



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

PERFORMANCE CERTIFICATION

FOR:
Option Care - Hayward
25901 Industrial
Hayward, CA 94545



Test Date:

July 28, 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 8/17/21

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: _____



Arne Gjertsen
RCCP-SC #1114

Date: _____

7/28/22

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

Cleanroom Performance Test Report

Customer:	Option Care Hayward	Dimensions:	522 square feet
Date:	7/28/2022	Volume:	4698 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	10	Location	Readings:
Particle Size	>0.5 micron	1	0.0 particle/cu. mtr.
		2	671.0 particle/cu. mtr.
		3	0.0 particle/cu. mtr.
		4	0.0 particle/cu. mtr.
		5	423.8 particle/cu. mtr.
		6	1,907.0 particle/cu. mtr.
		7	1,200.7 particle/cu. mtr.
		8	494.4 particle/cu. mtr.
		9	282.5 particle/cu. mtr.
Maximum count-	352,000 particle/cu. mtr.	10	882.9 particle/cu. mtr.
Pass/Fail	Pass		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM	
Air Change:		5	91	77	84.0	7.25	609	
Recommended=	30.0 /hour	6	82	70	76.0	7.25	551	
Actual=	68.6 /hour	7	85	98	91.5	7.25	663	
		8	111	94	102.5	7.25	743	
Pass/Fail	Pass	9	102	95	98.5	7.25	714	
		10	104	94	99.0	7.25	718	
		11	95	86	90.5	7.25	656	
		12	106	92	99.0	7.25	718	
		Total CFM =						5,372

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
5	33	<0.01%	N/R	Pass
6	37	<0.01%	N/R	Pass
7	31	<0.01%	N/R	Pass
8	27	<0.01%	N/R	Pass
9	28	<0.01%	N/R	Pass
10	28	<0.01%	N/R	Pass
11	31	<0.01%	N/R	Pass
12	28	<0.01%	N/R	Pass

Signature: 

Date: 7/28/22

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 Hayward	Dimensions:	166 square feet
Date:	7/28/2022	Volume:	1494 cubic feet
Room ID:	Ante Room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5	Location	Readings:
Particle Size	>0.5	1	600.3 particle/cu. mtr.
		2	1,200.7 particle/cu. mtr.
		3	529.7 particle/cu. mtr.
		4	671.0 particle/cu. mtr.
		5	1,200.7 particle/cu. mtr.

Maximum count- 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	85	82	83.5	7.25	605
Actual=	64.2 /hour	2	58	60	59.0	7.25	428
		4	77	79	78.0	7.25	566

Pass/Fail **Pass**

Total CFM = 1599

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
2	47	<0.01%	N/R	Pass
4	36	<0.01%	N/R	Pass

Signature: 

Date: 7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 1878070418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5			
		1		0.0 particle/Cubic Mtr.
		2		0.0 particle/Cubic Mtr.
		3		0.0 particle/Cubic Mtr.
		4		0.0 particle/Cubic Mtr.
		5		0.0 particle/Cubic Mtr.
		6		0.0 particle/Cubic Mtr.

Maximum count- 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	91	FPM Readings:					
Pass/Fail :	Pass	1-	94	9-	96	17-	90
		2-	91	10-	98	18-	88
		3-	91	11-	97	19-	87
Measured Values: Avg. +/- 20%		4-	82	12-	86	20-	88
Min. value =	73	5-	86	13-	83	21-	80
Max. value =	109	6-	103	14-	91	22-	88
Pass/Fail :	Pass	7-	102	15-	87	23-	100
		8-	93	16-	85	24-	89

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: _____



Date: _____

7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187808090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5			
		1		0.0 particle/Cubic Mtr.
		2		0.0 particle/Cubic Mtr.
		3		0.0 particle/Cubic Mtr.
		4		0.0 particle/Cubic Mtr.
		5		0.0 particle/Cubic Mtr.
		6		0.0 particle/Cubic Mtr.
Maximum count- Pass/Fail	3,520 particle/Cubic Mtr. Pass			

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	90	FPM Readings:					
Pass/Fail :	Pass	1-	95	9-	85	17-	93
		2-	95	10-	86	18-	91
		3-	91	11-	85	19-	88
Measured Values: Avg. +/- 20%		4-	87	12-	88	20-	92
Min. value =	72	5-	89	13-	84	21-	83
		6-	93	14-	87	22-	90
Pass/Fail :	Pass	7-	90	15-	90	23-	94
		8-	91	16-	91	24-	95

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	25	<0.01%	N/R	Pass
Right	25	<0.01%	N/R	Pass

Signature: _____



Date: _____

7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187809090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5	1		0.0 particle/Cubic Mtr.
		2		0.0 particle/Cubic Mtr.
		3		0.0 particle/Cubic Mtr.
		4		0.0 particle/Cubic Mtr.
		5		0.0 particle/Cubic Mtr.
		6		0.0 particle/Cubic Mtr.

