



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

PERFORMANCE CERTIFICATION

FOR:
Option Care - Everett
728 134th Street SW
Building A, Ste 128
Everett, WA 98204



Test Date:

September 20, 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 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 8/24/22

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 ISO 14644, CETA Guidelines including CAG-003, and IEST Recommended Practices as established in this report.

Signature: _____

Arne Gjertsen
RCCP-SC #1114

Date: _____

4/20/22

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

Cleanroom Performance Test Report

Customer:	Option Care Everett	Dimensions:	105 square feet
Date:	9/20/2022	Volume:	840 cubic feet
Room ID:	Ante room	Test Status:	Dynamic
Class:	7		

Particle Count

		Location	Readings:
Locations required:	6	1	11,477.3 Particle/M ³
Particle Size	>0.5	2	9,075.9 Particle/M ³
		3	3,460.8 Particle/M ³
		4	7,416.1 Particle/M ³
		5	1,624.5 Particle/M ³
		6	317.8 Particle/M ³

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

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		4	123	118	120.5	7.27	876
Required=	30.0 /hour						
Actual=	62.6 /hour						
Pass/Fail	Pass						

Total CFM = 876

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
4	15	<0.01%	N/R	Pass

Signature: _____

Date: _____

9/20/22

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 Everett	Dimensions:	199 square feet
Date:	9/20/2022	Volume:	1592 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5	1	4,626.2 Particle/M ³
		2	1,765.7 Particle/M ³
		3	1,024.1 Particle/M ³
		4	5,756.3 Particle/M ³
		5	4,343.7 Particle/M ³
		6	1,483.2 Particle/M ³

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

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	101	96	98.5	7.27	716
Required:	30.0 / hour	2	102	119	110.5	7.27	803
Actual:	82.3 / hour	3	95	88	91.5	7.27	665

Pass/Fail **Pass**

Total CFM = 2,185

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	19	<0.01%	N/R	Pass
2	17	<0.01%	N/R	Pass
3	20	<0.01%	N/R	Pass

Signature: _____

Date: _____

9/26/22

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 Everett
Date: 9/20/2022
Manufacturer: Nuaire
Hood ID: 030

Model # NU-201-630
Serial # 172103011216
Class: 5
Test Status: Dynamic

Particle Count

	Location	Readings:
Locations required: 6	1	0.0 Particle/M ³
Particle Size >0.5	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 count- 3,520.0 Particle/M³
Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	86.3	FPM Readings:					
Pass/Fail :	Pass	1-	86	6-	80	11-	80
		2-	88	7-	86	12-	83
		3-	82	8-	88	13-	85
Measured Values: Avg. +/- 20%		4-	93	9-	88	14-	88
Min. value =	69.0	5-	84	10-	92	15-	91
Max. value =	103.5						
Pass/Fail :	Pass						

13.4 sq ft = 1156 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: 9/20/22

See Test Summary Sheet for instrument data.

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

Clean Flow Hood Performance Test Report

Customer: Option Care Everett
Date: 9/20/2022
Manufacturer: Nuaire
Hood ID: 040

Model # NU-201-630
Serial # 172104011216
Class: 5
Test Status: Dynamic

Particle Count

	Location	Readings:
Locations required: 6	1	0.0 Particle/M ³
Particle Size >0.5	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 count- 3,520.0 Particle/M³
Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	90.1	FPM Readings:				
Pass/Fail :	Pass	1-	87	6-	88	11- 87
		2-	92	7-	92	12- 91
		3-	86	8-	98	13- 93
Measured Values: Avg. +/- 20%		4-	93	9-	85	14- 85
Min. value =	72.1	5-	96	10-	86	15- 92
Max. value =	108.1					
Pass/Fail :	Pass					

13.4 SQ FT= 1207 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail
11	<0.01%	N/R	Pass

Signature: _____

Date: 9/20/22

See Test Summary Sheet for instrument data.

