



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

PERFORMANCE CERTIFICATION

FOR
Option Care - Tempe
7850 S. Hardy Drive
Tempe, AZ 85284



Test Date:

April 14, 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.

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 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 CI150T, 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


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 CETA Guidelines including CAG 003, ISO 14644, NSF 49 and IEST Recommended Practices as established in this report.

Signature: 
Arne Gjertsen
RCCP-SC #1114

Date: 4/24/22

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

Cleanroom Performance Test Report

Customer:	Option Care Tempe	Dimensions:	375 square feet
Date:	4/14/2022	Volume:	3375 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:

Particle Size	9	Location	Readings:
	>0.5	1	105.9 particle/Cu.mtr
		2	282.5 particle/Cu.mtr
		3	0.0 particle/Cu.mtr
		4	0.0 particle/Cu.mtr
		5	0.0 particle/Cu.mtr
		6	0.0 particle/Cu.mtr
Maximum count-	352,000 particle/cu.mtr	7	317.8 particle/Cu.mtr
Pass/Fail	Pass	8	0.0 particle/Cu.mtr
		9	635.7 particle/Cu.mtr

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	96	94	95.0	5.45	518
Recommended=	30.0 /hour	2	97	92	94.5	5.45	515
Actual=	84.6 /hour	3	90	93	91.5	5.45	499
		4	95	102	98.5	5.45	537
Pass/Fail	Pass	5	104	91	97.5	5.45	531
		6	87	92	89.5	5.45	488
		7	81	95	88.0	5.45	480
		8	122	109	115.5	5.45	629
		9	98	109	103.5	5.45	564
					Total CFM =		4,761

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	39	<0.01%	N/R	Pass	None
2	39	<0.01%	N/R	Pass	None
3	41	<0.01%	N/R	Pass	None
4	38	<0.01%	N/R	Pass	None
5	38	<0.01%	N/R	Pass	None
6	42	<0.01%	N/R	Pass	None
7	42	<0.01%	N/R	Pass	None
8	32	<0.01%	N/R	Pass	None
9	36	<0.01%	N/R	Pass	None

Signature:



Date:

4/14/22

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 Tempe	Dimensions:	64 square feet
Date:	4/14/2022	Volume:	576 cubic feet
Room ID:	Chemo Room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5	Location	Readings:
Particle Size	>0.5	1	282.5 particle/Cu.mtr
		2	847.6 particle/Cu.mtr
		3	1,483.2 particle/Cu.mtr
		4	2,118.9 particle/Cu.mtr
Maximum count-	352,000 particle/Cu.mtr	5	1,518.5 particle/Cu.mtr
Pass/Fail	Pass		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		10	110	116	113.0	5.45	616
Recommended=	30.0 /hour						
Actual=	64.2 /hour						
Pass/Fail	Pass						

Total CFM = 616

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	33	<0.01%	N/R	Pass	None

Signature: 

Date: 4/14/22

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 Tempe	Dimensions:	167 square feet
Date:	4/14/2022	Volume:	1503 cubic feet
Room ID:	Ante room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5	1	353.1 particle/Cu.mtr
		2	2,613.3 particle/Cu.mtr
		3	565.0 particle/Cu.mtr
		4	459.1 particle/Cu.mtr
		5	706.3 particle/Cu.mtr
Maximum count-	352,000 particle/cu.mtr	6	423.8 particle/Cu.mtr
Pass/Fail	Pass		

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	103	115	109.0	5.45	594
Recommended=	30.0 /hour	2	100	102	101.0	5.45	550
Actual=	71.3 /min	3	122	113	117.5	5.45	640
Pass/Fail	Pass						

Total CFM = 1,785

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	34	<0.01%	N/R	Pass	None
2	37	<0.01%	N/R	Pass	None
3	32	<0.01%	N/R	Pass	None

Signature: _____



Date: _____

4/14/22

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

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

Safety Cabinet Performance Test Report

Customer:	Option Care Tempe	Model #	SG 404
Date:	4/14/2022	Serial #	118380
Manufacturer:	Baker	Class:	5
		Test Status:	Dynamic

