

PERFORMANCE CERTIFICATION

FOR
Option Care – Sun Valley
9401 Chivers Avenue
Sun Valley, CA 91352



Test Date: June 8, 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 #M13678; Calibrated 9/9/21

Pressure Differential

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

Test Instruments:

AirData Multimeter - Shortridge Model ADM-860C, serial #M13678; Calibrated 9/9/21

HEPA Filter Integrity Test

As required, HEPA filters were scanned for leaks following the recommended practices in IEST-RP-0006.

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

Test Instruments:

Photometer - ATI Model TDA-2i, serial #23806; Calibrated 1/28/22

Laminar Flow Benches

Particle Count

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

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

Test Instruments:

Laser Particle Counter - Climet model CI-150T, serial #131729; calibrated 3/2/22

HEPA Filter Integrity Test

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

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

Test Instruments:

Photometer - ATI Model TDA-2i, serial #23806; Calibrated 1/28/22 Aerosol Generator – ATI Model TDA-4BL (calibration not required) PAO was used as the aerosol

Air Flow

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

Test Instruments:

Thermal Anemometer - TSI Model 9545A, serial #1615003; Calibrated 8/17/21

Biological Safety Cabinet - Chemo

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-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 Aerosol Generator - ATI Model TDA-4BL (calibration not required) PAO was used as the aerosol

Air Flow

The Biological Safety Cabinet was measured and adjusted for airflow in accordance with IEST-RP-006 and NSF - 49. All data collected and calculations are presented in the individual component report 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, NSF 49 and IEST Recommended Practices as established in this report.

Signature:

Arne Gjertsen RCCP-SC #1114 Date:

6/8/22

Cleanroom Performance Test Report

Customer:

Option Care Sun Valley

Date: Room ID: 6/8/2022

Class:

Buffer Zone 7

Dimensions:

Volume: Test Status:

462 square feet 3696 cubic feet

Dynamic

Particle Count

Locations required: Particle Size

10 >0.5 micron

Readings: 565.0 Particle/M3 600.3 Particle/M3

Sq. Feet

7.25

7.25

7.25

7.25

7.25

7.25

529.7 Particle/M3 141.3 Particle/M³ 5 317.8 Particle/M³ 6 1,236.0 Particle/M3

7 141.3 Particle/M³ 8 176.6 Particle/M³ 9 1.871.7 Particle/M³ 10 2,966.4 Particle/M³

Maximum count-

352,000 Particle/M3

Pass/Fail

Pass

Air Flow

		Filter	Read 1	Read 2	Avg. FPM
Air Change:		1	128	133	130.5
Recommended=	45.0 /hour	2	119	112	115.5
Actual=	73.0 /hour	3	94	87	90.5
		4	101	109	105.0
Pass/Fail	Pass	5	97	92	94.5
		6	82	87	84.5

Pass/Fail

Pass

Total CFM =

4,499

CFM

946

837

656

761

685

613

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	21	<0.01%	N/R	Pass
2	24	<0.01%	N/R	Pass
3	31	<0.01%	N/R	Pass
4	27	<0.01%	N/R	Pass
5	30	<0.01%	N/R	Pass
6	33	<0.01%	N/R	Pass

Signature:

Date:

6/8/22

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

Cleanroom Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Room ID: Class:

Chemo Room 7

Dimensions:

79 square feet 671.5 cubic feet

Volume: Test Status:

Dynamic

Particle Count

Locations required:

5

Particle Size

>0.5 micron

Location 1

Readings: 7,875.2 Particle/M3

2

4,131.8 Particle/M³ 3,849.3 Particle/M3

3 4

988.8 Particle/M³

5

4,802.8 Particle/M3

Maximum count-

352,000 Particle/M3

Pass/Fail

Pass

Air Flow

Filter 1

Read 1 82

Read 2 78

Avg. FPM 80.0

Sq. Feet 7.25

CFM 580

Air Change:

Recommended= Actual=

30.0 /hour

51.8 /hour

Pass/Fail

Pass

Total CFM =

580

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter# Int. Ref. Leak Repaired Pass/Fail Prev. patch 35 <0.01% N/R Pass None

Signature:

Date:

6/8/22

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

Cleanroom Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Ante room

Room ID: Class:

Dimensions:

Volume:

Test Status:

112 square feet 896 cubic feet

Dynamic

Particle Count

Locations required:

5

Particle Size

>0.5 micron

Location

Readings: 7,239.5 Particle/M3

1 2

4,379.0 Particle/M3

3 4

2,860.5 Particle/M3 1,730.4 Particle/M3

5

4,273.1 Particle/M3

6

8,193.0 Particle/M3

Maximum count-

352,000 Particle/M3

Pass/Fail

Pass

Air Flow

Filter

Read 1 96

Read 2 98

Avg. FPM 97.0

Sq. Feet 7.25

CFM 703

Air Change:

Recommended=

Actual=

30.0 /hour 47.1 /hour

Pass/Fail

Pass

Total CFM =

703

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref. Leak Repaired Pass/Fail Prev. patch 29 < 0.01% N/R **Pass** None

Signature:

Date:

6/8/22

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

Safety Cabinet Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Occupancy State:

Model # Serial #

NU-425-400 133348101209

Class:

5

Test Status: Dynamic

Particle Count			
Locations required:	5	Location	Readings:
Particle Size	>0.5	1	0.0 Particle/M³
		2	0.0 Particle/M³
		3	0.0 Particle/M³
		4	0.0 Particle/M³
		5	0.0 Particle/M³

Maximum count-

3520 Particle/M3

Pass/Fail

Pass

Down Flow Air	Readings						
Requirement:	55-65						
FPM Readings:		1-	57	6-	58	11-	59
		2-	57	7-	57	12-	60
Avg. Velocity =	57.9	3-	55	8-	58	13-	60
		4-	57	9-	59	14-	58
Pass/Fail:	Pass	5-	58	10-	57	15-	59

~	CFM=	428.7	

Inflow Velocity - Restricted Sash Method

Requirement: 320-350 **FPM**

Average FPM= 347 1-360 5-349 2-335 6-357 3-339 7-350 4-356 8-328

Intake Velocity @ 10"sash=

(347 fpm x 1.0 / 3.2) =

108 **FPM**

Required Intake Veleocity-

100-110

Filter Integrity Test

Exhaust HEPA:

No scanned leaks greater than 0.01%

No scanned leaks greater than 0.01%

Int. Ref.

50

Pass/Fail:

Pass

Supply HEPA:

Combined with Exhaust Calc's

Int. Ref.

47

Pass/Fail:

Pass

Smoke test performed per NSF 49: PASS

Signature

Date 6/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Occupancy State: 1

Model # NU-301-630

Serial # 133249

Class: 5

Test Status: Dynamic

Particle Count

Locations required:
Particle Size

6 >0.5 Location 1

Readings: 0.0 Particle/M3

2 3 0.0 Particle/M3 0.0 Particle/M3

4 5

0.0 Particle/M3 0.0 Particle/M3

6

0.0 Particle/M³

Maximum count-

3,520 Particle/M3

Pass/Fail

Pass

Air	Flow
	IIOW

Requirement:

80-100 FPM

Avg. Ve	elocity =
Pass/F	ail :

93.1

FPM Readings: 1-

6-99

11-101 90

Pass

91 92 91

7-101 8-88

12-13-

Measured Values: Avg. +/- 20% Min. value = Max. value =

Pass/Fail:

74.5 111.8

Pass

4-5-

2-

3-

85 99

9-93 10-96

14-1589 95

87

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.

16

Pass/Fail:

Pass

Signature:

Date:

4/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Serial #

NU-301-630 133255

Class:

Model #

5

Test Status:

Dynamic

Particle Count

Occupancy State: 1

Locations required:
Particle Size

6 >0.5 Location 1 2

Readings: 0.0 Particle/M3 0.0 Particle/M3

3 4 0.0 Particle/M3 0.0 Particle/M3

5

0.0 Particle/M3

6

0.0 Particle/M3

Maximum count-

3,520 Particle/M3

Pass/Fail

Pass

Ai	r	FI	O	w

Requirement:

80-100 FPM

Avg.	Velocity =
Pass	/Fail :

91.7 FPM Readings: **Pass**

1-93 2-82

6-792 83 11-12-

99 98 90

Measured Values: Avg. +/- 20% Min. value =

73.3 110.0

4-5-

3-

86 99 93

8-9-10101 92 98 13-14-15-

85 84

Max. value =

Pass/Fail:

Pass

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.

17

Pass/Fail:

Pass

Signature:

Date:

4/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Occupancy State: 1

Model # NU-201-630

Serial # 166185

Class: 5

Test Status: Dynamic

Particle Count

Locations required	:t
Particle Size	

6 >0.5 Location 1

2

Readings: 0.0 Particle/M³

0.0 Particle/M3

3 4

0.0 Particle/M³ 0.0 Particle/M³

5 6 0.0 Particle/M3 0.0 Particle/M3

Maximum count-

3,520 Particle/M3

Pass/Fail

Pass

A :	-	-
AIr	F	ow

Requirement:

80-100 FPM

Avg.	Velocity =
Pass	/Fail :

92.4 FPM Readings: **Pass**

1-97 2-99

6-101 7-94 87

87

89

11-12-13-

92 87 84

Measured Values: Avg. +/- 20% Min. value =

73.9

3-92 4-94 5-96

8-9-10-

14-1590 97

Max. value = Pass/Fail:

110.9 Pass

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.

16

Pass/Fail:

Pass

Signature:

Date:

6/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer: Occupancy State: 1

Nuaire

Model#

NU-5201-630

Serial #

187218080218

Class:

Test Status: Dynamic

Particle Count

Locations required:
Particle Size

6 >0.5 Location 1

Readings: 0.0 Particle/M³

2 3

0.0 Particle/M3 0.0 Particle/M3

4 5

0.0 Particle/M3

6

0.0 Particle/M3 0.0 Particle/M3

Maximum count-

Pass/Fail

3,520 Particle/M3

Pass

Air Flow

Requirement:

80-100 FPM

Avg. Velocity = Pass/Fail:

98.9 **Pass**

FPM Readings: 1-106

2-

3-

4-

6-7-

8-

97 103 99 11-1298 96

100

Measured Values: Avg. +/- 20% Min. value =

Max. value =

Pass/Fail:

79.1

Pass

118.7

98 104

91

99

9-97 10-100

13-14-15-

97 99

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.