Maximum count- 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	90	FPM Readings:					
Pass/Fail :	Pass	1-	95	9-	90	17-	93
		2-	95	10-	92	18-	90
		3-	96	11-	102	19-	96
Measured Values: Avg. +/- 20%		4-	85	12-	89	20-	88
Min. value =	72	5-	85	13-	82	21-	83
Max. value =	108	6-	97	14-	88	22-	81
Pass/Fail :	Pass	7-	98	15-	90	23-	91
		8-	83	16-	92	24-	87

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: _____



Date: _____

7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187810090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Readings:		
Particle Size	>0.5	Location	1	0.0 particle/Cubic Mtr.
			2	0.0 particle/Cubic Mtr.
			3	0.0 particle/Cubic Mtr.
			4	0.0 particle/Cubic Mtr.
			5	0.0 particle/Cubic Mtr.
			6	0.0 particle/Cubic Mtr.

Maximum count- 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

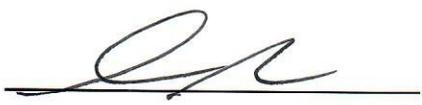
Requirement: 80-100 FPM

Avg. Velocity =	91	FPM Readings:					
Pass/Fail :	Pass	1-	94	9-	87	17-	92
		2-	97	10-	95	18-	87
		3-	94	11-	93	19-	91
Measured Values: Avg. +/- 20%		4-	88	12-	87	20-	88
Min. value =	73	5-	85	13-	85	21-	85
Max. value =	109	6-	93	14-	92	22-	87
Pass/Fail :	Pass	7-	91	15-	98	23-	93
		8-	92	16-	89	24-	93

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: 

Date: 7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187811090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5			
		1		0.0 particle/Cubic Mtr.
		2		0.0 particle/Cubic Mtr.
		3		0.0 particle/Cubic Mtr.
		4		0.0 particle/Cubic Mtr.
		5		0.0 particle/Cubic Mtr.
		6		0.0 particle/Cubic Mtr.

Maximum count- 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	89	FPM Readings:					
Pass/Fail :	Pass	1-	93	9-	85	17-	91
		2-	94	10-	92	18-	86
		3-	100	11-	85	19-	85
Measured Values: Avg. +/- 20%		4-	83	12-	84	20-	83
Min. value =	72	5-	84	13-	87	21-	82
Max. value =	107	6-	92	14-	90	22-	90
Pass/Fail :	Pass	7-	92	15-	87	23-	94
		8-	88	16-	99	24-	99

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	25	<0.01%	N/R	Pass
Right	25	<0.01%	N/R	Pass

Signature: _____



Date: _____

7/28/22

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 - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187812090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location		Readings:
Particle Size	>0.5		1	0.0 particle/Cubic Mtr.
			2	0.0 particle/Cubic Mtr.
			3	0.0 particle/Cubic Mtr.
			4	0.0 particle/Cubic Mtr.
			5	0.0 particle/Cubic Mtr.
			6	0.0 particle/Cubic Mtr.

Maximum UCL = 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	92	FPM Readings:					
Pass/Fail :	Pass	1-	91	9-	85	17-	93
		2-	97	10-	98	18-	97
		3-	94	11-	98	19-	91
Measured Values: Avg. +/- 20%		4-	93	12-	91	20-	96
Min. value =	74	5-	96	13-	83	21-	93
Max. value =	111	6-	91	14-	96	22-	85
Pass/Fail :	Pass	7-	99	15-	89	23-	85
		8-	90	16-	98	24-	89

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: 

Date: 7/28/22

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: Crescent - Hayward
 Date: 7/28/2022
 Manufacturer: NuAire

Model # NU-S201-830
 Serial # 187813090418
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5	1	0.0 particle/Cubic Mtr.
		2	0.0 particle/Cubic Mtr.
		3	0.0 particle/Cubic Mtr.
		4	0.0 particle/Cubic Mtr.
		5	0.0 particle/Cubic Mtr.
		6	0.0 particle/Cubic Mtr.