Particle Count

Locations required:	5		
Particle Size	>0.5	Location	Readings:
		1	0.0 particle/Cu. Meter
		2	0.0 particle/Cu. Meter
		3	0.0 particle/Cu. Meter
		4	0.0 particle/Cu. Meter
		5	0.0 particle/Cu. Meter

Maximum count-	3,520 particle/cu.mtr
Pass/Fail	Pass

Down Flow Air Readings

Requirement:
 Back & Middle - 52-62 FPM
 Front - 47-57 FPM

		FPM Readings:							
			Back			Middle			Front
		1-	53	8-	57	15-	57		
		2-	53	9-	55	16-	54		
Pass/Fail :	Pass	3-	52	10-	55	17-	57		
		4-	53	11-	53	18-	53		
		5-	53	12-	56	19-	56		
		6-	55	13-	59	20-	52		
		7-	61	14-	57	21-	54		
		Avg.	54.3		56.0		54.7		

Inflow Velocity - Restricted Sash Method

Requirement : 254-280 FPM

Average FPM=	260	1-	278	5-	259
		2-	259	6-	255
		3-	257	7-	249
		4-	258	8-	266

Intake Velocity @ 8"sash= 260 (FPM X.96/2.65)+10= 104 FPM

Required - 100-110 FPM

Pass/Fail : **Pass**

Filter Integrity Test

Exhaust HEPA:

Int. Ref. 77
Pass/Fail : **Pass**

No scanned leaks greater than 0.01%

Supply HEPA:

Int. Ref. 45
Pass/Fail : **Pass**

No scanned leaks greater than 0.01%

Smoke test performed per NSF 49: **PASS**

Signature:



Date:

4/14/22

See Test Summary Sheet for instrument data

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

Clean Flow Hood Performance Test Report

Customer: Option Care - Tempe
Date: 4/14/2022
Manufacturer: Baker

Model # EG-6252
Serial # 121214
Class: 5
Test Status: Dynamic

Particle Count

Locations required:	5	Location	1	Readings:
Particle Size	>0.5		2	0.0 Particle/Cu.meter
			3	0.0 Particle/Cu.meter
			4	141.3 Particle/Cu.meter
			5	0.0 Particle/Cu.meter
				0.0 Particle/Cu.meter

Maximum count- 3,520 particle/cu.mtr
Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	88.3	FPM Readings:					
Pass/Fail :	Pass	1-	86	6-	94	11-	83
		2-	85	7-	97	12-	86
		3-	91	8-	88	13-	88
Measured Values: Avg. +/- 20%		4-	83	9-	86	14-	93
Min. value =	70.6	5-	87	10-	85	15-	92
Max. value =	105.9						
Pass/Fail :	Pass						

13.7 sq. ft.

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref. 17
Pass/Fail : **Pass**

Signature:



Date:

4/14/22

See Test Summary Sheet for instrument data.

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

Clean Flow Hood Performance Test Report

Customer: Option Care - Tempe
Date: 4/14/2022
Manufacturer: Baker

Model # EG-6252
Serial # 121215
Class: 5
Test Status: Dynamic

Particle Count

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

Maximum count- 3,520 particle/cu.mtr
Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	85.6	FPM Readings:							
Pass/Fail :	Pass	1-	87	6-	84	11-	84		
		2-	85	7-	85	12-	85		
		3-	81	8-	86	13-	87		
Measured Values: Avg. +/- 20%		4-	86	9-	84	14-	91		
Min. value =	68.5	5-	87	10-	84	15-	88		
Max. value =	102.7								
Pass/Fail :	Pass								

13.7 sq. ft.

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref. 17
Pass/Fail : **Pass**

Signature: _____

Date: _____

4/14/22

See Test Summary Sheet for instrument data.

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

Clean Flow Hood Performance Test Report

Customer: Option Care - Tempe
Date: 4/14/2022
Manufacturer: Baker

Model # EG-6252
Serial # 121216
Class: 5
Test Status: Dynamic

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	0.0 Particle/Cu.meter
2	0.0 Particle/Cu.meter
3	0.0 Particle/Cu.meter
4	0.0 Particle/Cu.meter
5	0.0 Particle/Cu.meter

Maximum count- 3,520 particle/cu.mtr
Pass/Fail **Pass**

Air Flow

Requirement: 80-100 FPM

Avg. Velocity = 88.6 FPM Readings:
Pass/Fail : **Pass**

1-	90	6-	89	11-	87
2-	88	7-	86	12-	90
3-	84	8-	82	13-	84
4-	97	9-	94	14-	82
5-	98	10-	87	15-	91

Measured Values: Avg. +/- 20%
Min. value = 70.9
Max. value = 106.3
Pass/Fail : **Pass**

13.7 sq. ft.

