



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

PERFORMANCE CERTIFICATION

FOR
Option Care - Bakersfield
5800 District Blvd.
Suite 200
Bakersfield, CA 93313



Test Date:

March 9, 2022

CERTIFICATION PROCEDURES

CLEANROOMS/CLEAN ZONES

Particle Count

Particle count testing was performed in accordance with ISO 14644 and followed the recommended practices in IEST-RP-006 and CETA Guidelines.

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

Test Instruments:

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

Air Flow

All HEPA filters were measured and adjusted for airflow in accordance with ISO 14644-1, and IEST-RP-006.

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M15523; Calibrated 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-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 CI50T, 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 CI50T, 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. 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 and IEST Recommended Practices as established in this report.

Signature: _____

Arne Gjertsen
RCCP-SC #1114

Date: _____

3/9/22

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

Cleanroom Performance Test Report

Customer:	Option Care Bakersfield	Dimensions:	314 square feet
Date:	3/9/2022	Volume:	2826 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	8	Location	Readings:
Particle Size	>0.5 micron	1	2,860.5 Particle/M ³
		2	10,241.3 Particle/M ³
		3	3,743.4 Particle/M ³
		4	3,037.1 Particle/M ³
		5	565.0 Particle/M ³
		6	2,754.5 Particle/M ³
		7	4,449.6 Particle/M ³
		8	1,200.7 Particle/M ³

Maximum count-	352,000 Particle/M ³
Pass/Fail	Pass

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	93	99	96.0	7.25	696
Recommended=	30.0 /hour	2	116	100	108.0	7.25	783
Actual=	47.6 /hour	3	106	104	105.0	7.25	761

Pass/Fail	Pass
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Total CFM = 2,240

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	29	<0.01%	No	Pass	No
2	26	<0.01%	No	Pass	No
3	27	<0.01%	No	Pass	No

Signature: 

Date: 3/9/22

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 Bakersfield	Dimensions:	49 square feet
Date:	3/9/2022	Volume:	441 cubic feet
Room ID:	Chemo Room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5		
Particle Size	>0.5 micron	Location	Readings:
		1	1,130.1 Particle/M ³
		2	741.6 Particle/M ³
		3	317.8 Particle/M ³
		4	741.6 Particle/M ³
		5	388.5 Particle/M ³

Maximum UCL = 352,000 Particle/M³
 Pass/Fail **Pass**

Air Flow

		Filter	Read 1	Avg. FPM	Sq. Feet	CFM
Air Change:		1	80	80.0	3.25	260
Recommended=	30.0 /hour					
Actual=	35.4 /hour					
Pass/Fail	Pass					

Total CFM = 260

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

<u>Filter#</u>	<u>Int. Ref.</u>	<u>Leak</u>	<u>Repaired</u>	<u>Pass/Fail</u>	<u>Prev. patch</u>
1	78	<0.01%	No	Pass	No

Signature: _____



Date: _____

3/9/22

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 Bakersfield Dimensions: 98 square feet
Date: 3/9/2022 Volume: 882 cubic feet
Room ID: Ante Room Test Status: Dynamic
Class: 7

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	2,295.5 Particle/M ³
2	1,412.6 Particle/M ³
3	423.8 Particle/M ³
4	1,412.6 Particle/M ³
5	741.6 Particle/M ³

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

Air Flow

Air Change:	Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Recommended= 30.0 /hour	1	82	99	90.5	7.25	656
Actual= 44.6 /hour						

Pass/Fail **Pass**

Total CFM = 656

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	31	<0.01%	No	Pass	None

Signature: 

Date: 3/9/22

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 Bakersfield
 Date: 3/9/2022
 Manufacturer: Nuaire

Model # NU-425-400
 Serial # 131712070809
 Class: 5
 Test Status: Dynamic

Particle Count

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

Maximum Count- 3,520 Particle/M³
 Pass/Fail **Pass**

Down Flow Air Readings

Requirement: 55-65

FPM Readings:		1-	59	5-	60	9-	61
		2-	61	6-	59	10-	61
Avg. Velocity =	60.3	3-	64	7-	59	11-	60
		4-	59	8-	60	12-	61
Pass/Fail :	Pass						