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

Clean Flow Hood Performance Test Report

Customer: Option Care Everett
Date: 9/20/2022
Manufacturer: Nuaire
Hood ID: 720

Model # NU-S201-800
Serial # 190272020819
Class: 5
Test Status: Dynamic

Particle Count

		Location	Readings:
Locations required:	8	1	0.0 Particle/M ³
Particle Size	>0.5	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
		7	0.0 Particle/M ³
		8	0.0 Particle/M ³
Maximum count -	3,520 Particle/M ³		
Pass/Fail	Pass		

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	93.0	FPM Readings:			
Pass/Fail :	Pass	1- 94	9- 97	17-	93
		2- 97	10- 97	18-	96
		3- 93	11- 94	19-	92
Measured Values: Avg. +/- 20%		4- 91	12- 88	20-	93
Min. value =	74.4	5- 97	13- 89	21-	92
Max. value =	111.6	6- 85	14- 95	22-	97
Pass/Fail :	Pass	7- 95	15- 92	23-	93
		8- 92	16- 89	24-	91

10 sq. ft= 930 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	15	<0.01%	N/R	Pass
Right	15	<0.01%	N/R	Pass

Signature: _____

Date: 9/20/22

See Test Summary Sheet for instrument data.

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

Weight Scale – Calibration Report

Customer: Option care, Everett

Calibration Date: 9/20/2022

Calibration Due Date: 9/20/2023

Model # CS 2000-001

Scale Identification # Pharmacy

As Found Data

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	± 1g	Pass
2	200g	200.0g	200.0g	0g	± 1 g	Pass
3	500g	500g	500g	0g	± 1 g	Pass
4	1000g	1000.0g	1000.0g	0g	± 1 g	Pass

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

Troemner weight set calibration date: 10/7/2021

Signature:  Date: 9/20/22

Airflow Smoke Pattern Test

Option Care - Everett

September 20, 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.
- 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.
- No reflux around perimeter nor over operators' head was observed
- PEC: NuAire Hood #030 Smoke study validates 2 persons compounding maintains unidirectional airflow
- PEC: NuAire Hood #040 Smoke study validates 2 persons compounding maintains unidirectional airflow
- PEC: NuAire Hood #720 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:  Date: 9/20/22
Arne Gjertsen

Viable Air and Surface Sampling

Option Care - Everett

Viable air and Surface sampling were 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 all 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 September 20, 2022 and delivered on September 21, 2022 to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #220038804. All of the tests were within the allowable CFU and passed.

A SAS Model 360-Duo; s/n 21-D-16717 calibrated 5/6/2022 was used for all tests.

Manufacturer – Hardy Diagnostics

Air Sample Media

Malt Plates – Lot #551321P; expires 11/2/22

Tryptic Soy Plates – Lot #512770; expires 11/28/22

Contact Plate Media

Malt Plates – Lot #513012; expires 12/1/22

Tryptic Soy Plates – Lot #513025; expires 12/1/22

Signature:


Arne Gjertsen

Date:

9/27/22

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

Date Collected: 9/20/2022
Date Received: 9/21/2022
Date Analyzed: 9/26/2022
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Project ID: 22038804
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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 5 LFB	5	A				
6: Class 5 LFB	5	A				
7: Class 5 LFB	5	A				
8: Class 5 LFB	5	A				
9: Class 7 Buffer Zone	7	A				
10: Class 7 Buffer Zone	7	A				
11: Class 7 Buffer Zone	7	A				
12: Class 7 Buffer Zone	7	A				
13: Class 7 Ante Room	7	A				
14: Class 7 Ante Room	7	A				
15: Class 7 Pass Thru	7	A				
16: Class 7 Pass Thru	7	A				
17: Class 5 LFB	5	S				
18: Class 5 LFB	5	S				
19: Class 5 LFB	5	S				
20: Class 5 LFB	5	S				
21: Class 5 LFB	5	S				
22: Class 5 LFB	5	S				
23: Class 5 LFB	5	S				
24: Class 5 LFB	5	S				
25: Class 7 Buffer Zone	7	S				
26: Class 7 Buffer Zone	7	S				
27: Class 7 Buffer Zone	7	S				
28: Class 7 Buffer Zone	7	S				
29: Class 7 Pass Thru	7	S				
30: Class 7 Pass Thru	7	S				
31: Class 7 Ante Room	7	S				
32: Class 7 Ante Room	7	S				
33: Class 7 Ante Room	7	S				
34: Class 7 Ante Room	7	S				
35: Class 7 LFB Touchscreen	7	S				
36: Class 7 LFB Touchscreen	7	S				
37: Class 7 LFB Touchscreen	7	S				
38: Class 7 LFB Touchscreen	7	S				
39: Class 7 LFB Touchscreen	7	S				
40: Class 7 LFB Touchscreen	7	S				
41: Control , Lot# :513025 , Exp Date : 12/1/2022	NA	S				
42: Control , Lot# : 513012 , Exp Date : 12/1/2022	NA	S				