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref. 17
Pass/Fail : **Pass**

Signature:



Date:

4/14/22

See Test Summary Sheet for instrument data.

Airflow Smoke Pattern Test

Option Care Tempe AZ.

April 14, 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.

The smoke pattern shall be filmed and observed, with narrative, looking for unidirectional airflow, reflux, turbulence and dead spots as stated above.

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

Smoke study comments:

- Good outward unidirectional airflow was observed at each workstation location.
- No reflux was observed at front edge of panels.
- No reflux was observed around operator.
- No reflux around perimeter

Conclusion:

PEC: Baker #121214 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: Baker #121215 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: Baker #121216 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: Baker #121217 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: Baker #118380 Smoke Study validates 1 person compounding maintains unidirectional flow.

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

Signed:  _____ Date: 4/14/22
Arne Gjertsen

Viability Air and Surface Sampling

Option Care – Tempe AZ.

Viability air and Surface sampling were performed in accordance 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.

Note: For surface samples #24-36 Single plate sample testing was utilized as there were not enough MEA plates on hand for testing all locations.

Tryptic Soy Agar and Malt Extract Agar were used in each of the 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 April 14, 2022 and delivered April 15, 2022 to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #22013575. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics

Air Sample:

Tryptic Soy Plates – Lot #501545; expires 5/19/22

Malt Plates – Lot #500776; expires 5/8/22

Surface Sample:

Tryptic Soy Plates – Lot #514163; expires 6/30/22

Malt Plates – Lot #501566; expires 5/19/22

Signature: _____

Arne Gjertsen

Date: _____

4/25/22

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







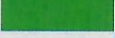


Date Collected: 4/14/2022
 Date Received: 4/15/2022
 Date Analyzed: 4/23/2022
 Date Reported: 4/25/2022
 Project ID: 22013575
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AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LFB	5	A				
2: Class 5 LFB	5	A				
3: Class 5 LFB	5	A				
4: Class 5 LFB	5	A				
5: Class 5 LFB	5	A				
6: Class 5 LFB	5	A				
7: Class 5 LFB	5	A				
8: Class 5 LFB	5	A				
9: Class 5 BSC	5	A				
10: Class 5 BSC	5	A				
11: Class 7 Pass Thru	7	A				
12: Class 7 Pass Thru	7	A				
13: Class 7 Buffer Zone	7	A				
14: Class 7 Buffer Zone	7	A				
15: Class 7 NPR	7	A				
16: Class 7 NPR	7	A				
17: Class 7 Ante Rm	7	A				
18: Class 7 Ante Rm	7	A				
19: Control / Op. Handling Lot # 501545; Exp. 5/19/22	NA	A				
20: Control Lot # 500776; Exp. 5/8/22	NA	A				
21: Class 5 LFB	5	S				
22: Class 5 LFB	5	S				
23: Class 5 LFB Touchscreen	5	S				
24: Class 5 LFB Touchscreen	5	S				
25: Class 5 LFB	5	S				
26: Class 5 LFB	5	S				
27: Class 5 LFB Touchscreen	5	S				
28: Class 5 LFB Touchscreen	5	S				
29: Class 5 LFB	5	S				
30: Class 5 LFB	5	S				
31: Class 5 LFB Touchscreen	5	S				
32: Class 5 LFB Touchscreen	5	S				
33: Class 5 LFB	5	S				
34: Class 5 LFB	5	S				
35: Class 5 LFB Touchscreen	5	S				
36: Class 5 LFB Touchscreen	5	S				
37: Class 5 BSC	5	S				
38: Class 5 BSC	5	S				
39: Class 7 Buffer Zone	7	S				
40: Class 7 Buffer Zone	7	S				
41: Class 7 Buffer Zone	7	S				
42: Class 7 Buffer Zone	7	S				
43: Class 7 Buffer Zone	7	S				

