	S				
30: Class 5 LFB Touchscreen	5	S				
31: Control; Lot: 145407P, Ex: 9/6/2022	NA	S				
32: Control; Lot: 507439, Ex: 8/29/2022	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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Project: **Option Care - Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 1
Sample Location: Class 5 LFB
Lab Sample #: 22025259-001
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 LFB
Lab Sample #: 22025259-002
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 LFB
Lab Sample #: 22025259-003
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 LFB
Lab Sample #: 22025259-004
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 7 Buffer Zone
Lab Sample #: 22025259-005
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 7 Buffer Zone
Lab Sample #: 22025259-006
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

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Project: **Option Care - Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 7
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22025259-007

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 7 Buffer Zone
Lab Sample #: 22025259-008

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 7 Ante Room
Lab Sample #: 22025259-009

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **2 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	1	1	50	Human
Micrococcus species	1	1	50	Human
	2	**2**	**~100%**	

Comments: Acceptable
Mold isolated on bacterial plate.

Client Sample #: 10
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-010

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

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Attn: Arne Gjertsen
Project: **Option Care - Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 11
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-011

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **1 CFU/m3**

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

Comments: Acceptable

Client Sample #: 12
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-012

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

Client Sample #: 13
Sample Location: Control/Op. Handling; Lot: 507933, Ex: 9/5/2022
Lab Sample #: 22025259-013

Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**

Client Sample #: 14
Sample Location: Control; Lot: 506483P, Ex: 8/11/2022
Lab Sample #: 22025259-014

Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Client Sample #: 15
Sample Location: Class 5 LFB
Lab Sample #: 22025259-015

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 #: 16
Sample Location: Class 5 LFB
Lab Sample #: 22025259-016

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**

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Attn: Arne Gjertsen
Project: **Option Care - Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 17
Sample Location: Class 5 LFB
Lab Sample #: 22025259-017

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 #: 18
Sample Location: Class 5 LFB
Lab Sample #: 22025259-018

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 #: 19
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22025259-019

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 #: 20
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22025259-020

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 #: 21
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22025259-021

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **1 CFU/25cm2**
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 #: 22
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22025259-022

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**

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Project: **Option Care - Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 23
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-023
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**

Client Sample #: 24
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-024
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 #: 25
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-025
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 #: 26
Sample Location: Class 7 Ante Room
Lab Sample #: 22025259-026
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 #: 27
Sample Location: Class 5 LFB Touchscreen
Lab Sample #: 22025259-027
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 #: 28
Sample Location: Class 5 LFB Touchscreen
Lab Sample #: 22025259-028
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 #: 29
Sample Location: Class 5 LFB Touchscreen
Lab Sample #: 22025259-029
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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7148958401

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

Date Collected: 6/29/2022
Date Received: 6/30/2022
Date Analyzed: 7/5/2022
Date Reported: 7/6/2022
Project ID: 22025259

Client Sample #: 30
Sample Location: Class 5 LFB Touchscreen
Lab Sample #: 22025259-030

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 #: 31
Sample Location: Control; Lot: 145407P, Ex: 9/6/2022
Lab Sample #: 22025259-031

Test: 1158 BACTERIAL SURFACE - USP 797 Negative (-) Control: 2.2
Results: **No Growth**

Client Sample #: 32
Sample Location: Control; Lot: 507439, Ex: 8/29/2022
Lab Sample #: 22025259-032

Test: 1159 FUNGAL SURFACE - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	6/29/2022
Date Received:	6/30/2022
Date Analyzed:	7/5/2022
Date Reported:	7/6/2022
Project ID:	22025259