Maximum UCL = 3,520 particle/Cubic Mtr.
 Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	92	FPM Readings:					
Pass/Fail :	Pass	1-	87	9-	99	17-	95
		2-	94	10-	95	18-	89
		3-	94	11-	84	19-	87
Measured Values: Avg. +/- 20%		4-	96	12-	96	20-	83
Min. value =	74	5-	88	13-	98	21-	95
Max. value =	111	6-	89	14-	89	22-	86
Pass/Fail :	Pass	7-	89	15-	96	23-	100
		8-	103	16-	91	24-	87

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature: 

Date: 7/28/22

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

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

Magnehelic Gauge – Calibration Report

Customer: Crescent Hayward
Date: 7/28/2022

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 3: Ante to Ambient

Dwyer Model 605-11

Pressure readings:

Magnehelic:	Shortridge: Before Adjustment	Shortridge: After Adjust. *
0.25	0.241	
0.20	0.198	
0.15	0.145	
0.10	0.098	
0.05	0.050	
0.00	-0.002	
-0.05	-0.057	
-0.10	-0.107	
-0.15	-0.159	
-0.20	-0.213	
-0.25	-0.264	

* No adjustment required

Signature: 

Date: 7/28/22

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

Magnehelic Gauge – Calibration Report

Customer: Crescent Hayward
Date: 7/28/2022

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 1: Buffer to Ante

Dwyer Model 605-11

Pressure readings:

Magnehelic:	Shortridge: Before Adjustment	Shortridge: After Adjust. *
0.25	0.259	
0.20	0.201	
0.15	0.155	
0.10	0.103	
0.05	0.054	
0.00	0.002	
-0.05	-0.054	
-0.10	-0.103	
-0.15	-0.148	
-0.20	-0.209	
-0.25	-0.262	

* No adjustment required

Signature: 

Date: 7/28/22

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

Magnehelic Gauge – Calibration Report

Customer: Crescent Hayward
Date: 7/28/2022

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 2: NPN to Ante

Dwyer Model 605-11

Pressure readings:

Magnehelic:	Shortridge: Before Adjustment	Shortridge: After Adjust. *
0.25	0.260	
0.20	0.209	
0.15	0.156	
0.10	0.104	
0.05	0.049	
0.00	-0.001	
-0.05	-0.052	
-0.10	-0.102	
-0.15	-0.154	
-0.20	-0.208	
-0.25	-0.262	

* No adjustment required

Signature: _____

Date: 7/28/22

Airflow Smoke Pattern Test

Option Care Hayward

July 28, 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 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 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.

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

Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- Good split of air at table was observed at each workstation.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of workstations.
- No reflux around perimeter nor over operators' head was observed
- Smoke observed flowing in correct direction at door openings

Conclusion:

- PEC: NuAire # 8070 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8080 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8090 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8100 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8110 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8120 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire # 8130 Smoke study validates 1 person compounding maintains unidirectional airflow

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

Signed:  Date: 7/28/22
Arne Gjertsen

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

Cleanroom Performance Test Report

Customer:	Option Care Hayward	Dimensions:	68 square feet
Date:	7/28/2022	Volume:	612 cubic feet
Room ID:	Storage Room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5	Location	Readings:
Particle Size	>0.5	1	10,700.3 particle/cu. mtr.
		2	7,168.9 particle/cu. mtr.
		3	3,990.6 particle/cu. mtr.
		4	2,436.7 particle/cu. mtr.
		5	4,131.8 particle/cu. mtr.

Maximum count- 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	3	51	53	52.0	7.25	377
Actual=	37.0 /hour						
Pass/Fail	Pass						

Total CFM = 377

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
3	54	<0.01%	N/R	Pass

Signature: 

Date: 7/28/22

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

Surface and Viable Air Sampling

Option Care - Hayward

Surface and Viable air sampling were performed, under dynamic conditions, 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, the Class 7 Storage room and the Class 7 Ante room as per attached Sample Plan.

Both Tryptic Soy Agar and Malt Extract Agar were used in each of the Classified 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 July 28, 2022 and delivered to Aerobiology Laboratory for analysis on July 29, 2022.

The results are attached, in Lab reports #22029821. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics:

Air Sample Media

Tryptic Soy: Lot #507933, Exp. 9/6/22; MEA: Lot #508181P, Exp. 9/11/22

Surface Sample Media

Tryptic Soy: Lot #509085, Exp. 9/25/22; MEA: Lot #507439, Exp. 8/29/22

Signature: _____

Arne Gjertsen

Date: _____

8/3/22

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Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