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

Date Collected: 4/14/2022
 Date Received: 4/15/2022
 Date Analyzed: 4/23/2022
 Date Reported: 4/25/2022
 Project ID: 22013575
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44: Class 7 Buffer Zone	7	S	
45: Class 7 NPR	7	S	
46: Class 7 NPR	7	S	
47: Class 7 Pass Thru	7	S	
48: Class 7 Pass Thru	7	S	
49: Class 7 Ante Room	7	S	
50: Class 7 Ante Room	7	S	
51: Class 7 Ante Room	7	S	
52: Class 7 Ante Room	7	S	
53: Control Lot # 504163; Exp. 6/30/22	NA	S	
54: Control Lot # 501566; Exp. 5/19/22	NA	S	

-  No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
-  Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
-  O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance with USP 797 and CAG-009 guidance documents.
-  Sample results not applicable to USP 797 and CAG-009 guidance documents.

Matrix* - A: Air S: Surface

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

Date Collected: 4/14/2022
Date Received: 4/15/2022
Date Analyzed: 4/23/2022
Date Reported: 4/25/2022
Project ID: 22013575

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Client Sample #: 1
Sample Location: Class 5 LFB

Lab Sample #: 22013575-001

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 2
Sample Location: Class 5 LFB

Lab Sample #: 22013575-002

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 3
Sample Location: Class 5 LFB

Lab Sample #: 22013575-003

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 4
Sample Location: Class 5 LFB

Lab Sample #: 22013575-004

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 5
Sample Location: Class 5 LFB

Lab Sample #: 22013575-005

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

Results: **No Growth**

Air Volume: **1000 L**

Positive Hole: **219**

MRL: **1 CFU/m3**

Comments: **Pass**

Client Sample #: 6
Sample Location: Class 5 LFB

Lab Sample #: 22013575-006

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**

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

Date Collected: 4/14/2022
Date Received: 4/15/2022
Date Analyzed: 4/23/2022
Date Reported: 4/25/2022
Project ID: 22013575
Page 4 of 13

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

Lab Sample #: 22013575-007
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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

Lab Sample #: 22013575-008
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 9
Sample Location: Class 5 BSC
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-009
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 10
Sample Location: Class 5 BSC
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-010
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 11
Sample Location: Class 7 Pass Thru
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-011
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 12
Sample Location: Class 7 Pass Thru
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-012
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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Anaheim CA, 92802
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Project: **Option Care - Tempe**
Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 13
Sample Location: Class 7 Buffer Zone
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-013
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 14
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-014
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 15
Sample Location: Class 7 NPR
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-015
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 16
Sample Location: Class 7 NPR
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-016
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 17
Sample Location: Class 7 Ante Rm
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-017
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 18
Sample Location: Class 7 Ante Rm
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-018
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 19
Sample Location: Control / Op. Handling Lot # 501545; Exp. 5/19/22
Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**

Lab Sample #: 22013575-019

Client Sample #: 20
Sample Location: Control Lot # 500776; Exp. 5/8/22
Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22013575-020

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

Lab Sample #: 22013575-021

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

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

Lab Sample #: 22013575-022

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

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

Lab Sample #: 22013575-023

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

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

Lab Sample #: 22013575-024

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

Client Sample #: 25
Sample Location: Class 5 LFB
Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-025

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

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Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 26
Sample Location: Class 5 LFB

Lab Sample #: 22013575-026

Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 27
Sample Location: Class 5 LFB Touchscreen

Lab Sample #: 22013575-027

Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 28
Sample Location: Class 5 LFB Touchscreen

Lab Sample #: 22013575-028

Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 29
Sample Location: Class 5 LFB

Lab Sample #: 22013575-029

Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 30
Sample Location: Class 5 LFB

Lab Sample #: 22013575-030

Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 31
Sample Location: Class 5 LFB Touchscreen

Lab Sample #: 22013575-031

Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
Results: **No Growth**
Comments: **Pass**