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

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43: Control / OP, Handling, NA A
Lot# : 512770 , Exp Date :
11/28/2022

44: Control , Lot#: 511231P , NA A
Exp Date : 11/2/2022

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

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Client Sample #: 1
Sample Location: Class 5 LFB
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**
client request a change on the project name Everett to Everest as per the COC

Lab Sample #: 22038804-001

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

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

Lab Sample #: 22038804-002

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

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

Lab Sample #: 22038804-003

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

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

Lab Sample #: 22038804-004

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

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

Lab Sample #: 22038804-005

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

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

Lab Sample #: 22038804-006

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 - Everett**
Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 7
Sample Location: Class 5 LFB
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-007

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

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

Lab Sample #: 22038804-008

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

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

Lab Sample #: 22038804-009

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

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

Lab Sample #: 22038804-010

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: **2 CFU/m3**

Lab Sample #: 22038804-011

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	50	Human
Micrococcus species	1	1	50	Human
	2	2	~100%	
Comments: Acceptable				

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
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Client Sample #: 12
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-012

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

Client Sample #: 13
Sample Location: Class 7 Ante Room
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **2 CFU/m3**

Lab Sample #: 22038804-013

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	Reservoirs
Micrococcus species	2	2	100	Human
	2	2	~100%	

Comments: **Acceptable**

Client Sample #: 14
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 #: 22038804-014

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

Client Sample #: 15
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 #: 22038804-015

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

Client Sample #: 16
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 #: 22038804-016

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 - Everett**
Condition of Sample(s) Upon Receipt: Acceptable

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Date Received: 9/21/2022
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Client Sample #: 17
Sample Location: Class 5 LFB
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-017

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 18
Sample Location: Class 5 LFB
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-018

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 19
Sample Location: Class 5 LFB
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-019

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 20
Sample Location: Class 5 LFB
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-020

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 21
Sample Location: Class 5 LFB
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-021

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 22
Sample Location: Class 5 LFB
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-022

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-023

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Date Collected: 9/20/2022
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Client Sample #: 24
Sample Location: Class 5 LFB
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-024

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

Client Sample #: 25
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-025

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

Client Sample #: 26
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-026

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

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

Lab Sample #: 22038804-027

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

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

Lab Sample #: 22038804-028

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

Client Sample #: 29
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 #: 22038804-029

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

Client Sample #: 30
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 #: 22038804-030

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

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Client Sample #: 31
Sample Location: Class 7 Ante Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-031

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 32
Sample Location: Class 7 Ante Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-032

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-033

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-034

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-035

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-036

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22038804-037

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Client Sample #: 38
Sample Location: Class 7 LFB Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-038

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 39
Sample Location: Class 7 LFB Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-039

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 40
Sample Location: Class 7 LFB Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22038804-040

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 41
Sample Location: Control, Lot#: 513025, Exp Date: 12/1/2022
Test: 1158 BACTERIAL SURFACE - Negative (-) Control: 2.2
Results: **No Growth**

Lab Sample #: 22038804-041

Client Sample #: 42
Sample Location: Control, Lot#: 513012, Exp Date: 12/1/2022
Test: 1159 FUNGAL SURFACE - Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22038804-042

Client Sample #: 43
Sample Location: Control / OP, Handling, Lot#: 512770, Exp Date: 11/28/2022
Test: 1156 BACTERIAL AIR - Negative (-) Control: SOP 2.2
Results: **No Growth**