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

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. Standard contact plates have an area of 25 cm ^{2} or plate, unless otherwise noted in the sample area.
9. The results in this report are related to this project and these samples only.
10. **MRL** Units for USP 797 Cultures are as follows: AIR is CFU/m ^{3}, SURFACE is CFU/25cm ^{2} or CFU/plate, and CONTROL is colony/sample.
MRL: Minimum Reporting Limit.
11. **TARGET IDENTIFICATIONS:** Any gram-negative rod, *Staphylococcus aureus*, yeast and molds
12. 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.
13. 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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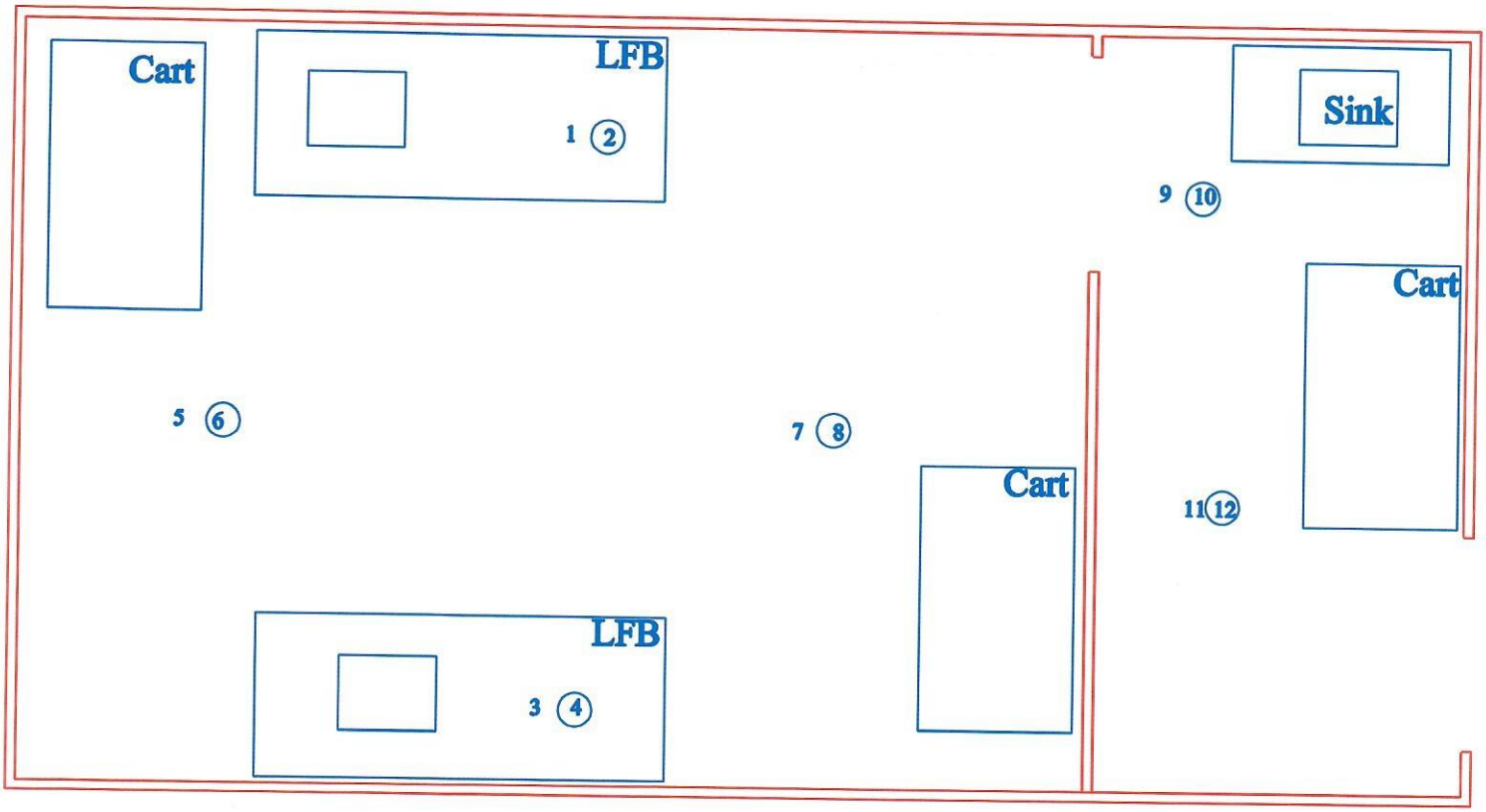
Project ID:	22025259

GLOSSARY

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.

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.