Inflow Velocity - Restricted Sash Method

Average FPM=	284	1-	270	5-	277
		2-	289	6-	281
		3-	296	7-	296
		4-	291	8-	273

Intake Velocity @ 8"sash= (284 fpm x 0.97/ 2.58) = 106.8 FPM

Required Intake Velocity- 100-120

Filter Integrity Test

Exhaust HEPA:

No scanned leaks greater than 0.01%

Int. Ref. 50

Pass/Fail : **Pass**

Supply HEPA: Combined with Exhaust Calc's

No scanned leaks greater than 0.01%

Int. Ref. 44

Pass/Fail : **Pass**

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

Signature:



Date:

3/9/22

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 - Bakersfield
 Date: 3/9/2022
 Manufacturer: Nuaire #1

Model # NU-301-630
 Serial # 131658070709
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	5	Location	1	Readings:	0.0 Particle/M ³
Particle Size	>0.5		2		0.0 Particle/M ³
			3		0.0 Particle/M ³
			4		0.0 Particle/M ³
			5		0.0 Particle/M ³
Maximum count- Pass/Fail	3,520 Particle/M ³ Pass				

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	90.5	FPM Readings:					
Pass/Fail :	Pass	1-	88	6-	94	11-	98
		2-	83	7-	94	12-	89
		3-	82	8-	97	13-	98
Measured Values: Avg. +/- 20%		4-	83	9-	94	14-	90
Min. value =	72.4	5-	85	10-	91	15-	91
Max. value =	108.6						
Pass/Fail :	Pass						

Filter Integrity Test 13.8 Sq. Ft.

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
16	<0.01%	No	Pass	No

Signature: 

Date: 3/9/22

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 - Bakersfield
 Date: 3/9/2022
 Manufacturer: Nuaire #3

Model # NU-301-630
 Serial # 131656070709
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	5	Location	1	Readings:
Particle Size	>0.5		2	0.0 Particle/M ³
			3	0.0 Particle/M ³
			4	0.0 Particle/M ³
			5	0.0 Particle/M ³
Maximum count-	3,520 Particle/M ³			
Pass/Fail	Pass			

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	95.0	FPM Readings:				
Pass/Fail :	Pass	1-	94	6-	90	11- 100
		2-	91	7-	92	12- 100
		3-	97	8-	87	13- 99
Measured Values: Avg. +/- 20%		4-	95	9-	92	14- 98
Min. value =	76.0	5-	97	10-	93	15- 100
Max. value =	114.0					
Pass/Fail :	Pass					

Filter Integrity Test 13.8 Sq. ft.

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
15	<0.01%	No	Pass	No

Signature: _____



Date: _____

3/9/22

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 - Bakersfield
 Date: 3/9/2022
 Manufacturer: Nuaire

Model # S201-830
 Serial # 168186042115
 Class: 5
 Test Status: Dynamic

Particle Count

Locations required:	5	Location	1	Readings:
Particle Size	>0.5		2	0.0 Particle/M ³
			3	0.0 Particle/M ³
			4	0.0 Particle/M ³
			5	0.0 Particle/M ³
Maximum count- Pass/Fail	3,520 Particle/M ³ Pass			

Air Flow

Requirement: 80-100 FPM

Avg. Velocity =	93.1	FPM Readings:				
Pass/Fail :	Pass	1-	102	9-	90	17- 93
		2-	91	10-	90	18- 100
		3-	88	11-	93	19- 102
Measured Values: Avg. +/- 20%		4-	94	12-	85	20- 97
Min. value =	74.5	5-	97	13-	84	21- 88
Max. value =	111.7	6-	100	14-	95	22- 87
Pass/Fail :	Pass	7-	89	15-	99	23- 89
		8-	97	16-	96	24- 88

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
Left Side	23	<0.01%	No	Pass	No
Right Side	23	<0.01%	No	Pass	No

Signature: _____



Date: _____

3/9/22

See Test Summary Sheet for instrument data.

Airflow Smoke Pattern Test

Option Care – Bakersfield

March 9, 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 unidirectional flowing outward and from the workstation 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 work station 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
- PEC: NuAire Hood #1 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire Hood #2 Smoke study validates 1 person compounding maintains unidirectional airflow
- PEC: NuAire Hood #3 Smoke study validates 1 person compounding maintains unidirectional airflow

Conclusion:

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

Signed:  _____ Date: 3/9/22
Arne Gjertsen

Viable Air and Surface Sampling

Option Care - Bakersfield

Viable air sampling and Surface sampling was 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 Chemo room and the Class 7 Ante room as per attached Sample Plan.