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

Client Sample #: 32
Sample Location: Class 5 LFB Touchscreen

Lab Sample #: 22013575-032

Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
Results: **No Growth**

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

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 Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 33
 Sample Location: Class 5 LFB
 Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-033
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 34
 Sample Location: Class 5 LFB
 Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-034
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 35
 Sample Location: Class 5 LFB Touchscreen
 Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-035
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 36
 Sample Location: Class 5 LFB Touchscreen
 Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-036
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 37
 Sample Location: Class 5 BSC
 Test: 1202 SINGLE PLATE PROTOCOL - TSA Culture, Surface Bacteria Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-037
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 38
 Sample Location: Class 5 BSC
 Test: 1202.1 SINGLE PLATE PROTOCOL - TSA Culture, Surface Fungal Count Only - Dual Incubation
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-038
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 39
 Sample Location: Class 7 Buffer Zone
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**
 Lab Sample #: 22013575-039
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Condition of Sample(s) Upon Receipt: Acceptable

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

Lab Sample #: 22013575-040
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 41
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-041
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 42
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-042
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 43
Sample Location: Class 7 Buffer Zone
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-043
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 44
Sample Location: Class 7 Buffer Zone
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-044
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 45
Sample Location: Class 7 NPR
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-045
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 46
Sample Location: Class 7 NPR
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22013575-046
Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Client Sample #: 47
 Sample Location: Class 7 Pass Thru
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22013575-047
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 48
 Sample Location: Class 7 Pass Thru
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22013575-048
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 49
 Sample Location: Class 7 Ante Room
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22013575-049
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 50
 Sample Location: Class 7 Ante Room
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22013575-050
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 51
 Sample Location: Class 7 Ante Room
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **1 CFU/25cm2**

Lab Sample #: 22013575-051
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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

Comments: **Acceptable**

Client Sample #: 52
 Sample Location: Class 7 Ante Room
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22013575-052
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 53
Sample Location: Control Lot # 504163; Exp. 6/30/22
Test: 1158 BACTERIAL SURFACE - USP 797 Negative (-) Control: 2.2
Results: **No Growth**

Lab Sample #: 22013575-053

Client Sample #: 54
Sample Location: Control Lot # 501566; Exp. 5/19/22
Test: 1159 FUNGAL SURFACE - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22013575-054

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USP 797 Class and Action Levels

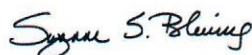
ISO Clean Room Classification	ISO, 0.5 u/m ³ Particulate	Viable Air Sampling 400-1000 CFU/m ³	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

