CRP CLEANROOMS PLUS

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

PERFORMANCE CERTIFICATION

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

Test Date:

February 7, 2022

1587 W. Sim Place, Anaheim, CA 92802 [phone] 714-534-2770 [fax] 714-534-9460 [email] info@cleanroomsplus.com
www.cleanroomsplus.com

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 CI150T, serial #131729; calibrated 3/4/21

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 4/1/21

Pressure Differential

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

Test Instruments:
AirData Multimeter – Shortridge Model ADM-860C, serial # M15523; Calibrated 4/1/21

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

Laminar Flow Benches

Particle Count

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

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

Test Instruments:
Laser Particle Counter – Climet model CI150T, serial #131729; calibrated 3/4/21

HEPA Filter Integrity Test

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

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

Test Instruments:
Photometer - ATI Model TDA-2g, serial #13237; Calibrated 1/10/22
Aerosol Generator – ATI Model TDA-4BL (calibration not required)
PAO was used as the aerosol

Air Flow

Clean flow benches were measured and adjusted for airflow in accordance 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: 2/7/22

Arne Gjertsen
RCCP-SC #1114

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

Cleanroom Performance Test Report

Customer:	Option Care Hayward	Dimensions:	522 square feet
Date:	2/7/2022	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	494.4 particle/cu. mtr.
		2	35.3 particle/cu. mtr.
		3	141.3 particle/cu. mtr.
		4	388.5 particle/cu. mtr.
		5	706.3 particle/cu. mtr.
		6	1,200.7 particle/cu. mtr.
		7	882.9 particle/cu. mtr.
		8	1,801.0 particle/cu. mtr.
		9	35.3 particle/cu. mtr.
Maximum count-	352,000 particle/cu. mtr.	10	5,191.3 particle/cu. mtr.
Pass/Fail	**Pass**		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		5	86	84	85.0	7.25	616
Recommended=	30.0 /hour	6	93	97	95.0	7.25	689
Actual=	64.8 /hour	7	80	100	90.0	7.25	653
		8	83	90	86.5	7.25	627
Pass/Fail	**Pass**	9	72	82	77.0	7.25	558
		10	95	84	89.5	7.25	649
		11	89	99	94.0	7.25	682
		12	82	84	83.0	7.25	602
				Total CFM =			5,075

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
5	22	<0.01%	N/R	Pass
6	20	<0.01%	N/R	Pass
7	21	<0.01%	N/R	Pass
8	22	<0.01%	N/R	Pass
9	24	<0.01%	N/R	Pass
10	21	<0.01%	N/R	Pass
11	20	<0.01%	N/R	Pass
12	22	<0.01%	N/R	Pass

Signature:  Date: 2/7/22

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:	2/7/2022	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	1,412.6 particle/cu. mtr.
		2	11,230.1 particle/cu. mtr.
		3	7,274.8 particle/cu. mtr.
		4	1,483.2 particle/cu. mtr.
		5	5,473.8 particle/cu. mtr.

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

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	46	48	47.0	7.25	341
Recommended=	30.0 /hour	2	44	47	45.5	7.25	330
Actual=	41.3 /hour	4	43	56	49.5	7.25	359

Pass/Fail **Pass**

Total CFM = **1030**

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	40	<0.01%	N/R	Pass
2	41	<0.01%	N/R	Pass
4	38	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	1878070418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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 = 92
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 74
Max. value = 111
Pass/Fail : **Pass**

FPM Readings:

1-	97	9-	86	17-	98		
2-	100	10-	89	18-	90		
3-	97	11-	93	19-	87		
4-	89	12-	84	20-	93		
5-	84	13-	86	21-	101		
6-	85	14-	92	22-	93		
7-	96	15-	97	23-	94		
8-	93	16-	99	24-	92		

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187808090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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 = 93
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 75
112
Pass/Fail : **Pass**

FPM Readings:

1-	95	9-	98	17-	91
2-	101	10-	96	18-	92
3-	93	11-	95	19-	95
4-	93	12-	93	20-	86
5-	86	13-	85	21-	98
6-	87	14-	91	22-	99
7-	95	15-	93	23-	96
8-	96	16-	93	24-	92

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187809090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 72
Max. value = 108
Pass/Fail : **Pass**

FPM Readings:

1-	89	9-	96	17-	92
2-	95	10-	88	18-	96
3-	94	11-	89	19-	91
4-	84	12-	90	20-	95
5-	84	13-	87	21-	86
6-	96	14-	81	22-	86
7-	100	15-	84	23-	94
8-	93	16-	89	24-	88