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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	Pass			
2: Class 5 LFB	5	A	Pass			
3: Class 5 LFB	5	A	Pass			
4: Class 5 LFB	5	A	Pass			
5: Class 5 LFB	5	A	Pass			
6: Class 5 LFB	5	A	Pass			
7: Class 5 LFB	5	A	Pass			
8: Class 5 LFB	5	A	Pass			
9: Class 5 LFB	5	A	Pass			
10: Class 5 LFB	5	A	Pass			
11: Class 5 LFB	5	A	Pass			
12: Class 5 LFB	5	A	Pass			
13: Class 5 LFB	5	A	Pass			
14: Class 5 LFB	5	A	Pass			
15: Class 5 LFB	5	A	Pass			
16: Class 5 LFB	5	A	Pass			
17: Class 5 LFB	5	A	Pass			
18: Class 5 LFB	5	A	Pass			
19: Class 5 LFB	5	A	Fail	Acpt		
20: Class 5 LFB	5	A	Pass			
21: Class 5 LFB	5	A	Pass			
22: Class 5 LFB	5	A	Pass			
23: Class 5 LFB	5	A	Pass			
24: Class 5 LFB	5	A	Pass			
25: Class 5 LFB	5	A	Pass			
26: Class 5 LFB	5	A	Pass			
27: Class 5 LFB	5	A	Pass			
28: Class 5 LFB	5	A	Pass			
29: Class 7 Buffer Zone	7	A	Pass			
30: Class 7 Buffer Zone	7	A	Pass			
31: Class 7 Buffer Zone	7	A	Pass			
32: Class 7 Buffer Zone	7	A	Pass			
33: Class 7 Buffer Zone	7	A	Pass			
34: Class 7 Buffer Zone	7	A	Pass			
35: Class 7 Buffer Zone	7	A	Pass			
36: Class 7 Buffer Zone	7	A	Pass			
37: Class 7 Pass Thru	7	A	Pass			
38: Class 7 Pass Thru	7	A	Pass			
39: Class 7 Ante Room	7	A	Fail	Acpt		
40: Class 7 Ante Room	7	A	Pass			
41: Class 7 Ante Room	7	A	Pass			
42: Class 7 Ante Room	7	A	Pass			
43: Class 7 Storage Room	7	A	Fail	Acpt		

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44: Class 7 Storage Room	7	A	
45: Class 7 Storage Room	7	A	
46: Class 7 Storage Room	7	A	
47: Class 5 LFB	5	S	
48: Class 5 LFB	5	S	
49: Class 5 LFB	5	S	
50: Class 5 LFB	5	S	
51: Class 5 LFB	5	S	
52: Class 5 LFB	5	S	
53: Class 5 LFB	5	S	
54: Class 5 LFB	5	S	
55: Class 5 LFB	5	S	
56: Class 5 LFB	5	S	
57: Class 5 LFB	5	S	
58: Class 5 LFB	5	S	
59: Class 5 LFB	5	S	
60: Class 5 LFB	5	S	
61: Class 5 LFB (Touchscreen)	5	S	
62: Class 5 LFB (Touchscreen)	5	S	
63: Class 5 LFB (Touchscreen)	5	S	
64: Class 5 LFB (Touchscreen)	5	S	
65: Class 5 LFB (Touchscreen)	5	S	
66: Class 5 LFB (Touchscreen)	5	S	
67: Class 5 LFB (Touchscreen)	5	S	
68: Class 5 LFB (Touchscreen)	5	S	
69: Class 7 Buffer Zone	7	S	
70: Class 7 Buffer Zone	7	S	
71: Class 7 Buffer Zone	7	S	
72: Class 7 Buffer Zone	7	S	
73: Class 7 Buffer Zone	7	S	
74: Class 7 Buffer Zone	7	S	
75: Class 7 Buffer Zone	7	S	
76: Class 7 Buffer Zone	7	S	
77: Class 7 Pass Thru	7	S	
78: Class 7 Pass Thru	7	S	
79: Class 7 Ante Room	7	S	
80: Class 7 Ante Room	7	S	
81: Class 7 Ante Room	7	S	
82: Class 7 Ante Room	7	S	
83: Class 7 Storage Room	7	S	
84: Class 7 Storage Room	7	S	
85: Class 7 Storage Room	7	S	
86: Class 7 Storage Room	7	S	
87: Control Lot #509085 Exp: 09/25/2022	NA	S	

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88: Control Lot #507439 Exp: 08/29/2022	NA	S	
89: Control/Op Handling Lot #507933 Exp: 09/06/2022	NA	A	
90: Control Lot #508181P Exp: 09/11/2022	NA	A	
91: Class 5 LFB (Touchscreen)	5	S	
92: Class 5 LFB (Touchscreen)	5	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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Client Sample #: 1
Sample Location: Class 5 LFB

Lab Sample #: 22029821-001

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 #: 22029821-002

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 #: 22029821-003

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 #: 22029821-004

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

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

Comments: **Pass**

Client Sample #: 5
Sample Location: Class 5 LFB

Lab Sample #: 22029821-005

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

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

Comments: **Pass**

Client Sample #: 6
Sample Location: Class 5 LFB

Lab Sample #: 22029821-006

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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Client Sample #: 7
Sample Location: Class 5 LFB