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

Source PIC/S, 2007

Footnotes and Additional Report Information

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



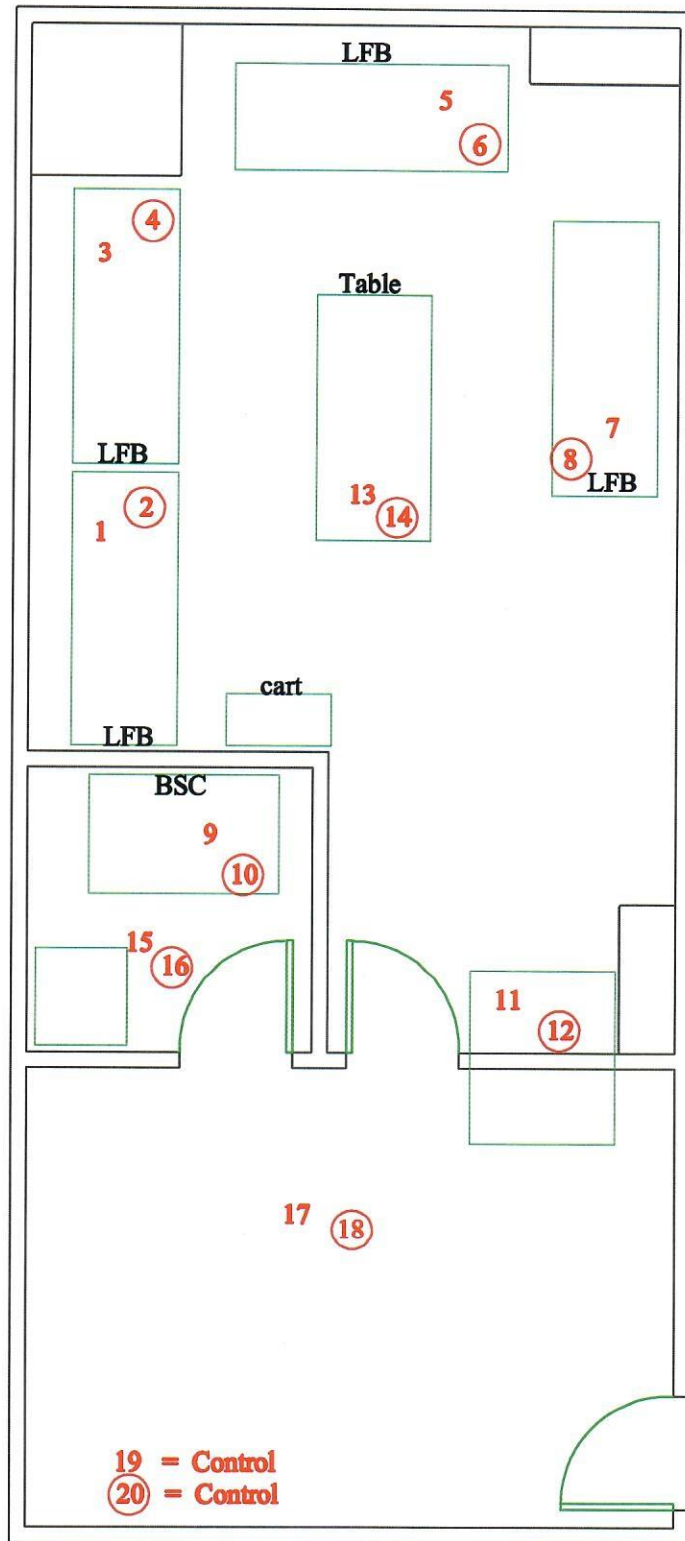
Suzanne Blevins
Laboratory Director

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

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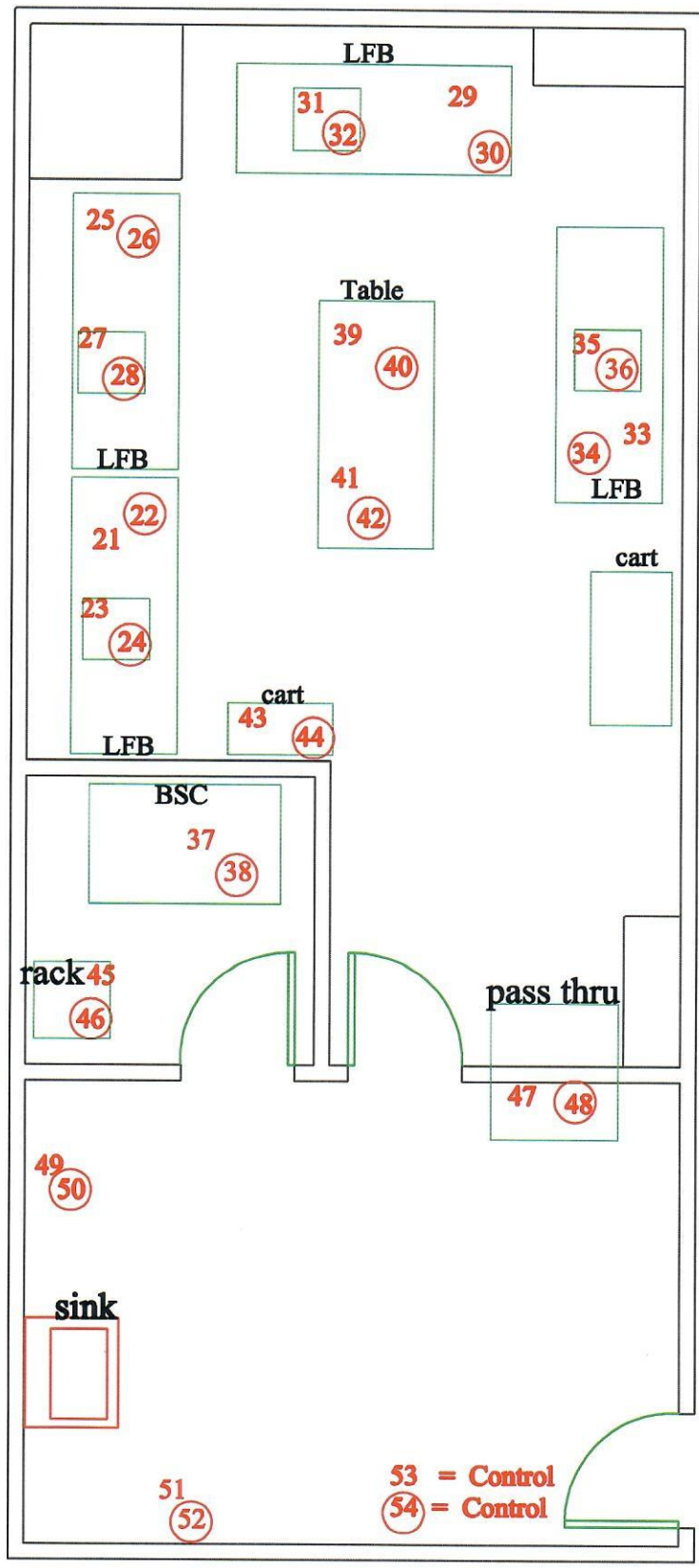
GLOSSARY