Lab Sample #: 22038804-043

Client Sample #: 44
Sample Location: Control, Lot#: 511231P, Exp Date: 11/2/2022
Test: 1157 FUNGAL AIR - Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22038804-044

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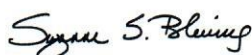
USP 797 Class and Action Levels

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

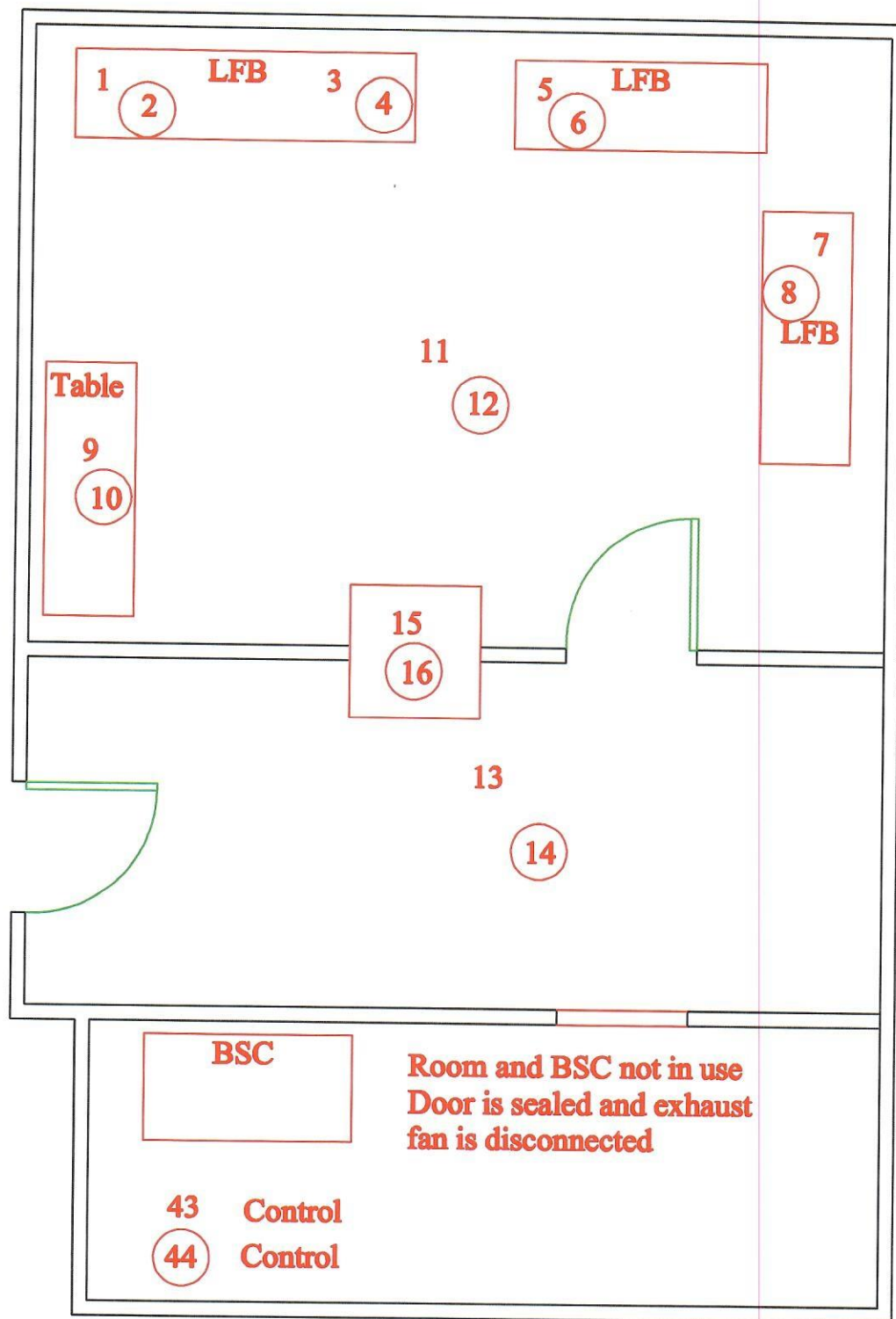
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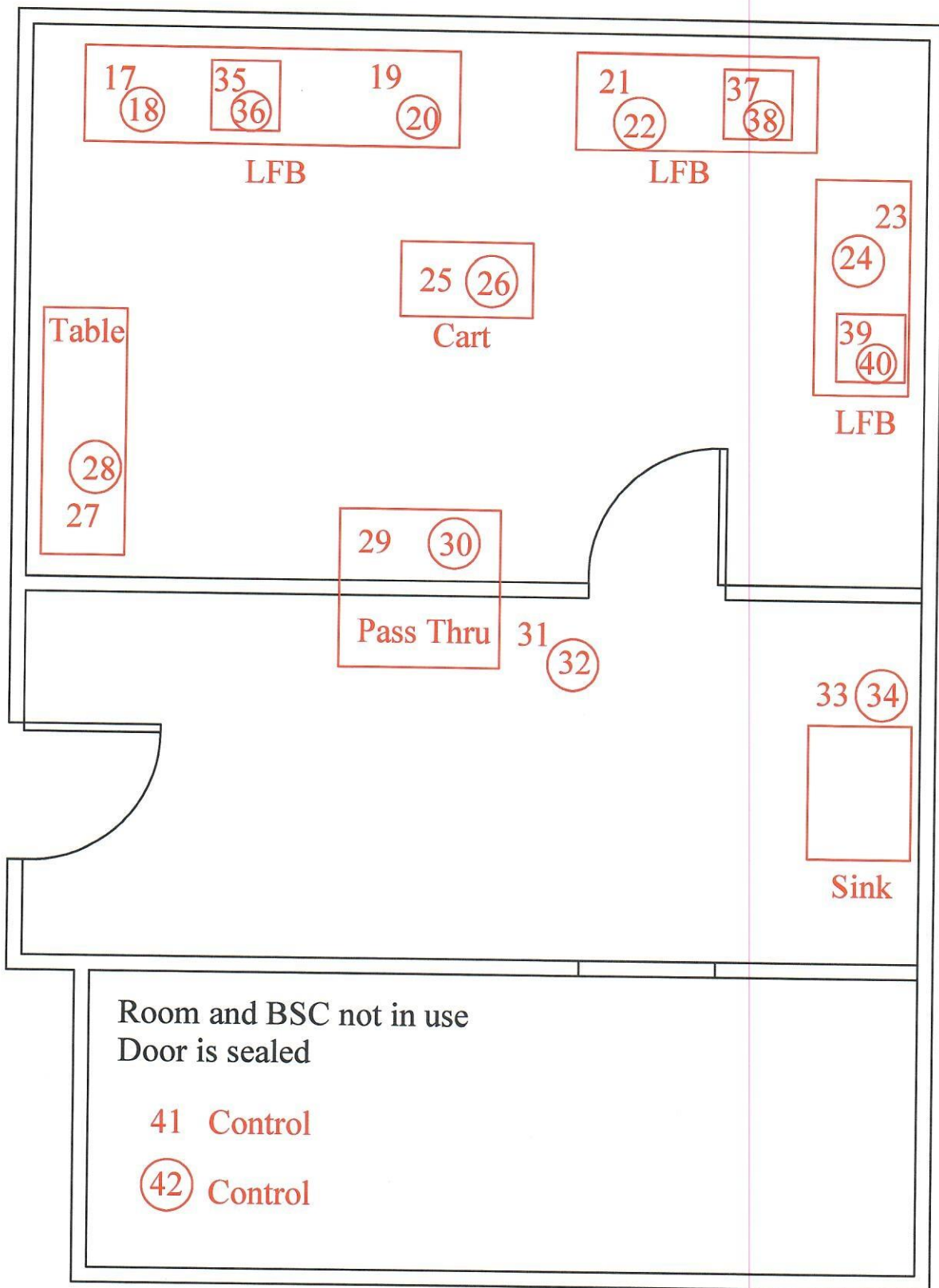
GLOSSARY

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.