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187810090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Readings:		
Locations required:	6	Location	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5		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 = 93
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 74
Max. value = 111
Pass/Fail : **Pass**

FPM Readings:

1-	95	9-	91	17-	93
2-	99	10-	90	18-	97
3-	93	11-	92	19-	98
4-	92	12-	94	20-	84
5-	86	13-	87	21-	88
6-	90	14-	94	22-	98
7-	96	15-	94	23-	94
8-	92	16-	94	24-	95

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187811090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 72
Max. value = 107
Pass/Fail : **Pass**

FPM Readings:

1-	94	9-	92	17-	95
2-	92	10-	88	18-	90
3-	90	11-	87	19-	93
4-	91	12-	84	20-	84
5-	81	13-	88	21-	82
6-	90	14-	87	22-	92
7-	93	15-	96	23-	87
8-	97	16-	85	24-	87

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187812090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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 = 93
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 74
Max. value = 112
Pass/Fail : **Pass**

FPM Readings:

1-	91	9-	86	17-	94
2-	94	10-	92	18-	99
3-	97	11-	93	19-	92
4-	98	12-	93	20-	95
5-	100	13-	96	21-	94
6-	89	14-	88	22-	93
7-	99	15-	86	23-	91
8-	88	16-	87	24-	96

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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	Model #	NU-S201-830
Date:	2/7/2022	Serial #	187813090418
Manufacturer:	NuAire	Class:	5
		Test Status:	Dynamic

Particle Count

		Location	Readings:
Locations required:	6	1	0.0 particle/Cubic Mtr.
Particle Size	>0.5	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 = 94
Pass/Fail : **Pass**

Measured Values: Avg. +/- 20%
Min. value = 75
Max. value = 112
Pass/Fail : **Pass**

FPM Readings:

1-	88	9-	94	17-	94
2-	95	10-	89	18-	91
3-	100	11-	92	19-	91
4-	93	12-	100	20-	96
5-	93	13-	93	21-	93
6-	91	14-	91	22-	89
7-	87	15-	101	23-	98
8-	101	16-	93	24-	91

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
Left	16	<0.01%	N/R	Pass
Right	16	<0.01%	N/R	Pass

Signature: 

Date: 2/7/22

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:	68 square feet
Date:	2/7/2022	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	5,438.5 particle/cu. mtr.
		2	12,466.1 particle/cu. mtr.
		3	18,999.3 particle/cu. mtr.
		4	19,564.3 particle/cu. mtr.
		5	22,813.3 particle/cu. mtr.

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

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		3	85	82	83.5	7.25	605
Recommended=	30.0 /hour						
Actual=	59.4 /hour						

Pass/Fail **Pass**

Total CFM = 605

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
3	22	<0.01%	N/R	Pass

Signature: _____ Date: 2/7/22

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

Airflow Smoke Pattern Test

Option Care Hayward

February 7, 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.

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 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 8130 Smoke study validates 2 person compounding maintains unidirectional airflow

All of the workstations 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: 2/7/22

Arne Gjertsen

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

Weight Scale – Calibration Report

Customer: Option Care

Calibration Date: 2/7/2022

Calibration Due Date: 2/7/2023

Model # CS-2000-001 Scale Identification # Pharmacy

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	200g	200g	0g	± 1 g	Pass
3	500g	500g	500g	0g	± 1 g	Pass
4	1000g	1000g	1000g	0g	± 1 g	Pass

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

Signature: _____ Date: 2/7/22

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 February 7, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab reports #22004682. All of the tests were within the allowable CFU and passed except Sample Location #35. It was retested on 2/17/22 and passed. It should be noted that the media for Sample Locations #5, #41 and #42 had cracked plates and were also retested on 2/17/22 and passed as per attached report #22006286.

A SAS Model 360-duo; s/n 21-D-16717 calibrated 5/3/21 was used for all tests.

Manufacturer – Hardy Diagnostics:
Air Sample Media
Tryptic Soy: Lot # 499315, Exp. 4/13/22; MEA: Lot # 498317, Exp. 3/27/22
Retest
Tryptic Soy: Lot # 497536, Exp. 3/13/22; MEA: Lot # 497094, Exp. 3/4/22

Surface Sample Media
Tryptic Soy: Lot # 488611, Exp. 10/14/21; MEA: Lot # 489264, Exp. 10/26/21