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.



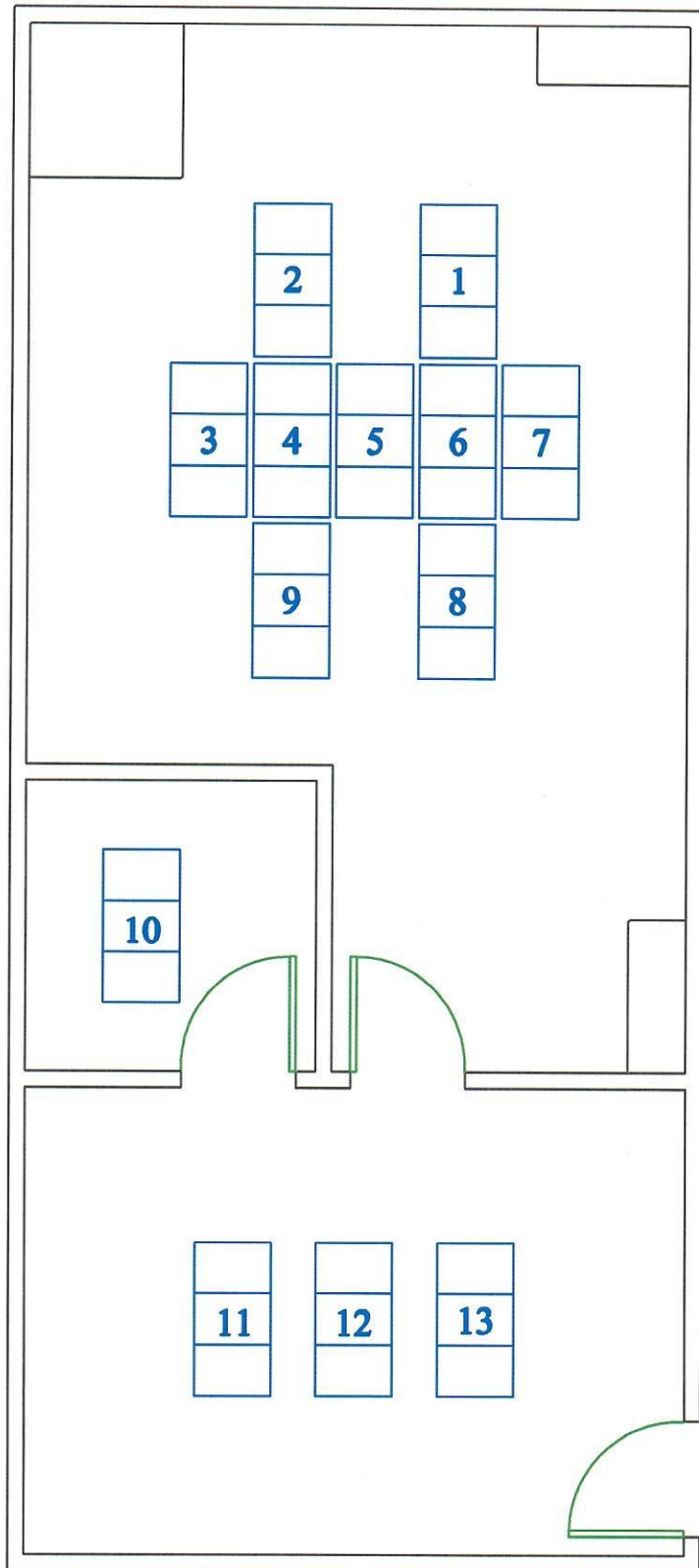
**Option Care - Tempe
Viable Air Sample Plan**