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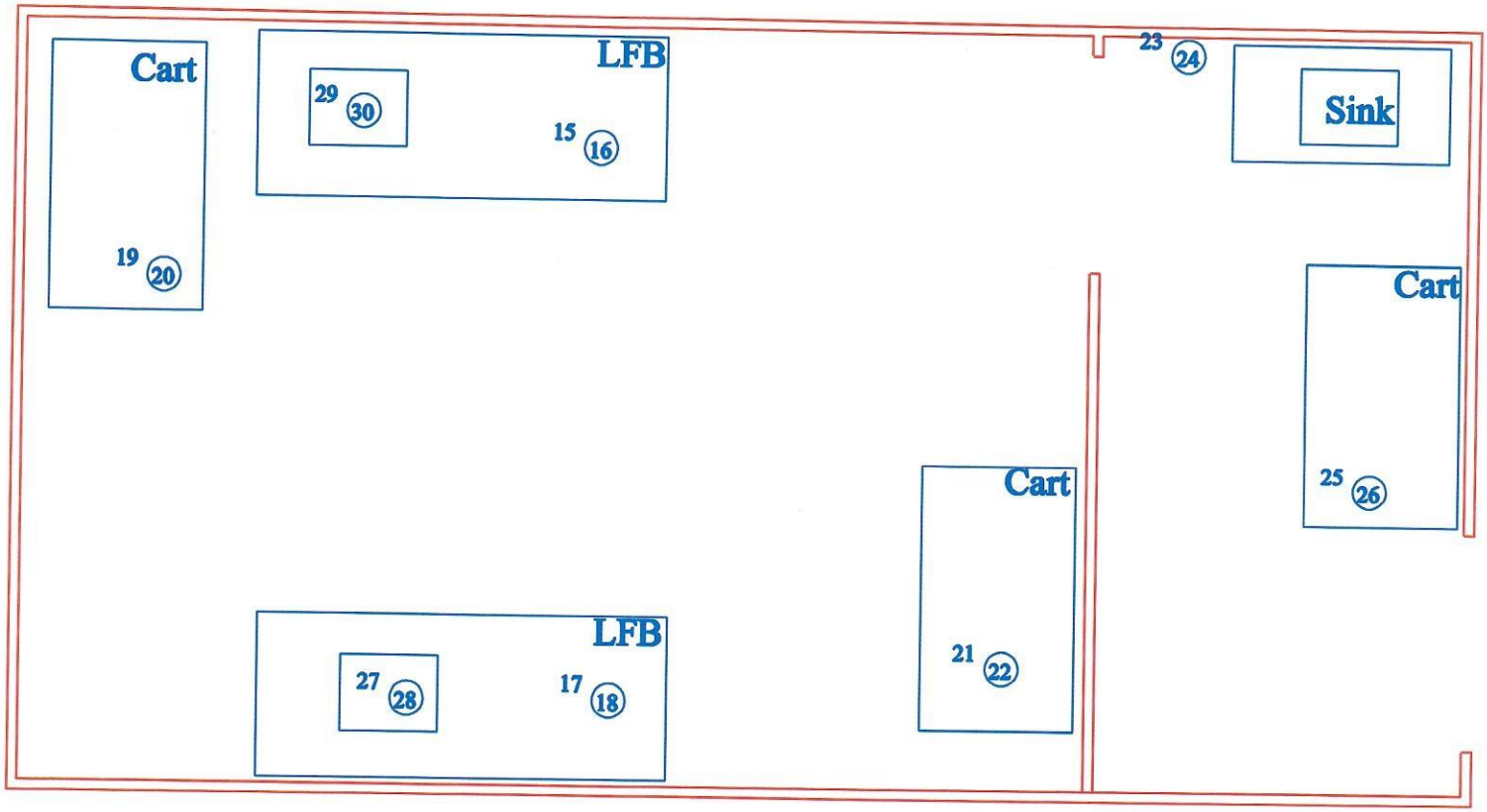
Air Sample Plan