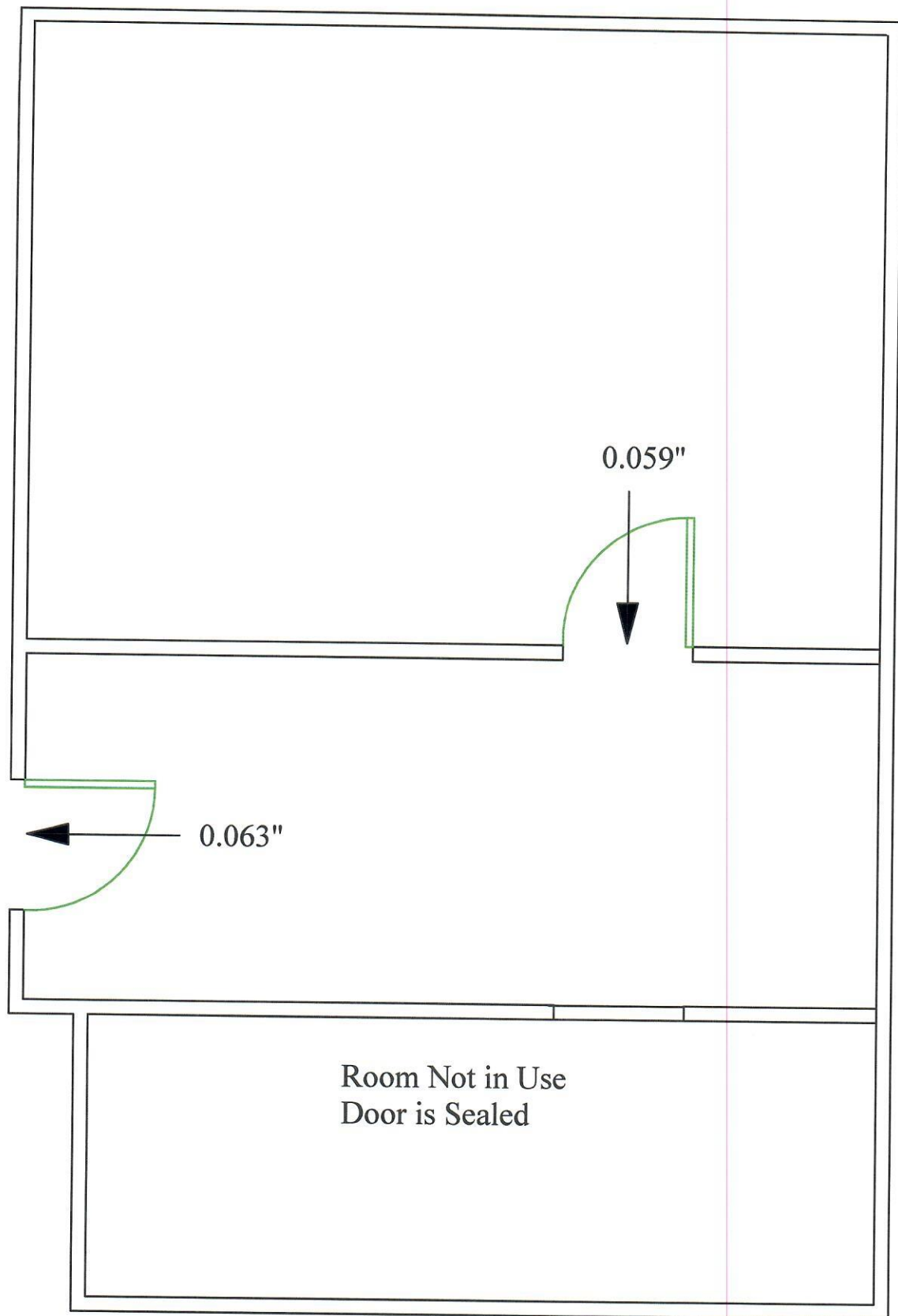
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Viable Air Sample Plan
= TSA Media
= MEA Media