Lab Sample #: 22029821-007

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

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

Comments: **Pass**

Client Sample #: 8
Sample Location: Class 5 LFB

Lab Sample #: 22029821-008

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

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

Comments: **Pass**

Client Sample #: 9
Sample Location: Class 5 LFB

Lab Sample #: 22029821-009

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

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

Comments: **Pass**

Client Sample #: 10
Sample Location: Class 5 LFB

Lab Sample #: 22029821-010

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

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

Comments: **Pass**

Client Sample #: 11
Sample Location: Class 5 LFB

Lab Sample #: 22029821-011

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

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

Comments: **Pass**

Client Sample #: 12
Sample Location: Class 5 LFB

Lab Sample #: 22029821-012

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**

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Client Sample #: 13
Sample Location: Class 5 LFB

Lab Sample #: 22029821-013

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 #: 14
Sample Location: Class 5 LFB

Lab Sample #: 22029821-014

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 #: 15
Sample Location: Class 5 LFB

Lab Sample #: 22029821-015

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 #: 16
Sample Location: Class 5 LFB

Lab Sample #: 22029821-016

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 #: 17
Sample Location: Class 5 LFB

Lab Sample #: 22029821-017

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 #: 18
Sample Location: Class 5 LFB

Lab Sample #: 22029821-018

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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Client Sample #: 19
 Sample Location: Class 5 LFB

Lab Sample #: 22029821-019

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 #: 20
 Sample Location: Class 5 LFB

Lab Sample #: 22029821-020

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 #: 21
 Sample Location: Class 5 LFB

Lab Sample #: 22029821-021

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 #: 22
 Sample Location: Class 5 LFB

Lab Sample #: 22029821-022

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 #: 23
 Sample Location: Class 5 LFB

Lab Sample #: 22029821-023

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**

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Client Sample #: 24
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 #: 22029821-024
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 25
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 #: 22029821-025
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 26
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 #: 22029821-026
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 27
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 #: 22029821-027
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 28
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 #: 22029821-028
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 29
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 #: 22029821-029
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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Client Sample #: 30
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-030

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 #: 31
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-031

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 #: 32
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-032

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 #: 33
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-033

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 #: 34
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-034

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 #: 35
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-035

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**

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Client Sample #: 36
 Sample Location: Class 7 Buffer Zone

Lab Sample #: 22029821-036

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 #: 37
 Sample Location: Class 7 Pass Thru

Lab Sample #: 22029821-037

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 #: 38
 Sample Location: Class 7 Pass Thru

Lab Sample #: 22029821-038

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 #: 39
 Sample Location: Class 7 Ante Room

Lab Sample #: 22029821-039

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 #: 40
 Sample Location: Class 7 Ante Room

Lab Sample #: 22029821-040

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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Client Sample #: 41
 Sample Location: Class 7 Ante Room
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-041
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 42
 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 #: 22029821-042
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 43
 Sample Location: Class 7 Storage Room
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **1 CFU/m3**

Lab Sample #: 22029821-043
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

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

Comments: **Acceptable**

Client Sample #: 44
 Sample Location: Class 7 Storage Room
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-044
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 45
 Sample Location: Class 7 Storage Room
 Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-045
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

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Client Sample #: 46
Sample Location: Class 7 Storage Room

Lab Sample #: 22029821-046

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 #: 47
Sample Location: Class 5 LFB

Lab Sample #: 22029821-047

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**

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

Comments: **Pass**

Client Sample #: 48
Sample Location: Class 5 LFB

Lab Sample #: 22029821-048

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**

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

Comments: **Pass**

Client Sample #: 49
Sample Location: Class 5 LFB

Lab Sample #: 22029821-049

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**

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

Comments: **Pass**

Client Sample #: 50
Sample Location: Class 5 LFB

Lab Sample #: 22029821-050

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**

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

Comments: **Pass**

Client Sample #: 51
Sample Location: Class 5 LFB

Lab Sample #: 22029821-051

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**

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

Comments: **Pass**

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 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **Option Care, Hayward**
 Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 52
 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 #: 22029821-052
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 53
 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 #: 22029821-053
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 54
 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 #: 22029821-054
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 55
 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 #: 22029821-055
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 56
 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 #: 22029821-056
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 57
 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 #: 22029821-057
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 58
 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 #: 22029821-058
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Client Sample #: 59
 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 #: 22029821-059
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 60
 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 #: 22029821-060
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 61
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **1 CFU/25cm2**

Lab Sample #: 22029821-061
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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