Both Tryptic Soy Agar and Malt Extract Agar were used in all 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 March 9, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab reports #22008489. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics:

Air Sample Media

Tryptic Soy: Lot #501545, Exp. 5/19/2022; MEA: Lot #500776, Exp. 5/8/2022

Surface Sample Media

Tryptic Soy: Lot #142696, Exp. 5/2/2022; MEA: Lot #501556, Exp. 5/19/2022

Signature:


Arne Gjertsen

Date:

3/14/22

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **O.C. Bakersfield**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
 Date Received: 3/9/2022
 Date Analyzed: 3/14/2022
 Date Reported: 3/14/2022
 Project ID: 22008489
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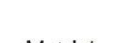
AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LAFW	5	S				
2: Class 5 LAFW	5	S				
3: Class 5 LAFW	5	S				
4: Class 5 LAFW	5	S				
5: Class 5 LAFW	5	S				
6: Class 5 LAFW	5	S				
7: Class 5 LAFW	5	S				
8: Class 5 LAFW	5	S				
9: Class 5 BSC	5	S				
10: Class 5 BSC	5	S				
11: Class 7 Buffer Zone	7	S				
12: Class 7 Buffer Zone	7	S				
13: Class 7 Buffer Zone	7	S				
14: Class 7 Buffer Zone	7	S				
15: Class 7 Buffer	7	S				
16: Class 7 Buffer	7	S				
17: Class 7 Chemo Room	7	S				
18: Class 7 Chemo Room	7	S				
19: Class 7 Ante	7	S				
20: Class 7 Ante	7	S				
21: Class 5 LAFW Touch Screen	5	S				
22: Class 5 LAFW Touch Screen	5	S				
23: Class 5 LAFW Touch Screen	5	S				
24: Class 5 LAFW Touch Screen	5	S				
25: Class 5 LAFW Touch Screen	5	S				
26: Class 5 LAFW Touch Screen	5	S				
27: Class 7 NPR	7	S				
28: Class 7 NPR	7	S				
29: Class 5 LAFW	5	A				
30: Class 5 LAFW	5	A				
31: Class 5 LAFW	5	A				
32: Class 5 LAFW	5	A				
33: Class 5 LAFW	5	A				
34: Class 5 LAFW	5	A				
35: Class 5 LAFW	5	A				
36: Class 5 LAFW	5	A				
37: Class 5 BSC	5	A				
38: Class 5 BSC	5	A				
39: Class 7 Buffer	7	A				

Cleanrooms Plus
 1587 Sim Place
 Anaheim CA, 92802
 Attn: Arne Gjertsen
 Project: **O.C. Bakersfield**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
 Date Received: 3/9/2022
 Date Analyzed: 3/14/2022
 Date Reported: 3/14/2022
 Project ID: 22008489
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40: Class 7 Buffer	7	A	
41: Class 7 Buffer	7	A	
42: Class 7 Buffer	7	A	
43: Class 7 Chemo Rm.	7	A	
44: Class 7 Chemo Rm.	7	A	
45: Class 7 Ante	7	A	
46: Class 7 Ante	7	A	
47: Class 7 Ante	7	A	
48: Class 7 Ante	7	A	
49: Control/Operator Handling; Lot: 501545, Ex: 5/19/2022	NA	A	
50: Control; Lot: 500776, Ex: 5/8/2022	NA	A	
51: Control; Lot: 142696, Ex: 5/5/2022	NA	S	
52: Control; Lot: 501556, Ex: 5/19/2022	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: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
Date Received: 3/9/2022
Date Analyzed: 3/14/2022
Date Reported: 3/14/2022
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Client Sample #: 1
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-001
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 2
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-002
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 3
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-003
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 4
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-004
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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