Signature: _____ Date: 2/24/22
Arne Gjertsen

Aerobiology Laboratory Associates, Incorporated
A Pace® Laboratory

Certificate of Analysis
AIHA-LAP EMLAP# 218951

15061 Springdale St
Suite 111
Huntington Beach, CA 92649
7148958401

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

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682
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AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LAFW	5	A				
2: Class 5 LAFW	5	A				
3: Class 5 LAFW	5	A				
4: Class 5 LAFW	5	A				
5: Class 5 LAFW	5	A				
6: Class 5 LAFW	5	A				
7: Class 5 LAFW	5	A				
8: Class 5 LAFW	5	A				
9: Class 5 LAFW	5	A				
10: Class 5 LAFW	5	A				
11: Class 5 LAFW	5	A				
12: Class 5 LAFW	5	A				
13: Class 5 LAFW	5	A				
14: Class 5 LAFW	5	A				
15: Class 5 LAFW	5	A				
16: Class 5 LAFW	5	A				
17: Class 5 LAFW	5	A				
18: Class 5 LAFW	5	A				
19: Class 5 LAFW	5	A				
20: Class 5 LAFW	5	A				
21: Class 5 LAFW	5	A				
22: Class 5 LAFW	5	A				
23: Class 5 LAFW	5	A				
24: Class 5 LAFW	5	A				
25: Class 5 LAFW	5	A				
26: Class 5 LAFW	5	A				
27: Class 5 LAFW	5	A				
28: Class 7 Buffer Zone	7	A				
29: Class 7 Buffer Zone	7	A				
30: Class 7 Buffer Zone	7	A				
31: Class 7 Buffer Zone	7	A				
32: Class 7 Buffer Zone	7	A				
33: Class 7 Buffer Zone	7	A				
34: Class 7 Buffer Zone	7	A				
35: Class 7 Buffer Zone	7	A				Presence of actionable microorganisms
36: Class 7 Pass Thru	7	A				
37: Class 7 Pass Thru	7	A				
38: Class 7 Ante Room	7	A				
39: Class 7 Ante Room	7	A				
40: Class 7 NPR Storage	7	A				
41: Class 7 NPR Storage	7	A				
42: Class 7 NPR Storage	7	A				
43: Class 7 NPR Storage	7	A				
44: Class 5 LAFW	5	S				
45: Class 5 LAFW	5	S				

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15061 Springdale St
Suite 111
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7148958401

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

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682
	Page 2 of 19

46: Class 5 LAFW	5	S	
47: Class 5 LAFW	5	S	
48: Class 5 LAFW	5	S	
49: Class 5 LAFW	5	S	
50: Class 5 LAFW	5	S	
51: Class 5 LAFW	5	S	
52: Class 5 LAFW	5	S	
53: Class 5 LAFW	5	S	
54: Class 5 LAFW	5	S	
55: Class 5 LAFW	5	S	
56: Class 5 LAFW	5	S	
57: Class 5 LAFW	5	S	
58: Class 5 LAFW Touchscreen	5	S	
59: Class 5 LAFW Touchscreen	5	S	
60: Class 5 LAFW Touchscreen	5	S	
61: Class 5 LAFW Touchscreen	5	S	
62: Class 5 LAFW Touchscreen	5	S	
63: Class 5 LAFW Touchscreen	5	S	
64: Class 5 LAFW Touchscreen	5	S	
65: Class 5 LAFW Touchscreen	5	S	
66: Class 7 Buffer Zone	7	S	
67: Class 7 Buffer Zone	7	S	
68: Class 7 Buffer Zone	7	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 Pass Thru	7	S	
75: Class 7 Pass Thru	7	S	
76: Class 7 Ante Room	7	S	
77: Class 7 Ante Room	7	S	
78: Class 7 Ante Room	7	S	
79: Class 7 Ante Room	7	S	
80: Class 7 NPR Storage	7	S	
81: Class 7 NPR Storage	7	S	
82: Class 7 NPR Storage	7	S	
83: Class 7 NPR Storage	7	S	
84: Control Lot #489161 Exp: 04-11-2022	NA	S	
85: Control Lot #498889 Exp: 04-06-2022	NA	S	
86: Control / OP. Handling Lot #499315 Exp: 04-13-2022	NA	A	
87: Control Lot # 498317 Exp: 03-27-2022	NA	A	

No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.