Comments: **Acceptable**

Client Sample #: 62
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-062
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 63
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-063
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 64
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-064
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Client Sample #: 65
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-065
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 66
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-066
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 67
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-067
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 68
 Sample Location: Class 5 LFB (Touchscreen)
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22029821-068
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 69
 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 #: 22029821-069
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 70
 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 #: 22029821-070
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 71
 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 #: 22029821-071
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

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Client Sample #: 72
 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 #: 22029821-072
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 73
 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 #: 22029821-073
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 74
 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 #: 22029821-074
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 75
 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 #: 22029821-075
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 76
 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 #: 22029821-076
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 77
 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 #: 22029821-077
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

Client Sample #: 78
 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 #: 22029821-078
 Area: **25 cm²**
 MRL: **1 CFU/25cm²**

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Client Sample #: 79
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 #: 22029821-079

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 80
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 #: 22029821-080

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 81
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 #: 22029821-081

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 82
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 #: 22029821-082

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 83
Sample Location: Class 7 Storage Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22029821-083

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 84
Sample Location: Class 7 Storage Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22029821-084

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 85
Sample Location: Class 7 Storage Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22029821-085

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Client Sample #: 86
Sample Location: Class 7 Storage Room

Lab Sample #: 22029821-086

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 #: 87
Sample Location: Control Lot #509085 Exp: 09/25/2022

Lab Sample #: 22029821-087

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

Client Sample #: 88
Sample Location: Control Lot #507439 Exp: 08/29/2022

Lab Sample #: 22029821-088

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

Client Sample #: 89
Sample Location: Control/Op Handling Lot #507933 Exp: 09/06/2022

Lab Sample #: 22029821-089

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

Client Sample #: 90
Sample Location: Control Lot #508181P Exp: 09/11/2022

Lab Sample #: 22029821-090

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

Client Sample #: 91
Sample Location: Class 5 LFB (Touchscreen)

Lab Sample #: 22029821-091

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 #: 92
Sample Location: Class 5 LFB (Touchscreen)

Lab Sample #: 22029821-092

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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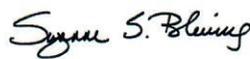
USP 797 Class and Action Levels

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

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

Footnotes and Additional Report Information

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


Suzanne Blevins
Laboratory Director

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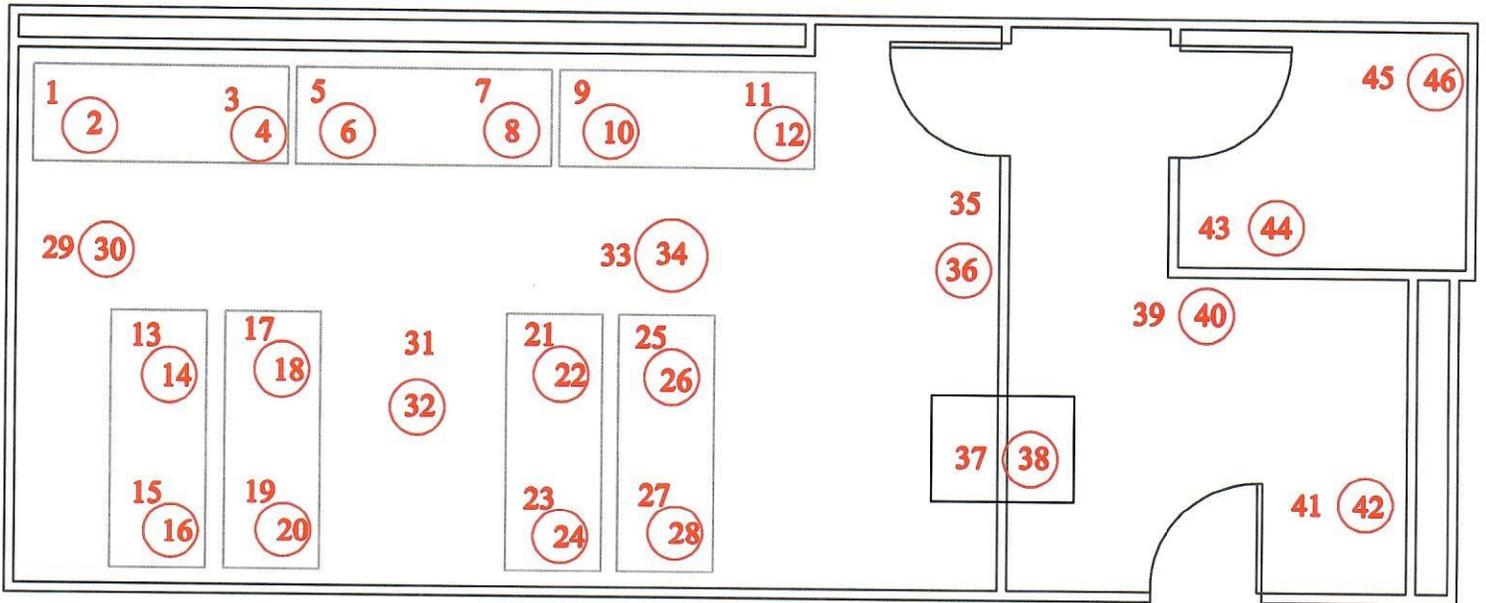
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GLOSSARY

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

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.