15

Pass/Fail:

Pass

Signature:

Date:

6/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Model# Serial #

S201-830 168185042115

Class:

Occupancy State: 1

Test Status:

Dynamic

Particle Count

Locations required:	
Particle Size	

6 >0.5

Location 1

5

6

Readings: 0.0 Particle/M³ 0.0 Particle/M³

2 3 4

0.0 Particle/M3 0.0 Particle/M³

0.0 Particle/M3 0.0 Particle/M3

Maximum count -

3,520 Particle/M³

Pass/Fail

Pass

Air Flow

Requirement:

80-100 FPM

Avg. Velocity =	94.2	FPM Read	ings:				
Pass/Fail:	Pass	1-	102	9-	87	17-	89
		2-	94	10-	92	18-	93
		3-	95	11-	101	19-	96
Measured Values:	Avg. +/- 20%	4-	101	12-	95	20-	96
Min. value =	75.4	5-	93	13-	98	21-	82
Max. value =	113.1	6-	100	14-	89	22-	94
Pass/Fail:	Pass	7-	96	15-	85	23-	97
		8-	100	16-	89	24-	97

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

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

Signature:

Date:

6/8/22

Clean Flow Hood Performance Test Report

Customer:

Option Care Sun Valley

Date:

6/8/2022

Manufacturer:

Nuaire

Model #

NU-5201-830-L 188548101518

Serial #

Class: 5

Test Status:

Dynamic

Particle Count

Occupancy State: 1

Locations required: Particle Size	6	Location	Readings:
Particle Size	>0.5	1	0.0 Particle/M³
		2	0.0 Particle/M³
		3	0.0 Particle/M³
		4	0.0 Particle/M³
		5	0.0 Particle/M³
		6	0.0 Particle/M³

Maximum count -

3,520 Particle/M³

Pass/Fail

Pass

Air	014
AII	OW

Requirement:

80-100 FPM

Avg. Velocity =	93.4	FPM Readi	ngs:				
Pass/Fail:	Pass	1-	89	9-	93	17-	84
		2-	92	10-	95	18-	85
		3-	95	11-	103	19-	89
Measured Values:	Avg. +/- 20%	4-	93	12-	97	20-	100
Min. value =	74.7	5-	98	13-	96	21-	105
Max. value =	112.1	6-	98	14-	90	22-	88
Pass/Fail:	Pass	7-	93	15-	89	23-	92
		8-	93	16-	88	24-	97

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail
8	24	<0.01%	N/R	Pass

Signature:

Date:

6/8/22

Airflow Smoke Pattern Test

Option Care Sun Valley
June 8, 2022

Objective:

To perform airflow smoke pattern tests on the Laminar Flow Benches at the abovementioned Walgreens 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 DegreeC smoke generator shall be used with a glycol-based fog fluid. The fluid provides smoke with a density slightly lighter than air, as shown at the conclusion of the smoke study film.

Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- Good split of air at table was observed at each workstation.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of workstations.
- No reflux around perimeter nor over operators' head was observed
- PEC: NuAire # 133249 Smoke study validates 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 133255 Smoke study validates 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 166185 Smoke study validates 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 187218 Smoke study validates 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 168185042115 Smoke study validates 2 person compounding maintains unidirectional airflow
- PEC: NuAire # 188548101518 Smoke study validates 2 person compounding maintains unidirectional airflow

Conclusion:

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

Weight Scale - Calibration Report

Customer:

Option Care, Sun Valley

Calibration Date:

6/8/2022

Calibration Due Date:

6/8/2023

Model #

Ohaus Model #CS-2000

ID # Scale #1

As Found Data

Test procedure:

Using a known weight, measure and record the scales calibration weight. Confirm range of scale by using multiple smaller weights and measure and record findings.

Reading #	Master	Scale As Found	Scale As Left	Deviation	Acceptable Deviation	Pass/Fail
1	0g	0g	0g	0g	± 1g	Pass
2	1000g	1000.0g	1000.0g	0g	± 1 g	Pass
3	500g	500.0g	500.0g	0g	±1 g	Pass
4	200g	200.0g	200.0g	0g	± 1 g	Pass

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

Troemner weight set calibration date: 10/7/21

Signature:

Date: 6/8/22

Weight Scale - Calibration Report

Customer:

Option Care, Sun Valley

Calibration Date:

6/8/2022

Calibration Due Date:

6/8/2023

Model #

Ohaus Model #CX-2200

ID # Scale #2

As Found Data

Test procedure:

Using a known weight, measure and record the scales calibration weight. Confirm range of scale by using multiple smaller weights and measure and record findings.

Reading #	Master	Scale As Found	Scale As Left	Deviation	Acceptable Deviation	Pass/Fail
1	0g	0g	0g	0g	± 1g	Pass
2	1000g	1000.0g	1000.0g	0g	± 1 g	Pass
3	500g	500.0g	500.0g	0g	± 1 g	Pass
4	200g	200.0g	200.0g	0g	± 1 g	Pass

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

Troemner weight set calibration date: 10/7/21

Signature

Date: 6/8/22

Viable Air and Surface Sampling

Option Care - Sun Valley

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

Tryptic Soy Agar and Malt Extract Agar were used in each of the zones

A SAS 360-Duo air sampling device was used for the air sampling and 1000 liters of air was used for each of the media tests.