Lab Sample #: 22008489-005
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 6
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-006
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 7
Sample Location: Class 5 LAFW
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-007
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
Date Received: 3/9/2022
Date Analyzed: 3/14/2022
Date Reported: 3/14/2022
Project ID: 22008489
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Client Sample #: 8
Sample Location: Class 5 LAFW
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22008489-008
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 9
Sample Location: Class 5 BSC
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22008489-009
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 10
Sample Location: Class 5 BSC
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**
Lab Sample #: 22008489-010
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 11
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 #: 22008489-011
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 12
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 #: 22008489-012
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 13
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 #: 22008489-013
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 14
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 #: 22008489-014
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
Date Received: 3/9/2022
Date Analyzed: 3/14/2022
Date Reported: 3/14/2022
Project ID: 22008489
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Client Sample #: 15
Sample Location: Class 7 Buffer

Lab Sample #: 22008489-015

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

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

Organism(s) Isolated:

Organism(s) Isolated:	Raw Count	CFU/25cm2	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	100	Human

1 **1** **~100%**

Comments: **Acceptable**

Client Sample #: 16
Sample Location: Class 7 Buffer

Lab Sample #: 22008489-016

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

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

Comments: **Pass**

Client Sample #: 17
Sample Location: Class 7 Chemo Room

Lab Sample #: 22008489-017

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

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

Comments: **Pass**

Client Sample #: 18
Sample Location: Class 7 Chemo Room

Lab Sample #: 22008489-018

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

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

Comments: **Pass**

Client Sample #: 19
Sample Location: Class 7 Ante

Lab Sample #: 22008489-019

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

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

Comments: **Pass**

Client Sample #: 20
Sample Location: Class 7 Ante

Lab Sample #: 22008489-020

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

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

Comments: **Pass**

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Attn: Arne Gjertsen
Project: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 3/9/2022
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Client Sample #: 21 Lab Sample #: 22008489-021
Sample Location: Class 5 LAFW Touch Screen

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/25cm ²	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	100	Human

Comments: **Acceptable**

Client Sample #: 22 Lab Sample #: 22008489-022
Sample Location: Class 5 LAFW Touch Screen

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 #: 23 Lab Sample #: 22008489-023
Sample Location: Class 5 LAFW Touch Screen

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 #: 24 Lab Sample #: 22008489-024
Sample Location: Class 5 LAFW Touch Screen

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 #: 25 Lab Sample #: 22008489-025
Sample Location: Class 5 LAFW Touch Screen

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 #: 26 Lab Sample #: 22008489-026
Sample Location: Class 5 LAFW Touch Screen

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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Project: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 27
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 #: 22008489-027
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 28
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 #: 22008489-028
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 29
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-029
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 30
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-030
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 31
Sample Location: Class 5 LAFW
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-031
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 32
Sample Location: Class 5 LAFW
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-032
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 #: 33
Sample Location: Class 5 LAFW

Lab Sample #: 22008489-033

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

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

Comments: **Pass**

Client Sample #: 34
Sample Location: Class 5 LAFW

Lab Sample #: 22008489-034

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 5 LAFW

Lab Sample #: 22008489-035

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 5 LAFW

Lab Sample #: 22008489-036

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

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

Comments: **Pass**

Client Sample #: 37
Sample Location: Class 5 BSC

Lab Sample #: 22008489-037

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 5 BSC

Lab Sample #: 22008489-038

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**

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Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 39
Sample Location: Class 7 Buffer

Lab Sample #: 22008489-039

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 Buffer

Lab Sample #: 22008489-040

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 #: 41
Sample Location: Class 7 Buffer

Lab Sample #: 22008489-041

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 #: 42
Sample Location: Class 7 Buffer

Lab Sample #: 22008489-042

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 Chemo Rm.

Lab Sample #: 22008489-043

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 Chemo Rm.