Option Care Hayward

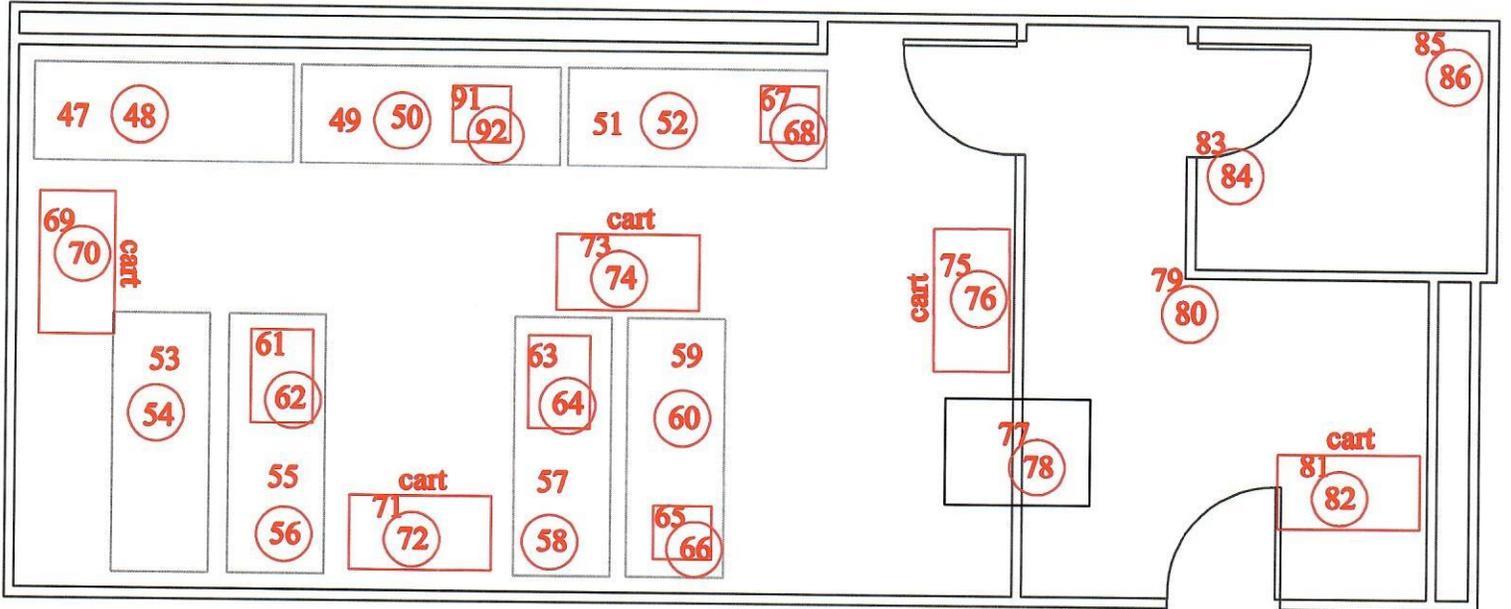
Viable Air Sample Plan

89 = Control/Operator Handling

90 = Control

= TSA AIR

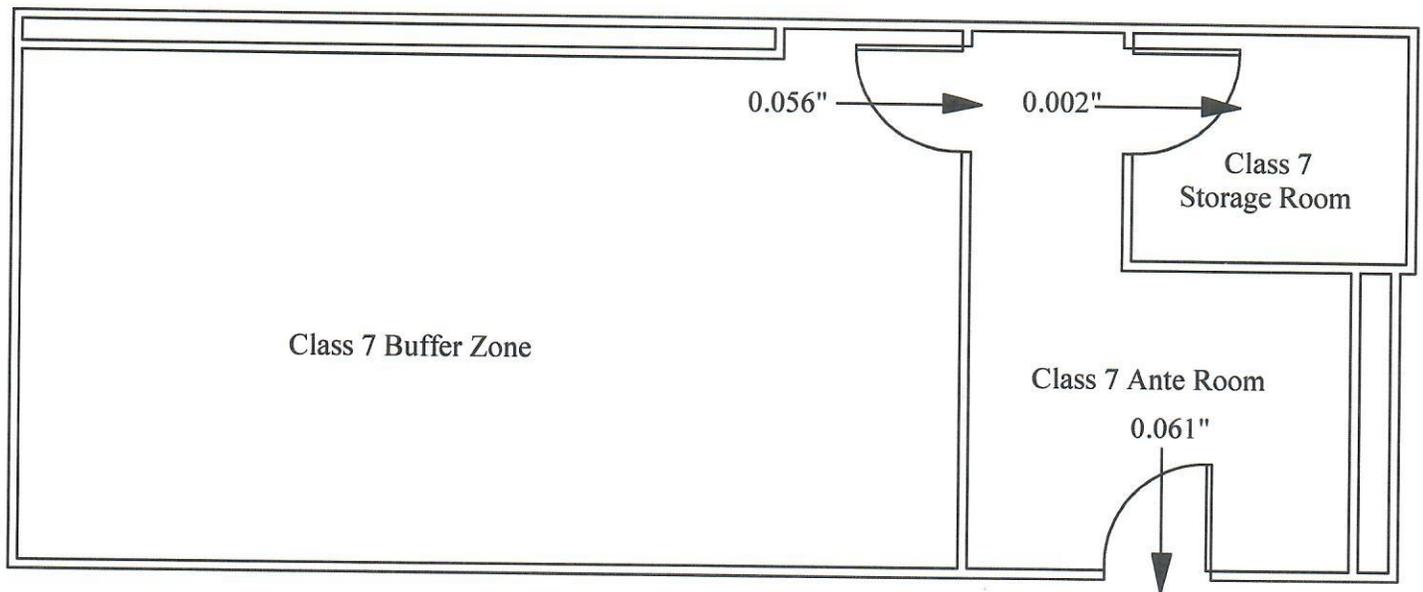
⊙ = MEA AIR