The test samples were taken on June 8, 2022. and delivered the same day to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #22021692. All of the tests were within the allowable CFU and passed.

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

Manufacturer - Hardy Diagnostics

(Air) Malt Plates – Lot #504698P; expires 7/11/22

(Air) Tryptic Soy Plates – Lot #504874; expires 7/13/22

(Surface) Sabdex Plates- Lot #506482; expires 8/11/22

(Surface) Tryptic Soy Plates- Lot #507373; expires 8/25/22

Signature:

Arne Gjertsen

Date:

6/13/22



43: Class 7 Buffer Zone

Certificate of Analysis AIHA-LAP EMLAP# 218951

15061 Springdale St Suite 111 Huntington Beach, CA 92649 7148958401

Cleanrooms Plus Date Collected: 6/8/2022 1587 Sim Place Date Received: 6/8/2022 Anaheim CA, 92802 Date Analyzed: 6/13/2022 Attn: Arne Gjertsen Date Reported: 6/13/2022 Project: Option Care - Sun Valley Project ID: 22021692 Condition of Sample(s) Upon Receipt: Acceptable Page 1 of 16

Sample Location	Class	Metric 79			
Class 5 LFB	Class 5	Property and a second	Pass	Acpt	O.O.C.
: Class 5 LFB	5	A			
: Class 5 LFB	5				
1: Class 5 LFB		A			
5: Class 5 LFB	5	A			
6: Class 5 LFB	5	Α			
7: Class 5 LFB	5	A			
	5	Α			
8: Class 5 LFB	5	Α			
9: Class 5 LFB	5	Α			
10: Class 5 LFB	5	Α			
11: Class 5 LFB	5	Α			
12: Class 5 LFB	5	Α			
13: Class 7 Pass Thru	7	Α			
14: Class 7 Pass Thru	7	Α			
15: Class 7 Buffer Zone	7	Α	NAME OF		
16: Class 7 Buffer Zone	7	Α	No State		
17: Class 7 Buffer Zone	7	Α			
18: Class 7 Buffer Zone	7	Α			
19: Class 5 BSC	5	Α			
20: Class 5 BSC	5	Α			
21: Class 7 NPR	7	Α			
22: Class 7 NPR	7	Α			
23: Class 7 Ante Room	7	Α			
24: Class 7 Ante Room	7	Α	ALC: N		
25: Class 7 Ante Room	7	A	t to 1		
26: Class 7 Ante Room	7	Α	A BE		
27: Conrol/Op. Handling; Lot:	NA	Α			
504874, Ex: 7/13/2022					
28: Control; Lot: 504698P, Ex:	NA	Α			
7/11/2022					
29: Class 5 LFB	5	S			
30: Class 5 LFB	5	S	B 300		
31: Class 5 LFB	5	S			
32: Class 5 LFB	5	S			
33: Class 5 LFB	5	S	K STA		
34: Class 5 LFB	5	-	MESS		
35: Class 5 LFB	5	S	A Visit		
36: Class 5 LFB		S			
37: Class 5 LFB	5	S	\$ 4/45-4		
38: Class 5 LFB	5	S	A SHARING		
39: Class 5 LFB	5	S	1-91		
	5	S			
40: Class 5 LFB	5	S			
11: Class 7 Pass Thru	7	S			
12: Class 7 Pass Thru	7	S			



15061 Springdale St Suite 111 Huntington Beach, CA 92649 7148958401

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Cleanrooms Plus 1587 Sim Place Anaheim CA, 92802 Attn: Arne Gjertsen

Project: Option Care - Sun Valley

Condition of Sample(s) Upon Receipt: Acceptable

 Date Collected:
 6/8/2022

 Date Received:
 6/8/2022

 Date Analyzed:
 6/13/2022

 Date Reported:
 6/13/2022

 Project ID:
 22021692

44: Class 7 Buffer Zone	7	S
45: Class 7 Buffer Zone	7	S
46: Class 7 Buffer Zone	7	S
47: Class 5 BSC	5	S
48: Class 5 BSC	5	S
49: Class 7 NPR	7	S
50: Class 7 NPR	7	S
51: Class 7 NPR	7	S
52: Class 7 NPR	7	S
53: Class 7 Ante Room	7	S
54: Class 7 Ante Room	7	S
55: Class 7 Ante Room	7	S
56: Class 7 Ante Room	7	S
57: Class 5 LFB (Touchscreen)	5	S
58: Class 5 LFB (Touchscreen)	5	S
59: Class 5 LFB (Touchscreen)	5	S
60: Class 5 LFB (Touchscreen)	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: Control; Lot: 507373, Ex:	NA	S
8/25/2022		
70: Control; Lot: 506482, Ex:	NA	S
8/11/2022		
71: Class 5 LFB	5	Α
72: Class 5 LFB	5	Α
73: Class 5 LFB	5	Α
74: Class 5 LFB	5	Α
75: Class 5 LFB	5	S
76: Class 5 LFB	5	S
77: Class 5 LFB	5	S
78: Class 5 LFB	5	S
N. d. C.		