Lab Sample #: 22008489-044

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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Condition of Sample(s) Upon Receipt: Acceptable

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

Lab Sample #: 22008489-045
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 46
Sample Location: Class 7 Ante
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-046
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 47
Sample Location: Class 7 Ante
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-047
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 48
Sample Location: Class 7 Ante
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22008489-048
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 49
Sample Location: Control/Operator Handling; Lot: 501545, Ex: 5/19/2022
Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**

Lab Sample #: 22008489-049

Client Sample #: 50
Sample Location: Control; Lot: 500776, Ex: 5/8/2022
Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22008489-050

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Condition of Sample(s) Upon Receipt: Acceptable

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Client Sample #: 51
Sample Location: Control; Lot: 142696, Ex: 5/5/2022
Test: 1158 BACTERIAL SURFACE - USP 797 Negative (-) Control: 2.2
Results: **No Growth**

Lab Sample #: 22008489-051

Client Sample #: 52
Sample Location: Control; Lot: 501556, Ex: 5/19/2022
Test: 1159 FUNGAL SURFACE - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22008489-052

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Condition of Sample(s) Upon Receipt: Acceptable

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USP 797 Class and Action Levels

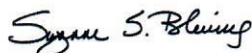
ISO Clean Room Classification	ISO, 0.5 u/m ³ Particulate	Viable Air Sampling 400-1000 CFU/m ³	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

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

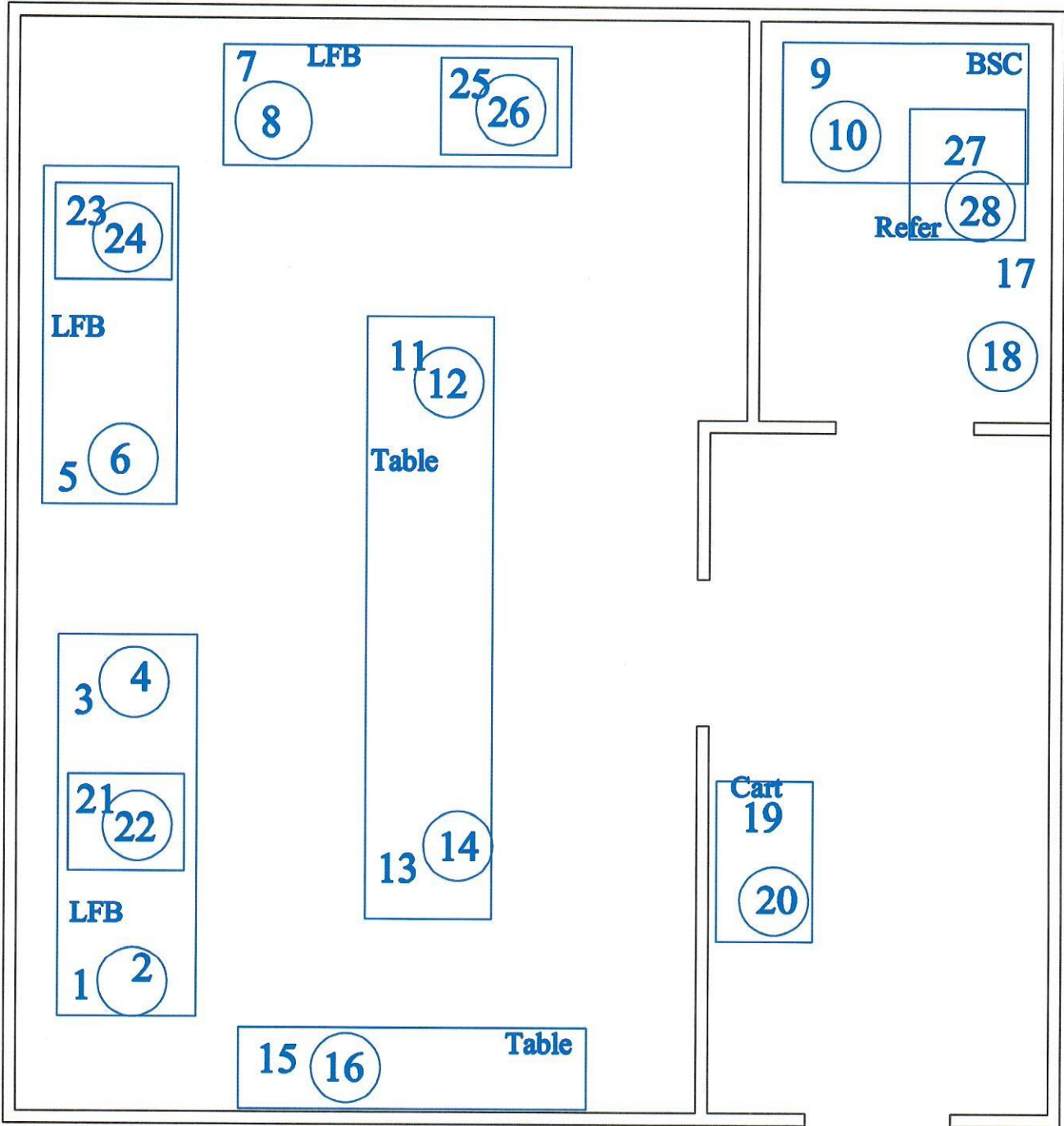
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Project: **O.C. Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