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Condition of Sample(s) Upon Receipt: Acceptable

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Date Reported:	2/15/2022
Project ID:	22004682

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, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 1
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-001

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 LAFW
Lab Sample #: 22004682-002

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 LAFW
Lab Sample #: 22004682-003

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 LAFW
Lab Sample #: 22004682-004

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 #: 6
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-006

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

Client Sample #: 7
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-007

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

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

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682

Client Sample #: 8
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-008

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 LAFW
Lab Sample #: 22004682-009

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 LAFW
Lab Sample #: 22004682-010

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 LAFW
Lab Sample #: 22004682-011

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 LAFW
Lab Sample #: 22004682-012

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: Class 5 LAFW
Lab Sample #: 22004682-013

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

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682

Client Sample #: 14
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-014

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 LAFW
Lab Sample #: 22004682-015

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 LAFW
Lab Sample #: 22004682-016

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 LAFW
Lab Sample #: 22004682-017

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 LAFW
Lab Sample #: 22004682-018

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

Client Sample #: 19
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-019

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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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 20
Lab Sample #: 22004682-020
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 21
Lab Sample #: 22004682-021
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 22
Lab Sample #: 22004682-022
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 23
Lab Sample #: 22004682-023
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 24
Lab Sample #: 22004682-024
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 25
Lab Sample #: 22004682-025
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 26
Lab Sample #: 22004682-026
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 27
Lab Sample #: 22004682-027
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 28
Lab Sample #: 22004682-028
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 29
Lab Sample #: 22004682-029
Sample Location: Class 7 Buffer Zone
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 30
Lab Sample #: 22004682-030
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

Client Sample #: 31
Lab Sample #: 22004682-031
Sample Location: Class 7 Buffer Zone
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Air Volume: **1000 L**
Results: **No Growth**
Positive Hole: **219**
MRL: **1 CFU/m3**
Comments: Pass

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 32
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22004682-032

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 #: 22004682-033

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
Micrococcus species	1	1	100
	1	**1**	**~100%**

Comments: Acceptable

Client Sample #: 34
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22004682-034

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 #: 22004682-035

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

Client Sample #: 36
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22004682-036

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **1 CFU/m3**
Air Volume: **1000 L**
Positive Hole: **219**

Organism(s) Isolated:	Raw Count	CFU/m3	% Total	MRL
Yeast	1	1	100	1 CFU/m3
	1	**1**	**~100%**	

Comments: [illegible]

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 37
Sample Location: Class 7 Pass Thru
Lab Sample #: 22004682-037

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 #: 22004682-038

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 #: 22004682-039

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 #: 40
Sample Location: Class 7 Ante Room
Lab Sample #: 22004682-040

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

Client Sample #: 43
Sample Location: Class 7 NPR Storage
Lab Sample #: 22004682-043

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 #: 44
Sample Location: Class 7 NPR Storage
Lab Sample #: 22004682-044

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, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 45
Lab Sample #: 22004682-045
Sample Location: Class 7 NPR Storage

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **4 CFU/m3**

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total
Coag-negative Staphylococcus species	3	3	75
Micrococcus species	1	1	25
	4	**4**	**~100%**

Comments: Acceptable

Client Sample #: 46
Lab Sample #: 22004682-046
Sample Location: Class 7 NPR Storage

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
Lab Sample #: 22004682-047
Sample Location: Class 5 LAFW

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 #: 48
Lab Sample #: 22004682-048
Sample Location: Class 5 LAFW

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 #: 49
Lab Sample #: 22004682-049
Sample Location: Class 5 LAFW

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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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 50 — Lab Sample #: 22004682-050
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 51 — Lab Sample #: 22004682-051
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 52 — Lab Sample #: 22004682-052
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 53 — Lab Sample #: 22004682-053
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 54 — Lab Sample #: 22004682-054
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 55 — Lab Sample #: 22004682-055
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 56 — Lab Sample #: 22004682-056
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

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

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 57
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-057

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 #: 58
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-058

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 #: 59
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-059

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 #: 60
Sample Location: Class 5 LAFW
Lab Sample #: 22004682-060

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 #: 61
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22004682-061

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 #: 62
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22004682-062

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 #: 63
Sample Location: Class 5 LAFW Touchscreen
Lab Sample #: 22004682-063

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 64 — Lab Sample #: 22004682-064
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 65 — Lab Sample #: 22004682-065
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 66 — Lab Sample #: 22004682-066
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 67 — Lab Sample #: 22004682-067
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 68 — Lab Sample #: 22004682-068
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 69 — Lab Sample #: 22004682-069
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 70 — Lab Sample #: 22004682-070
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 71 — Lab Sample #: 22004682-071
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 72 — Lab Sample #: 22004682-072
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 73 — Lab Sample #: 22004682-073
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 74 — Lab Sample #: 22004682-074
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 75 — Lab Sample #: 22004682-075
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 76 — Lab Sample #: 22004682-076
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 77 — Lab Sample #: 22004682-077
Sample Location: Class 7 Pass Thru
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 78 — Lab Sample #: 22004682-078
Sample Location: Class 7 Pass Thru
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 79 — Lab Sample #: 22004682-079
Sample Location: Class 7 Ante Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 80 — Lab Sample #: 22004682-080
Sample Location: Class 7 Ante Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 81 — Lab Sample #: 22004682-081
Sample Location: Class 7 Ante Room
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 82 — Lab Sample #: 22004682-082
Sample Location: Class 7 Ante Room
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 83 — Lab Sample #: 22004682-083
Sample Location: Class 7 NPR Storage
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 84 — Lab Sample #: 22004682-084
Sample Location: Class 7 NPR Storage
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/7/2022
Date Received: 2/8/2022
Date Analyzed: 2/14/2022
Date Reported: 2/15/2022
Project ID: 22004682