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.



Sample Location: Class 5 LFB

Comments: Pass

Certificate of Analysis AIHA-LAP EMLAP# 218951

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Cleanrooms Plus Date Collected: 6/8/2022 1587 Sim Place Date Received: 6/8/2022 Anaheim CA, 92802 Date Analyzed: 6/13/2022 Attn: Arne Gjertsen Date Reported: 6/13/2022 Project: Option Care - Sun Valley Project ID: 22021692 Condition of Sample(s) Upon Receipt: Acceptable Page 3 of 16

Client Sample #: 1

Sample Location: Class 5 LFB

Lab Sample #: 22021692-001

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Air Volume: 1000 L

Positive Hole: 219

Comments: Pass

MRL: 1 CFU/m3

Client Sample #: 2 Lab Sample #: 22021692-002

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Air Volume: 1000 L

Results: No Growth

Positive Hole: 219

MRL: 1 CFU/m3

Comments: Pass

Client Sample #: 3 Lab Sample #: 22021692-003

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 #: 4 Lab Sample #: 22021692-004

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

MRL: 1CFU/m3

Comments: Pass

Client Sample #: 5
Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth Positive Hole: 219

MRL: 1 CFU/m3

Comments: Pass

Client Sample #: 6 Lab Sample #: 22021692-006

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

MRL: 1 CFU/m3



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Project: Option Care - Sun Valley

Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/8/2022 Date Received: 6/8/2022 Date Analyzed: 6/13/2022 Date Reported: 6/13/2022 Project ID: 22021692

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Client Sample #: 7

Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 8

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 9

Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 10

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 11

Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments:

Client Sample #: 12

Sample Location: Class 5 LFB

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

Lab Sample #: 22021692-007

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-008

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-009

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-010

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-011

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-012

Comments: Pass



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Client Sample #: 13

Sample Location: Class 7 Pass Thru

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 14

Sample Location: Class 7 Pass Thru

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 15

Sample Location: Class 7 Buffer Zone

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #:

Sample Location: Class 7 Buffer Zone

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 17

Sample Location: Class 7 Buffer Zone

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 18

Sample Location: Class 7 Buffer Zone

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Lab Sample #: 22021692-013

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

Lab Sample #: 22021692-014

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-015

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-016

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-017

Air Volume: 1000 L

Positive Hole: 219 MRL: 1 CFU/m3

Air Volume: 1000 L

Lab Sample #: 22021692-018

Positive Hole: 219

MRL: 1 CFU/m3



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Date Collected: 6/8/2022 Date Received: 6/8/2022 Date Analyzed: 6/13/2022 Date Reported: 6/13/2022 Project ID: 22021692

Lab Sample #: 22021692-019

Air Volume: 1000 L

Air Volume: 1000 L

Positive Hole: 219 MRL: 1 CFU/m3

Air Volume: 1000 L

Positive Hole: 219 MRL: 1 CFU/m3

Air Volume: 1000 L

Air Volume: 1000 L

Positive Hole: 219 MRL: 1 CFU/m3

Air Volume: 1000 L

Lab Sample #: 22021692-023

Positive Hole: 219 MRL: 1 CFU/m3

Positive Hole: 219 MRL: 1 CFU/m3

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Client Sample #: 19

Sample Location: Class 5 BSC

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 20 Lab Sample #: 22021692-020

Sample Location: Class 5 BSC

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 21 Lab Sample #: 22021692-021

Sample Location: Class 7 NPR

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 22 Lab Sample #: 22021692-022

Sample Location: Class 7 NPR

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 23

Sample Location: Class 7 Ante Room

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: Lab Sample #: 22021692-024

Sample Location: Class 7 Ante Room

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Positive Hole: 219 MRL: 1 CFU/m3 Comments: Pass



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Date Collected: 6/8/2022 Date Received: 6/8/2022 Date Analyzed: Date Reported: 6/13/2022 Project ID: 22021692

Client Sample #: 25

Sample Location: Class 7 Ante Room

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 26

Sample Location: Class 7 Ante Room

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #:

Sample Location: Conrol/Op. Handling; Lot: 504874, Ex: 7/13/2022

Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2

Results: No Growth

Client Sample #:

Sample Location: Control; Lot: 504698P, Ex: 7/11/2022

Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2

Results: No Growth

Client Sample #:

Sample Location: Class 5 LFB

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth

Comments: Pass

Client Sample #: 30

Sample Location: Class 5 LFB

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Results: No Growth

Comments: Pass

Client Sample #:

Sample Location: Class 5 LFB

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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Lab Sample #: 22021692-025

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-026

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-027

Lab Sample #: 22021692-028

Lab Sample #: 22021692-029

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-030

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-031



Comments: Pass

Sample Location: Class 5 LFB

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Client Sample #: 32 Lab Sample #: 22021692-032