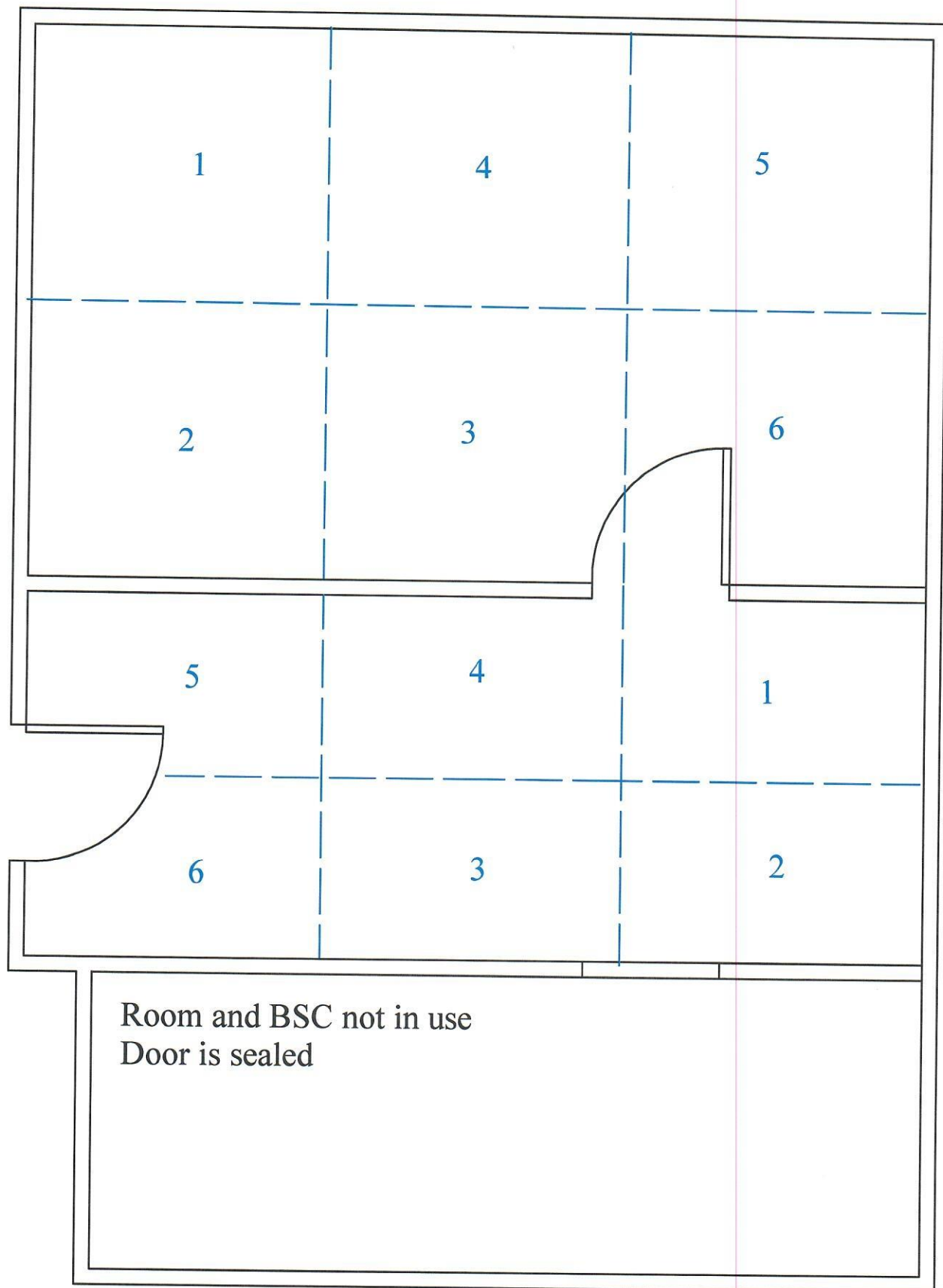
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Surface Sample Plan