Client Sample #: 85 — Lab Sample #: 22004682-085
Sample Location: Class 7 NPR Storage

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 86 — Lab Sample #: 22004682-086
Sample Location: Class 7 NPR Storage

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9 — Area: **25 cm2**
Results: **No Growth** — MRL: **1 CFU/25cm2**
Comments: Pass

Client Sample #: 87 — Lab Sample #: 22004682-087
Sample Location: Control Lot #489161 Exp: 04-11-2022

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

Client Sample #: 88 — Lab Sample #: 22004682-088
Sample Location: Control Lot #498889 Exp: 04-06-2022

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

Client Sample #: 89 — Lab Sample #: 22004682-089
Sample Location: Control / OP. Handling Lot #499315 Exp: 04-13-2022

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

Client Sample #: 90 — Lab Sample #: 22004682-090
Sample Location: Control Lot # 498317 Exp: 03-27-2022

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

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682

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

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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 S. Blevins

Suzanne Blevins
Laboratory Director

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Project: **Option Care, Hayward**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	2/7/2022
Date Received:	2/8/2022
Date Analyzed:	2/14/2022
Date Reported:	2/15/2022
Project ID:	22004682

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.

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

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Project: **Option Care Hayward Re-test**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	2/17/2022
Date Received:	2/19/2022
Date Analyzed:	2/24/2022
Date Reported:	2/24/2022
Project ID:	22006286

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LFB	5	A				
2: Class 7 Buffer Zone	7	A				
3: Class 7 Ante Room	7	A				
4: Class 7 Ante Room	7	A				
5: Control / Operator Handling Lot # 497536, Exp: 3/13/22	NA	A				
6: Control Lot # 497094, Exp: 3/4/22	NA	A				

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 Hayward Re-test**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 2/17/2022
Date Received: 2/19/2022
Date Analyzed: 2/24/2022
Date Reported: 2/24/2022
Project ID: 22006286

Client Sample #: 1 (5)
Sample Location: Class 5 LFB
Lab Sample #: 22006286-001

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 (35)
Sample Location: Class 7 Buffer Zone
Lab Sample #: 22006286-002

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 (41)
Sample Location: Class 7 Ante Room
Lab Sample #: 22006286-003

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 (42)
Sample Location: Class 7 Ante Room
Lab Sample #: 22006286-004

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: Control / Operator Handling Lot # 497536, Exp: 3/13/22
Lab Sample #: 22006286-005

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

Client Sample #: 6
Sample Location: Control Lot # 497094, Exp: 3/4/22
Lab Sample #: 22006286-006

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

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Project: **Option Care Hayward Re-test**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected:	2/17/2022
Date Received:	2/19/2022
Date Analyzed:	2/24/2022
Date Reported:	2/24/2022
Project ID:	22006286