Sample Location: Class 5 LFB

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Area: 25 cm2

Results: No Growth

Comments: Pass

MRL: 1 CFU/25cm2

Client Sample #: 33 Lab Sample #: 22021692-033

Sample Location: Class 5 LFB

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Area: 25 cm2

Results: No Growth

Comments: Pass

MRL: 1 CFU/25cm2

Client Sample #: 34 Lab Sample #: 22021692-034

Sample Location: Class 5 LFB

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Area: 25 cm2

Results: No Growth

MRI: 1 CFU/25cm2

Results: No Growth

Comments: Pass

MRL: 1 CFU/25cm2

Client Sample #: 35

Lab Sample #: 22021692-035

Sample Location: Class 5 LFB

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Area: 25 cm2

Results: No Growth MRL: 1 CFU/25cm2

Client Sample #: 36 Lab Sample #: 22021692-036

Sample Location: Class 5 LFB

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Area: 25 cm2

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Results: No Growth

Area: 25 cm2

MRL: 1 CFU/25cm2

Results: No Growth

MRL: 1 CFU/25cm2

Comments: Pass

Client Sample #: 37 Lab Sample #: 22021692-037

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 Area: 25 cm2

Results: No Growth

Comments: Pass

Client Sample #: 38 Lab Sample #: 22021692-038

Sample Location: Class 5 LFB

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 #: 43

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6/13/2022

6/13/2022

Cleanrooms Plus Date Collected: 1587 Sim Place Date Received: Anaheim CA, 92802 Date Analyzed: Attn: Arne Gjertsen Date Reported: Project: Option Care - Sun Valley Project ID:

22021692 Condition of Sample(s) Upon Receipt: Acceptable Page 9 of 16 Client Sample #: 39 Lab Sample #: 22021692-039 Sample Location: Class 5 LFB 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 #: 40 Lab Sample #: 22021692-040 Sample Location: Class 5 LFB 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 #: 41 Lab Sample #: 22021692-041 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 Comments: Pass Client Sample #: 42 Lab Sample #: 22021692-042 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

Lab Sample #: 22021692-043 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 #: 44 Lab Sample #: 22021692-044 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 #: 45 Lab Sample #: 22021692-045 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



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Lab Sample #: 22021692-046

Sample Location: Class 7 Buffer Zone Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Area: 25 cm2 MRL: 1 CFU/25cm2

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Results: No Growth Comments: Pass

Client Sample #: 46

Client Sample #: 47 Lab Sample #: 22021692-047

Sample Location: Class 5 BSC

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 #: 48 Lab Sample #: 22021692-048

Sample Location: Class 5 BSC

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 #: 49 Lab Sample #: 22021692-049

Sample Location: Class 7 NPR

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 #:

Lab Sample #: 22021692-050 Sample Location: Class 7 NPR

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 #: Lab Sample #: 22021692-051

Sample Location: Class 7 NPR

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23 Area: 25 cm2 Results: 1 CFU/25cm2 MRL: 1 CFU/25cm2

Organism(s) Isolated: Raw Count CFU/25cm2 % Total Reservoirs Micrococcus species 100 1 Human



Sample Location: Class 7 Ante Room

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Client Sample #: 52 Lab Sample #: 22021692-052

Sample Location: Class 7 NPR

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 #: 22021692-053

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 #: 54 Lab Sample #: 22021692-054

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 #: 55 Lab Sample #: 22021692-055

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 #: 56 Lab Sample #: 22021692-056

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 #: 57 Lab Sample #: 22021692-057

Sample Location: Class 5 LFB (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: Pas

Client Sample #: Lab Sample #: 22021692-058 Sample Location: Class 5 LFB (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



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Client Sample #: 59

Sample Location: Class 5 LFB (Touchscreen)

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth Comments: Pass

Client Sample #: 60

Sample Location: Class 5 LFB (Touchscreen)

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Results: No Growth Comments: Pass

Client Sample #: 61

Sample Location: Class 5 LFB (Touchscreen)

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth

Comments: Pass

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

Client Sample #:

Sample Location: Class 5 LFB (Touchscreen)

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth

Comments: Pass

Client Sample #:

Sample Location: Class 5 LFB (Touchscreen)

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Results: No Growth

Comments: Pass

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

Area: 25 cm2

MRL: 1 CFU/25cm2

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Lab Sample #: 22021692-059

Area: 25 cm2 MRL: 1 CFU/25cm2

Lab Sample #: 22021692-060

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-061

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-062

MRL: 1 CFU/25cm2

Area: 25 cm2

Lab Sample #:

22021692-063

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-064

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-065



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

Date Collected: 6/8/2022

Date Received: 6/8/2022

Date Analyzed: 6/13/2022

Date Reported: 6/13/2022

Project ID: 22021692

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Lab Sample #: 22021692-066

Lab Sample #: 22021692-067

Lab Sample #: 22021692-068

Lab Sample #: 22021692-069

Lab Sample #: 22021692-070

Area: 25 cm2

Area: 25 cm2

Area: 25 cm2

MRL: 1 CFU/25cm2

MRL: 1 CFU/25cm2

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

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

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

Client Sample #: 69

Sample Location: Control; Lot: 507373, Ex: 8/25/2022

Test: 1158 BACTERIAL SURFACE - USP 797 Negative (-) Control: 2.2

Results: No Growth

Client Sample #: 70

Sample Location: Control; Lot: 506482, Ex: 8/11/2022

Test: 1159 FUNGAL SURFACE - USP 797 Negative (-) Control: SOP 3.2

Results: No Growth

Client Sample #: 71

Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 72

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Air Volume: 1000 L

Lab Sample #: 22021692-071

Positive Hole: 219

MRL: 1 CFU/m3

Lab Sample #: 22021692-072

Air Volume: 1000 L Positive Hole: 219

MRL: 1 CFU/m3

Comments: Pass



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

 Date Collected:
 6/8/2022

 Date Received:
 6/8/2022

 Date Analyzed:
 6/13/2022

 Date Reported:
 6/13/2022

 Project ID:
 22021692

Client Sample #: 73

Sample Location: Class 5 LFB

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Results: No Growth

Comments: Pass

Client Sample #: 74

Sample Location: Class 5 LFB

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Results: No Growth

Comments: Pass

Client Sample #: 75

Sample Location: Class 5 LFB

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth

Comments: Pass

Client Sample #: 76

Sample Location: Class 5 LFB

Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9

Results: No Growth

Comments: Pass

Client Sample #: 77

Sample Location: Class 5 LFB

Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Results: No Growth

Comments: Pass

Client Sample #: 78

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 #: 22021692-073

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

MRL: 1 CFU/m3

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Lab Sample #: 22021692-074

Air Volume: 1000 L

Positive Hole: 219 MRL: 1 CFU/m3

Lab Sample #: 22021692-075

Area: 25 cm2

MRL: **1 CFU/25cm2**

Lab Sample #: 22021692-076

Area: 25 cm2
MRL: 1 CFU/25cm2

VIKL. I CFO/25CIII2

Area: 25 cm2

MRL: 1 CFU/25cm2

Lab Sample #: 22021692-078

Lab Sample #: 22021692-077

Area: 25 cm2

MRL: 1 CFU/25cm2



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Cleanrooms Plus	Date Collected:	6/8/2022
1587 Sim Place	Date Received:	6/8/2022
Anaheim CA, 92802	Date Analyzed:	6/13/2022
Attn: Arne Gjertsen	Date Reported:	6/13/2022
Project: Option Care - Sun Valley	Project ID:	22021692
Condition of Sample(s) Upon Receipt: Acceptable		Page 15 of 16

USP 797 Class and Action Levels

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

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

Footnotes and Additional Report Information

- 1. Regardless of the number of CFU identified, further corrective actions are required if any pathogenic organisms are identified. It is therefore suggested to identify any colonies seen on the plate to genus level to rule out pathogens such as: gram-negative rods bacteria, and coagulase positive staphylococcus spp., yeasts, and mold.
- 2. Regardless of ISO Class, any fungal ID from fungal media or appropriate media for single plate protocol on an air or surface plate will result in sample being Out of Compliance.
- 3. Positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into account multiple particles can impact on the same hole. For this reason the sum of calculated counts may be less than the positive hole corrected total.
- 4. TSA (Tryptic Soy Agar) for bacteria is incubated at 30-35°C for 2-4 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 30°C for 5 to 7 days. If single plate protocol is being followed, TSA or the appropriate media for bacteria is incubated at 30-35°C for 2-4 days and then the same plate is re-incubated at 26 to 30°C for 5-7 days for fungal.
- 5. MEDIA CONTROLS. An unexposed TSA plate or MEA plate from each sampling event/project should be submitted for quality control purposes. The lot number for controls should be the same as those plates being submitted for analysis.
- 6. Semi-annual monitoring for viable bacteria and fungi in air, surface contact plates, gloved fingertip and particulates is required for both Class 5 and Class 7 defined areas.
- 7. Viable cultures must be collected using an impaction style sampler for volumetric capture. A sufficient volume of air (400 to 1000 liters) should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
- 8. Standard contact plates have an area of 25 cm² or plate, unless otherwise noted in the sample area.
- 9. The results in this report are related to this project and these samples only.
- 10. **MRL** Units for USP 797 Cultures are as follows: AIR is CFU/m ³, SURFACE is CFU/25cm ² or CFU/plate, and CONTROL is colony/sample.

MRL: Minimum Reporting Limit.

- 11. TARGET IDENTIFICATIONS: Any gram-negative rod, Staphylococcus aureus, yeast and molds
- 12. Non-sporulating colony is a colony that does not produce spores and/or conidiophores. Unless distinctive spores or conidiophores are formed, fungal identification may not be possible.
- 13. If the final quantitative result is corrected for contamination based on the blank, the blank correction is stated in the sample comments section of the report.

Due to rounding totals may not equal 100%.