- # = TSA Media
- ⊙ = MEA Media

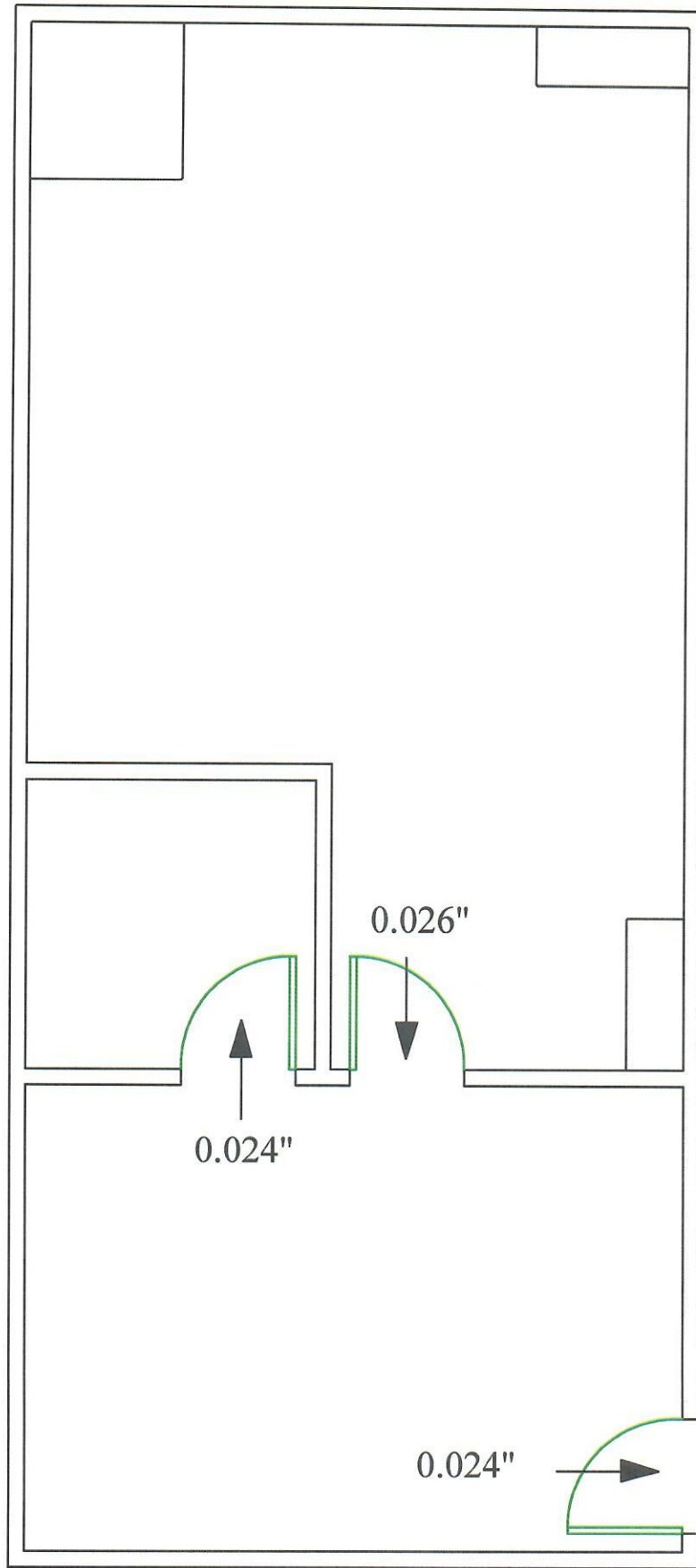


**Option Care - Tempe
Surface Sample Plan**

- # = Bacteria Media
- Ⓝ = Fungal Media



Option Care - Tempe
HEPA Filter Locations



Option Care - Tempe
Pressure Gradients