USP 797 Class and Action Levels

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Source PIC/S, 2007

Footnotes and Additional Report Information

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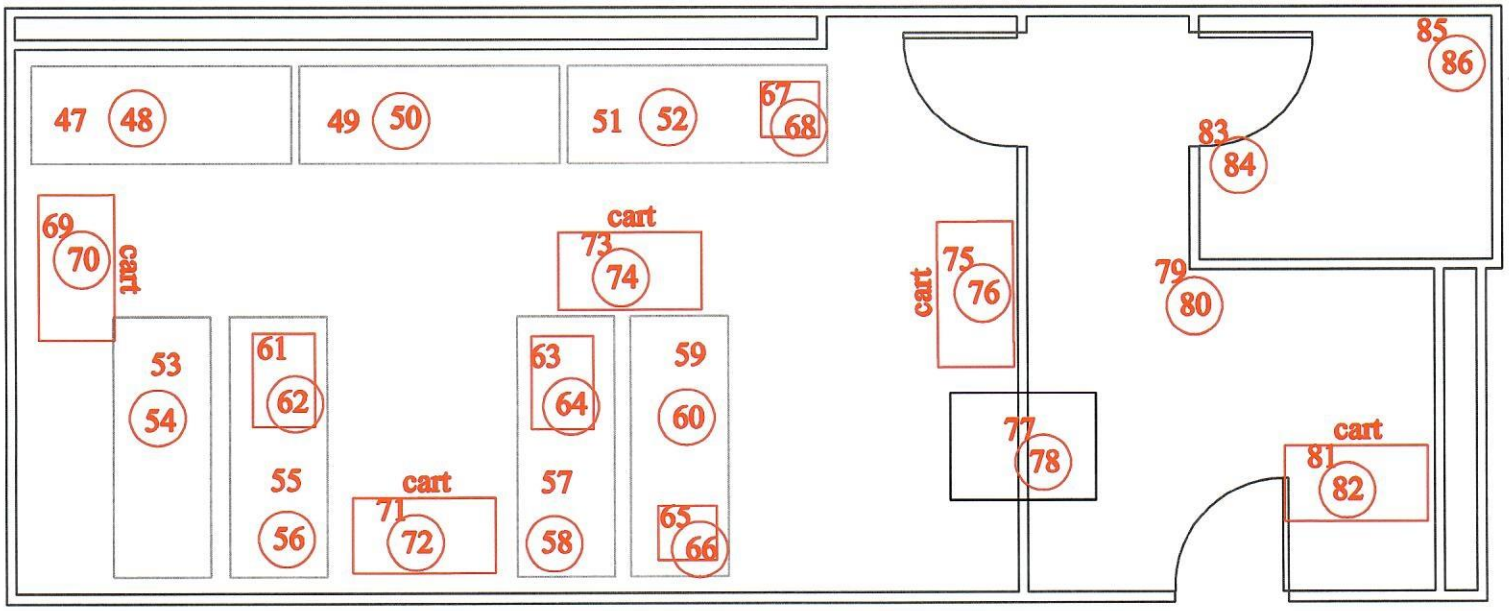
Due to rounding totals may not equal 100%.