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GLOSSARY

Coag-negative Staphylococcus species: Staphylococcus are non spore-forming, gram-positive cocci. Coagulase Negative Staphylococcus species constitute a major part of the normal microbiota of humans.

51 = Control
52 = Control

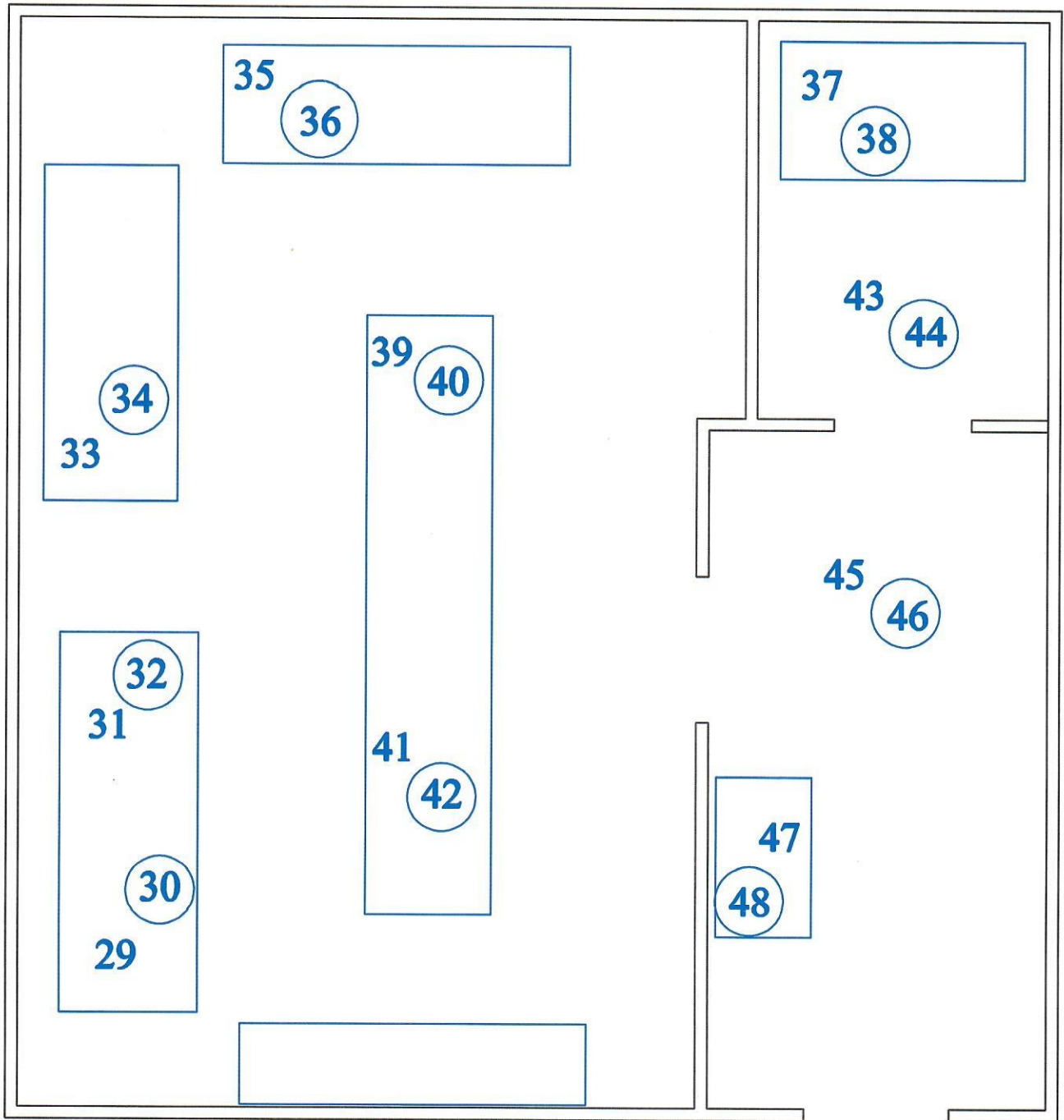


**Option Care Bakersfield
Surface Sample Locations**

= TSA Media Sample