31 Control
32 Control

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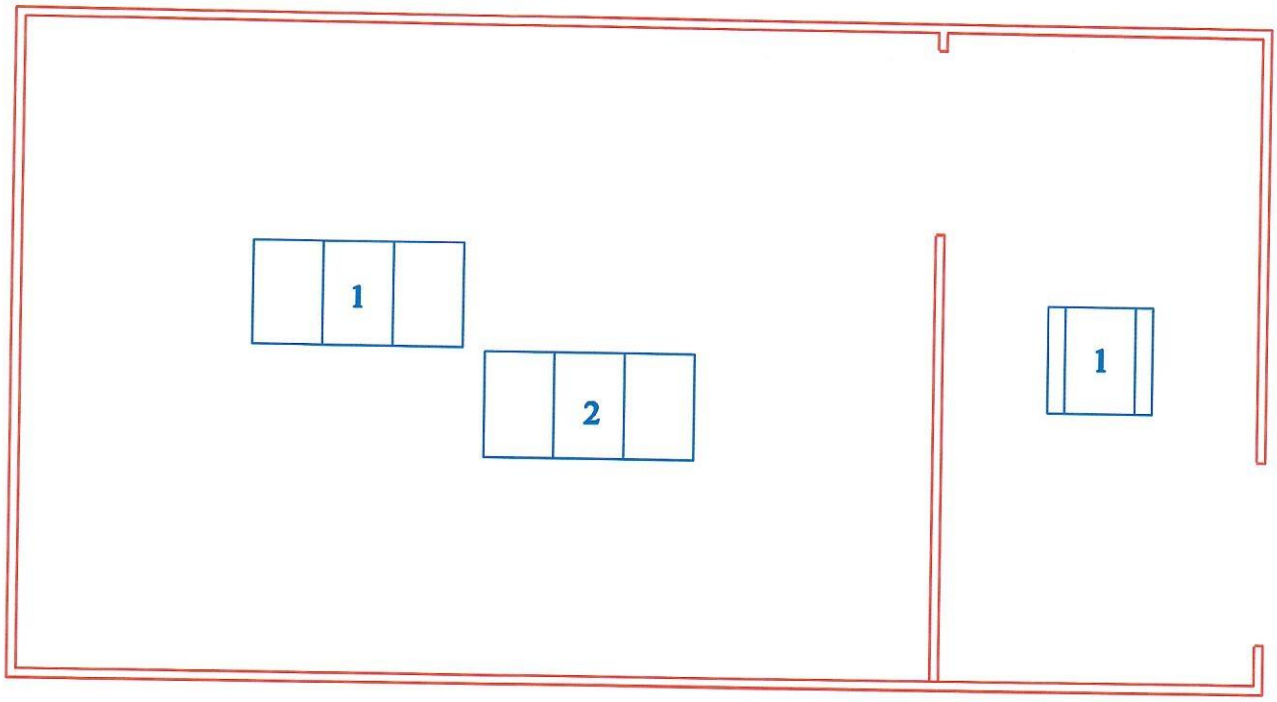
Surface Sample Plan



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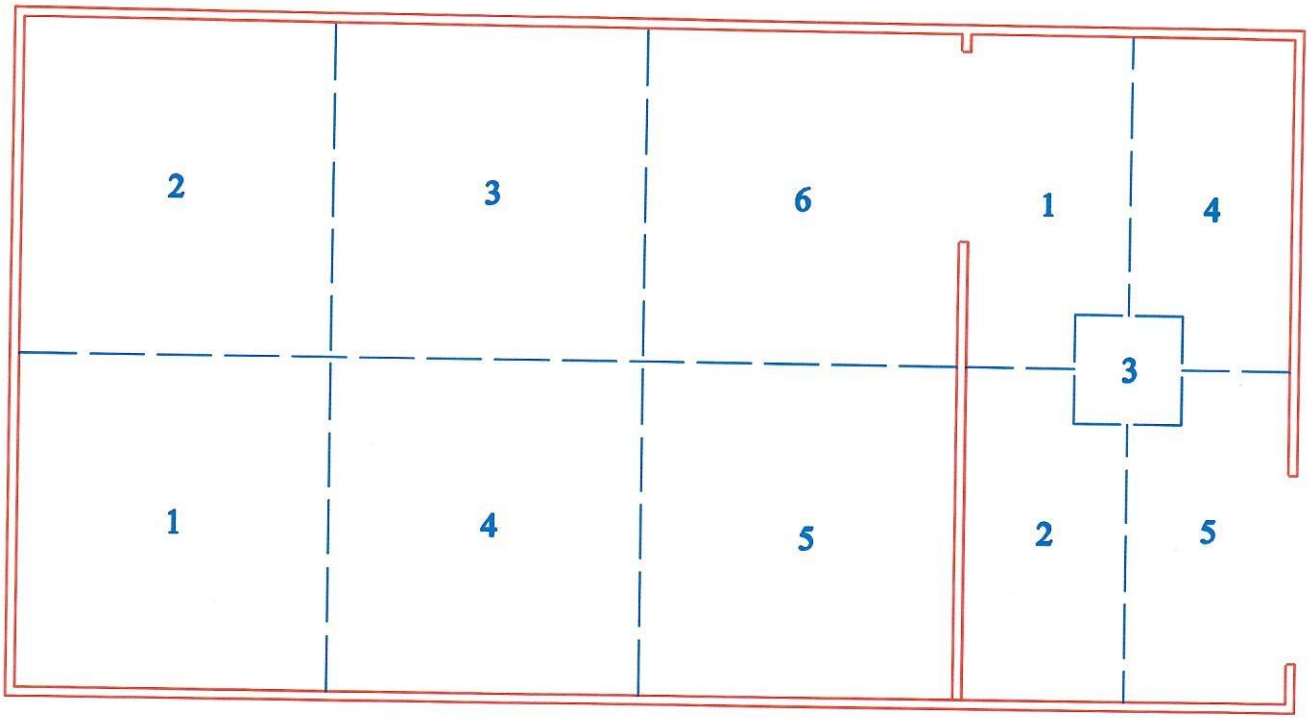
HEPA Filter Locations