Suzanne S. Blevins

Suzanne Blevins
Laboratory Director



Option Care Hayward

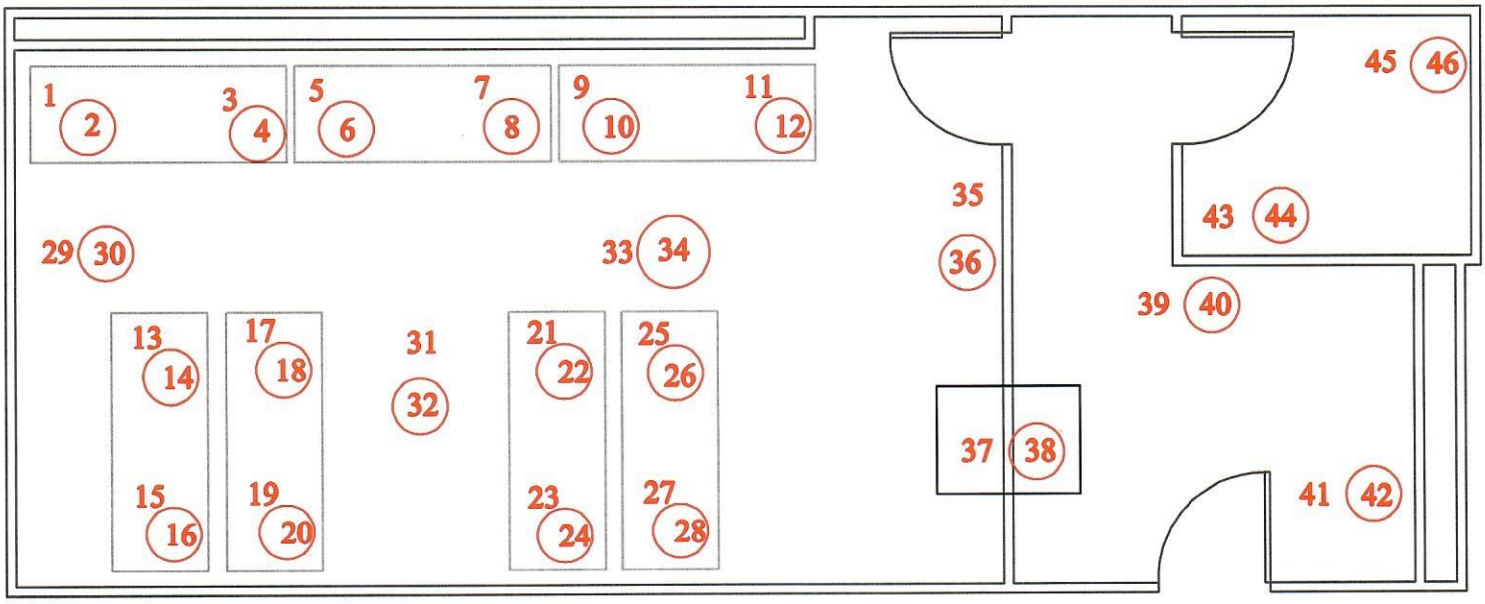
Surface Sample Plan

\# = TSA AIR

(#) = MEA AIR

87 = Control

(88) = Control



Option Care Hayward

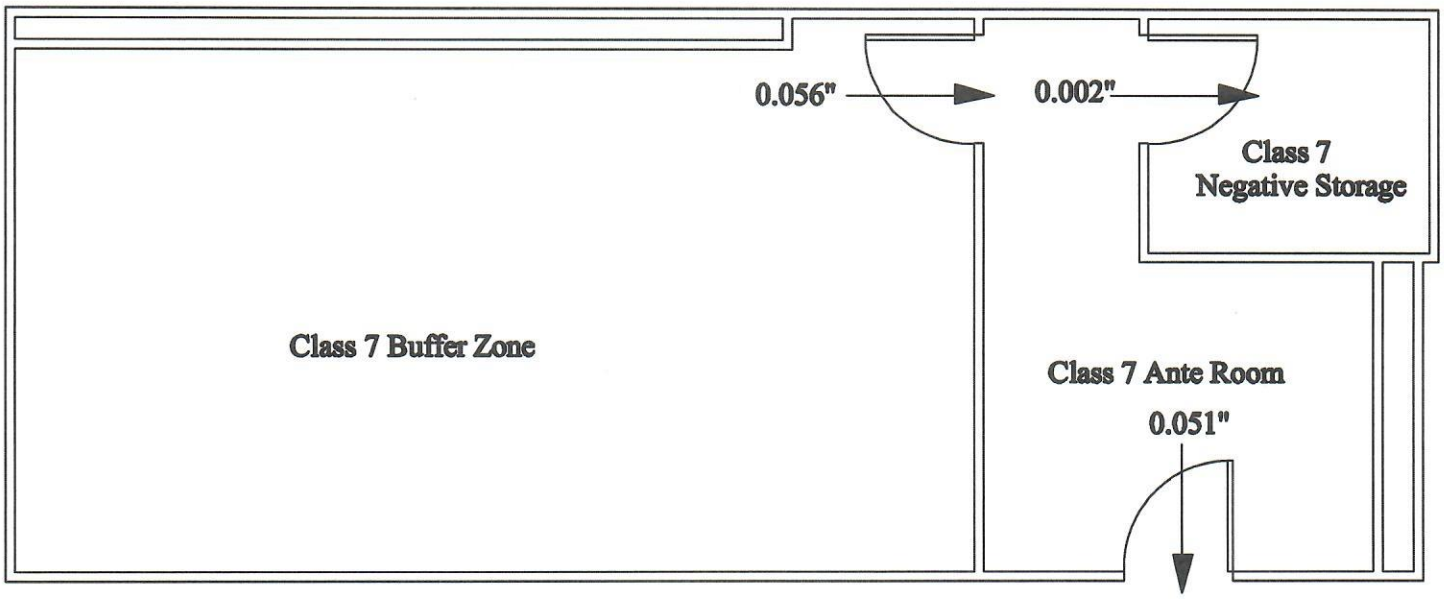
Viable Air Sample Plan