= TSA Media
 ⊕ = MEA Media

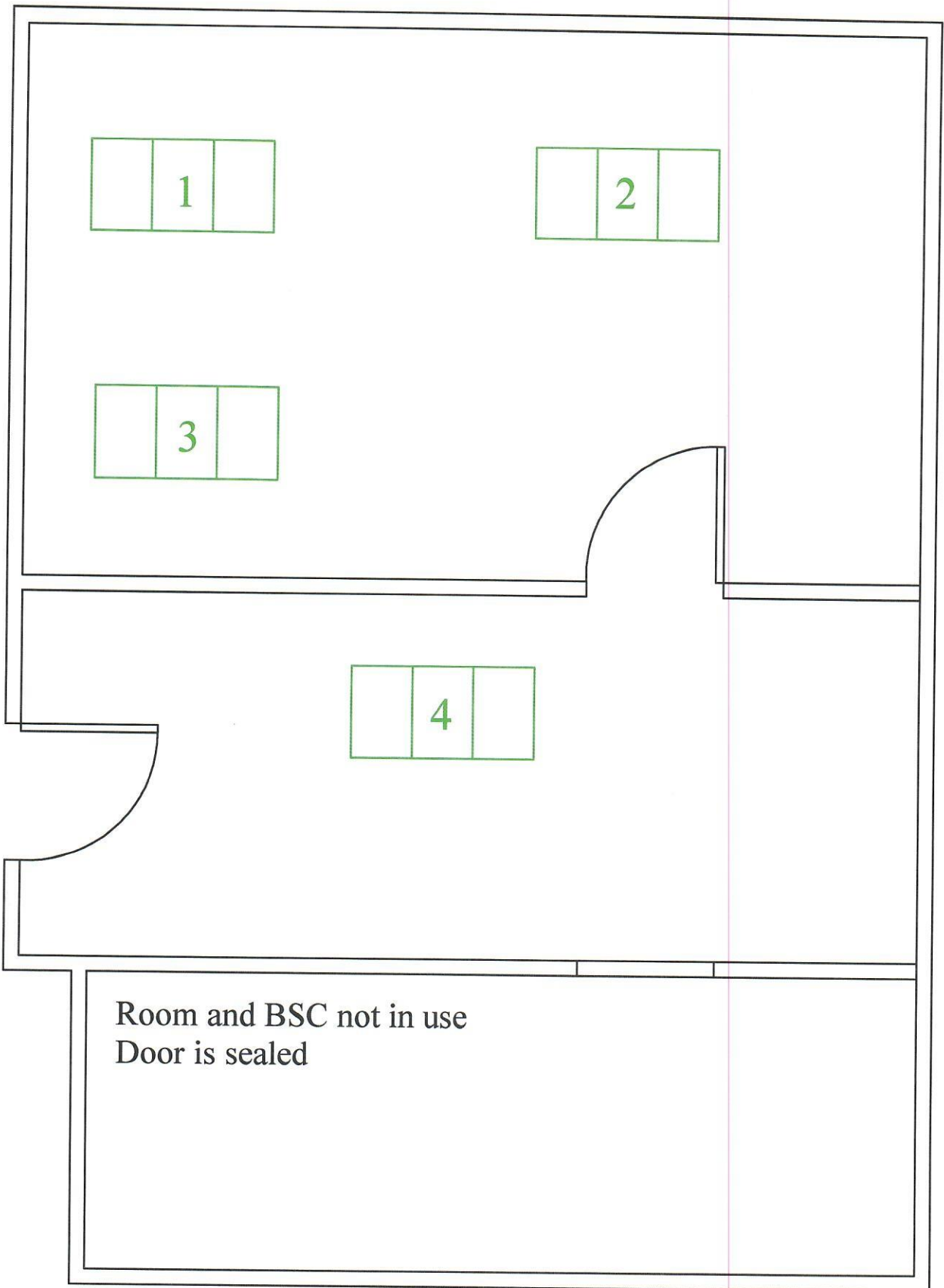


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Pressure Differentials



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Particle count Locations



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HEPA Filter Locations