Suzanne Blevins
Laboratory Director



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

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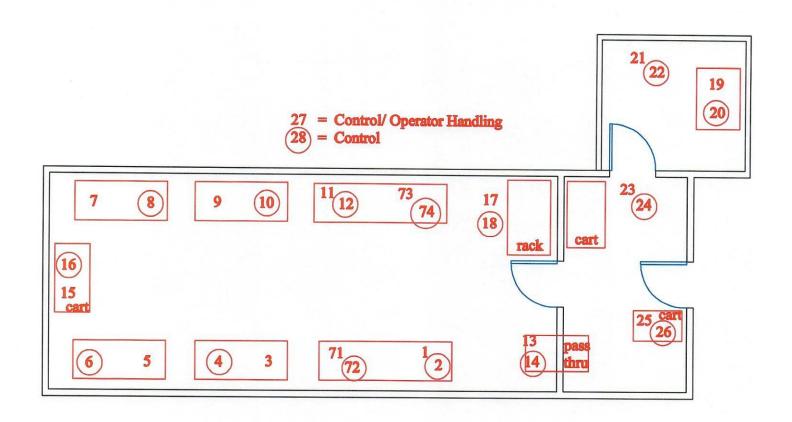
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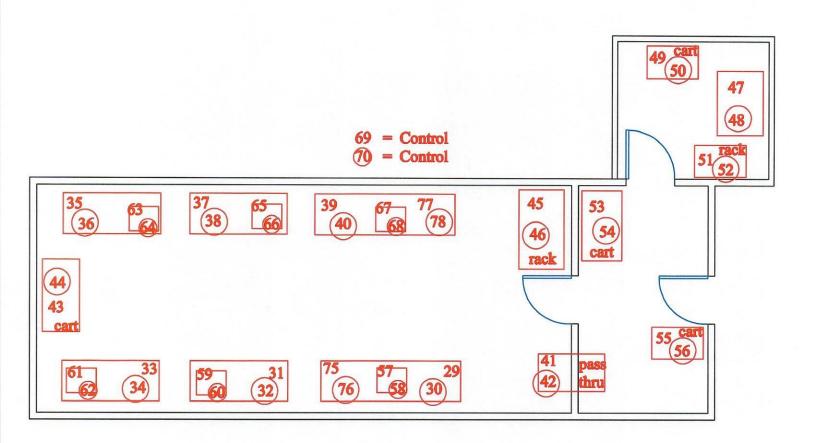
GLOSSARY

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.



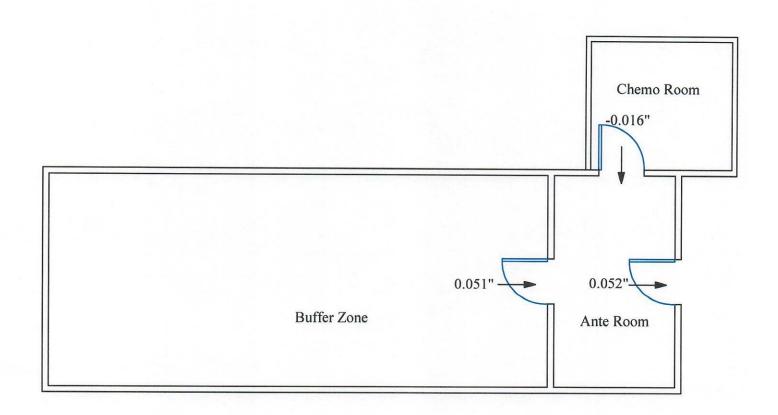
Option Care - Sun Valley Viable Air Sample Plan

- TSA Sample
- MEA Sample

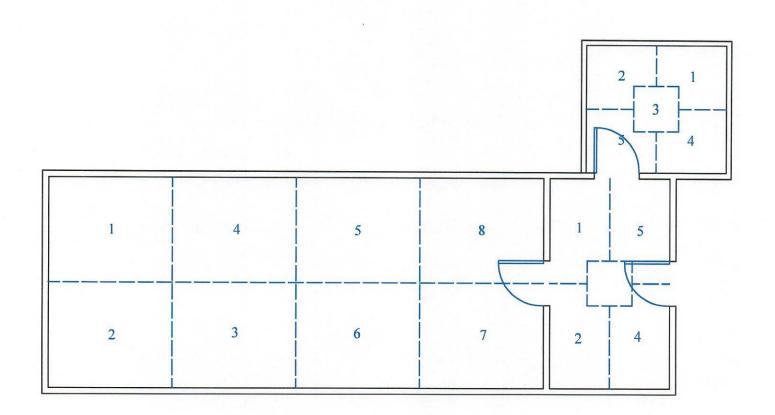


Option Care - Sun Valley Surface Sample Plan

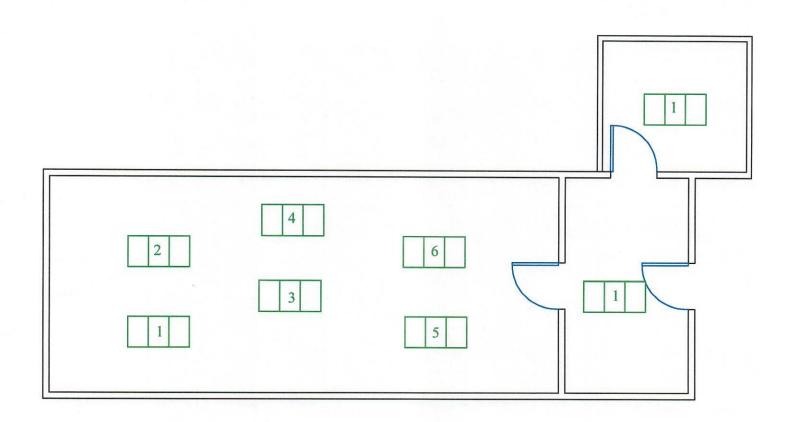
- TSA Sample
- MEA Sample



Option Care - Sun Valley Pressure Gradients



Option Care - Sun Valley Particle Count Locations



Option Care - Sun Valley
HEPA Filter Locations