= TSA AIR

(#) = MEA AIR

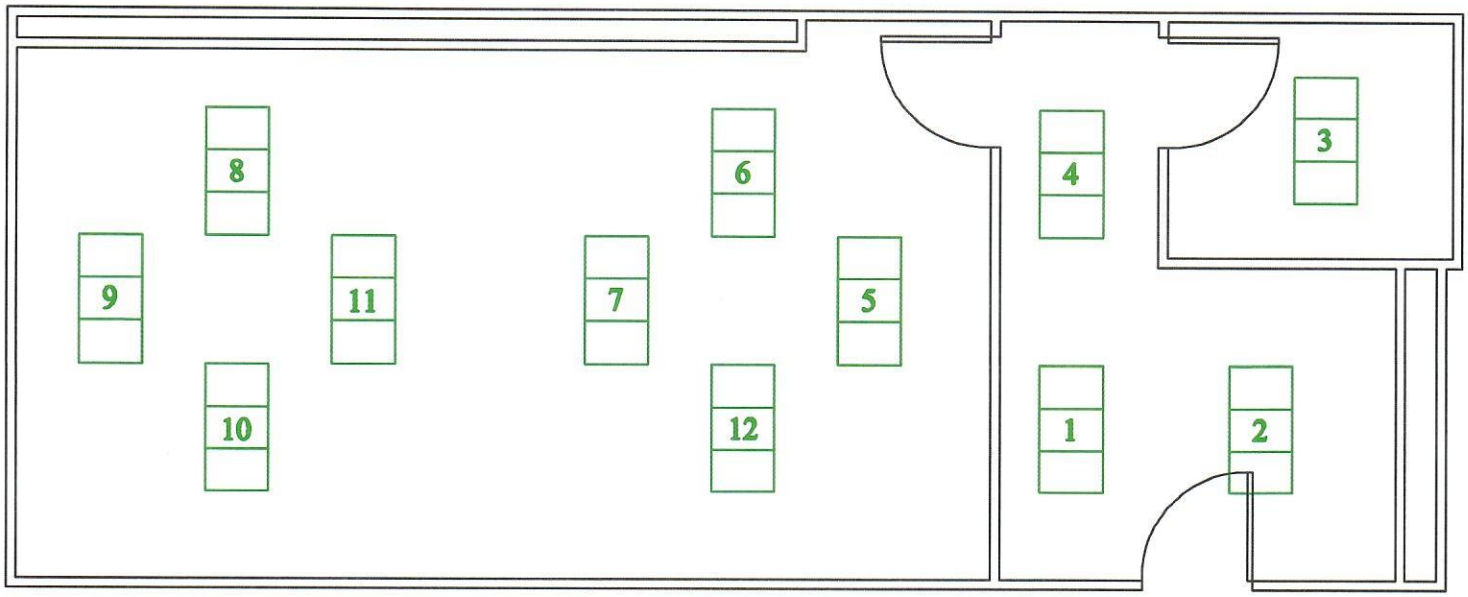
89 = Control/Operator Handling

(90) = Control

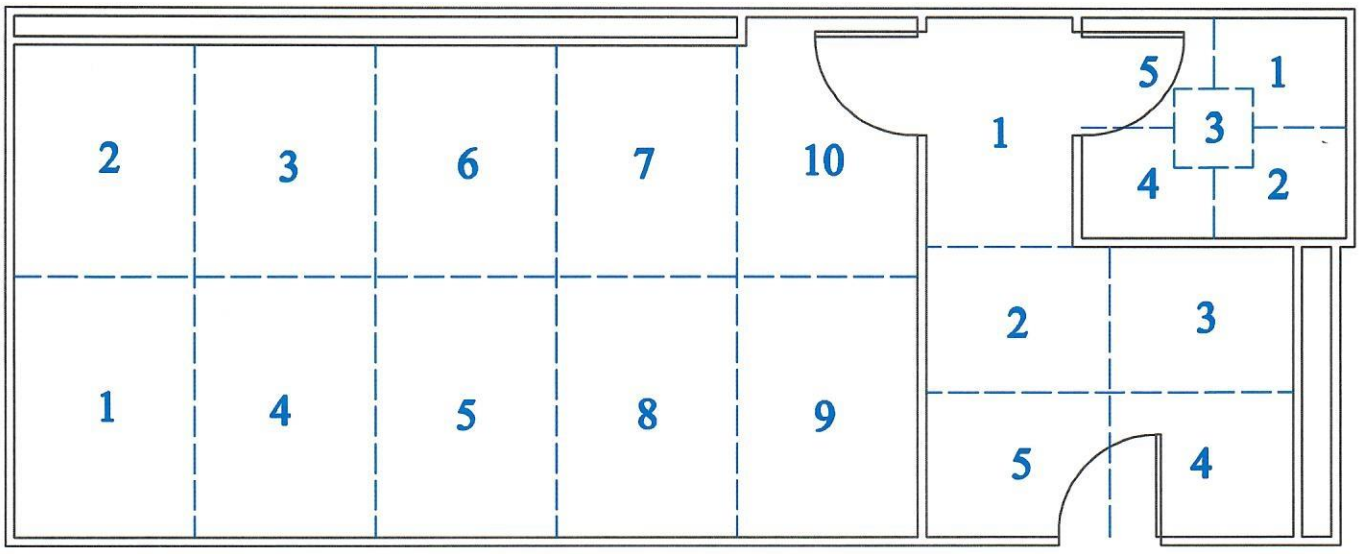


Crescent Hayward

Pressure Gradients



Crescent Hayward
HEPA Filter Locations



Crescent Hayward

Particle Count Locations