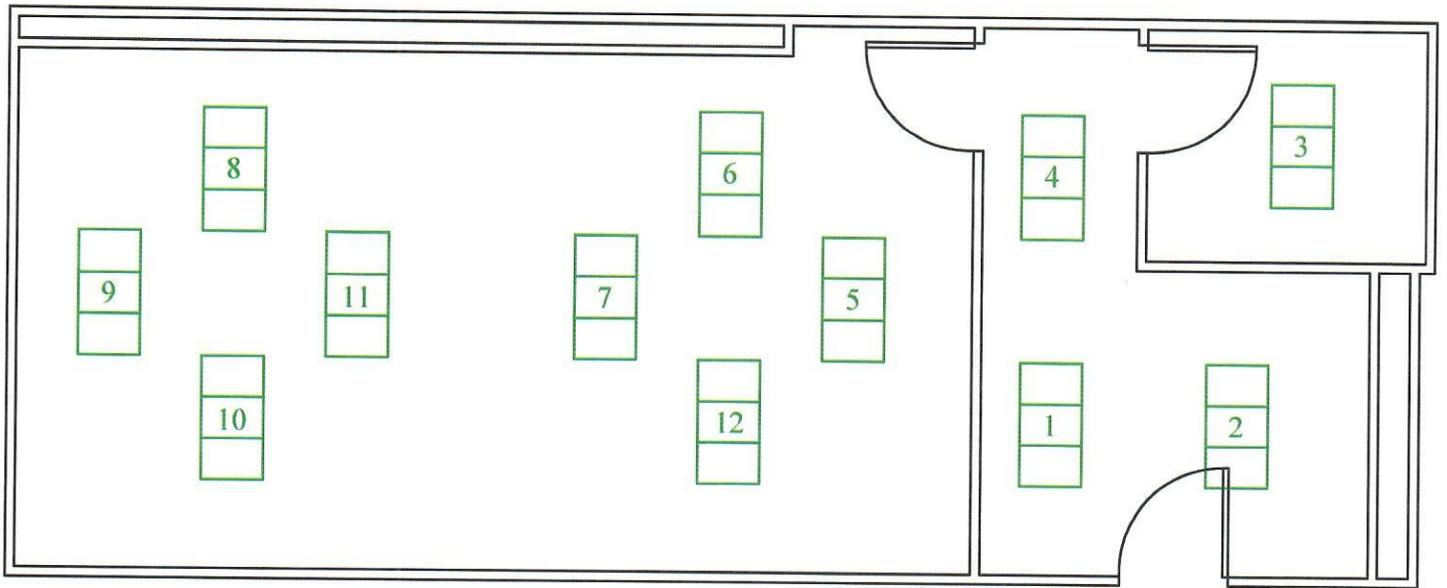
**Option Care Hayward
Surface Sample Plan**

= TSA AIR
 (#) = MEA AIR

87 = Control
 (88) = Control



Option Care Hayward
Pressure Gradients



Option Care Hayward
HEPA Filter Locations