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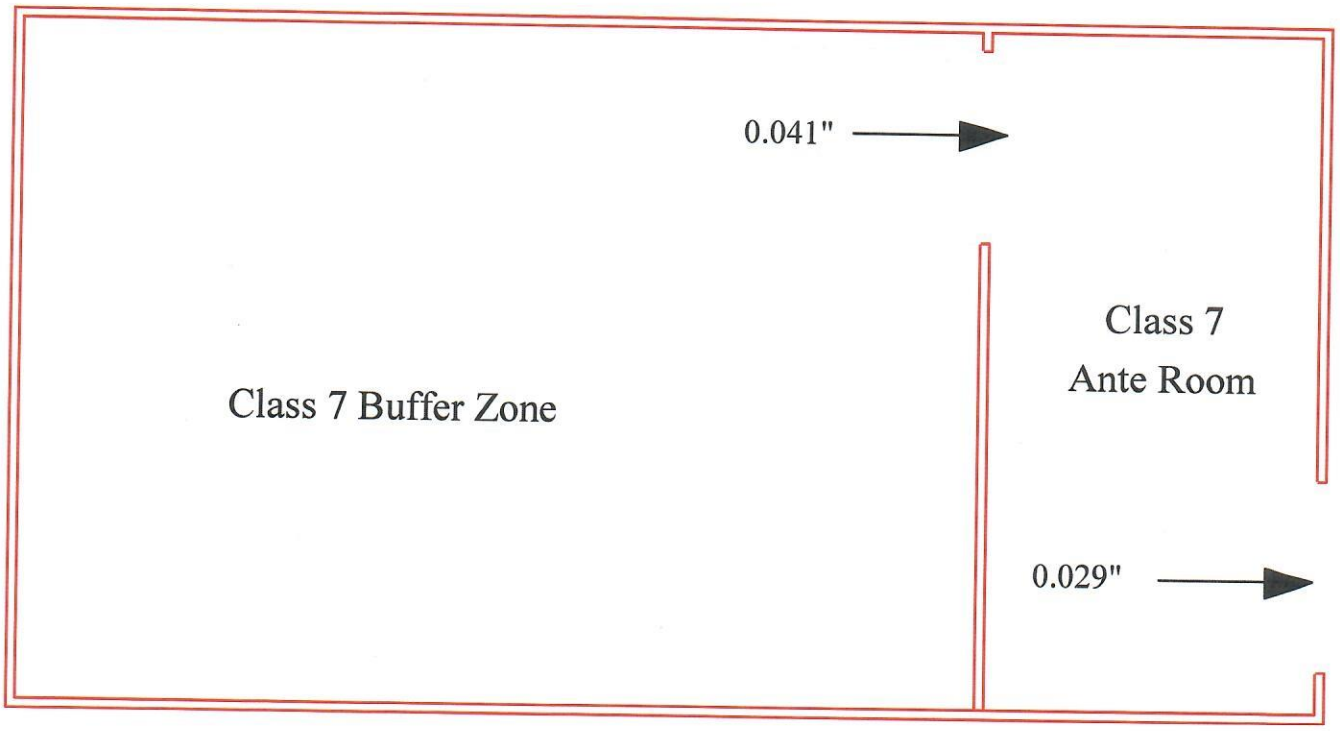
Particle Count Locations



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Pressure Gradients