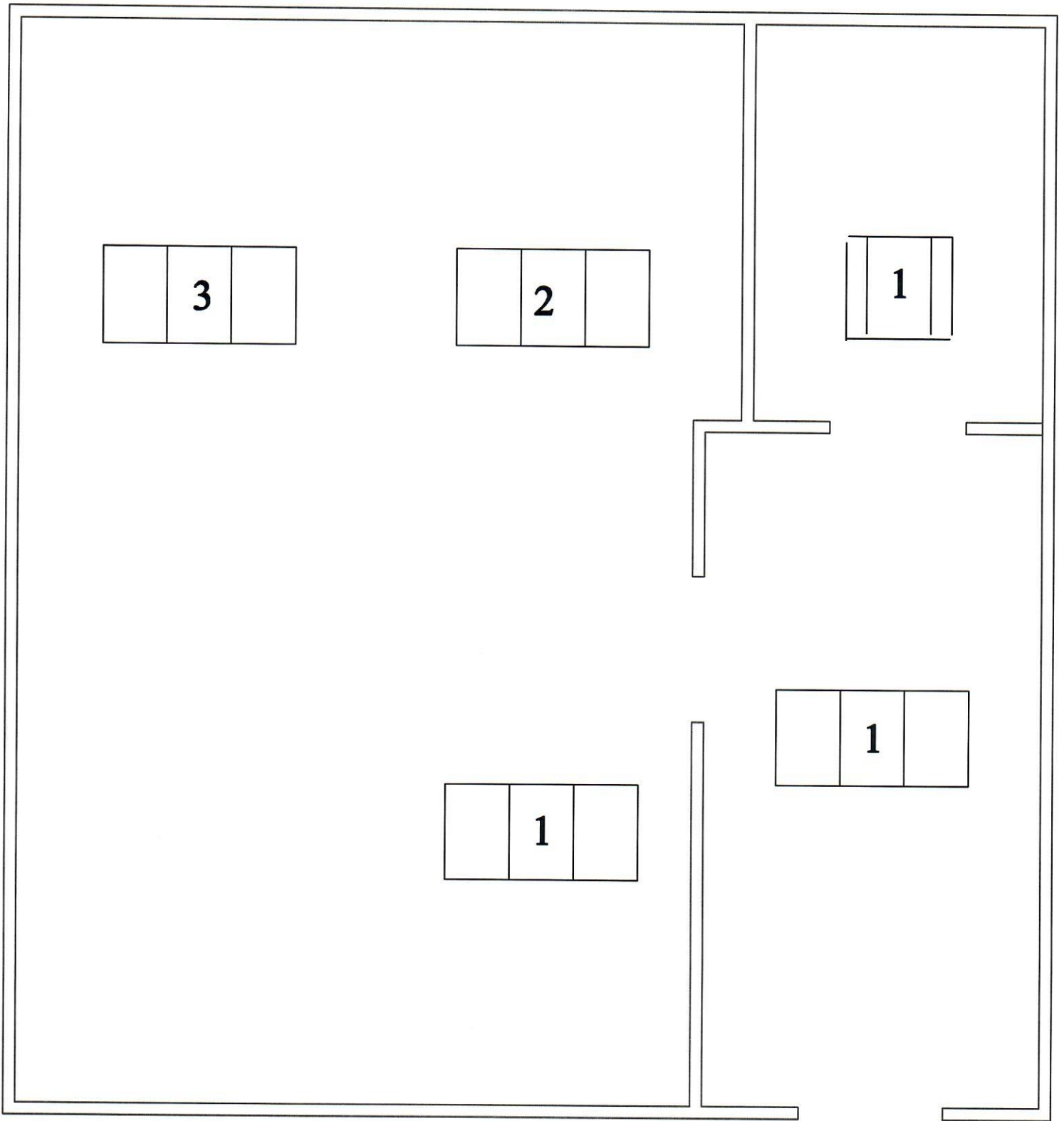
⊙ = MEA Media Sample

49 = Control/Operator Handling
50 = Control

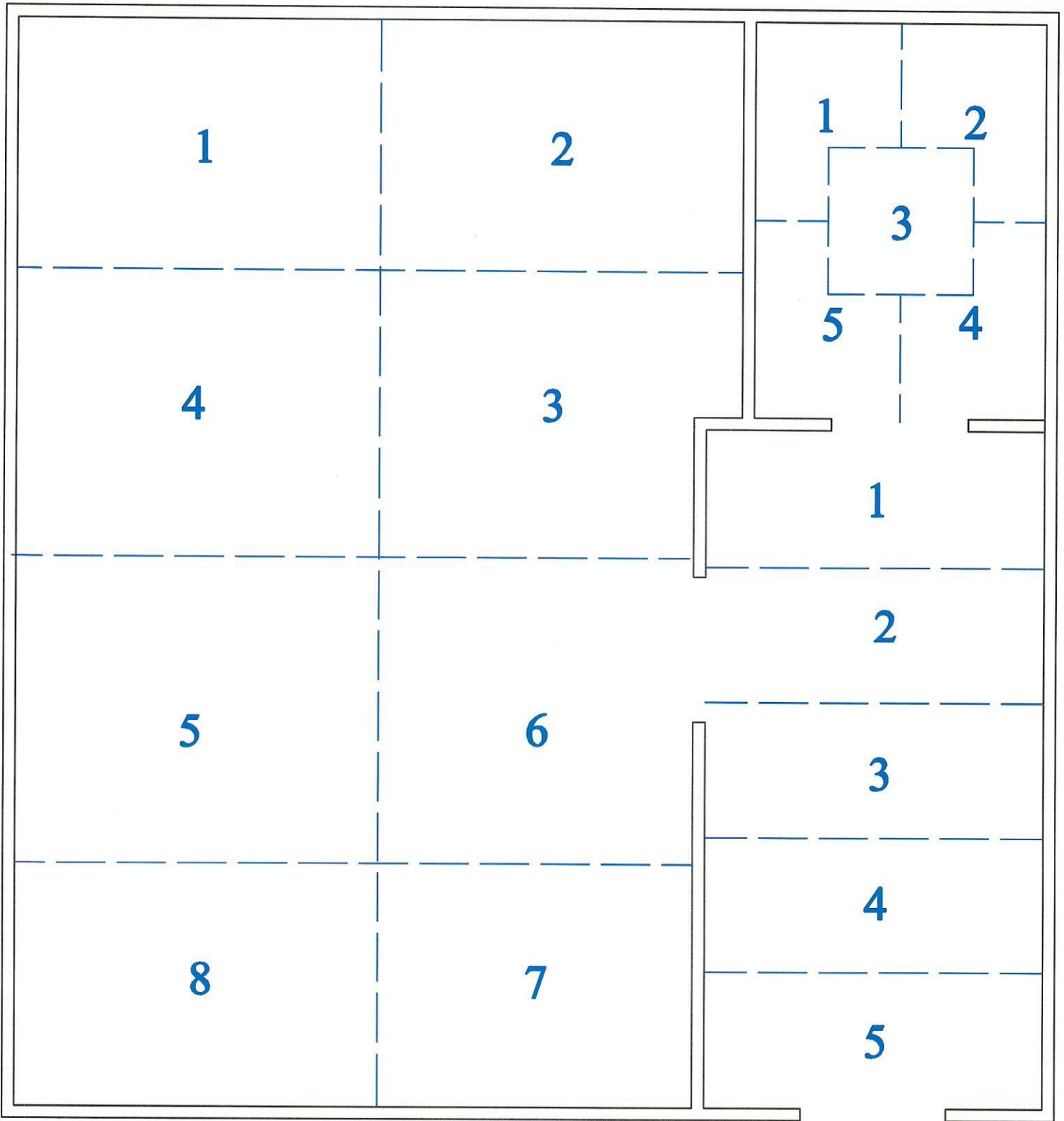


**Option Care Bakersfield
Viable Air Sample Locations**

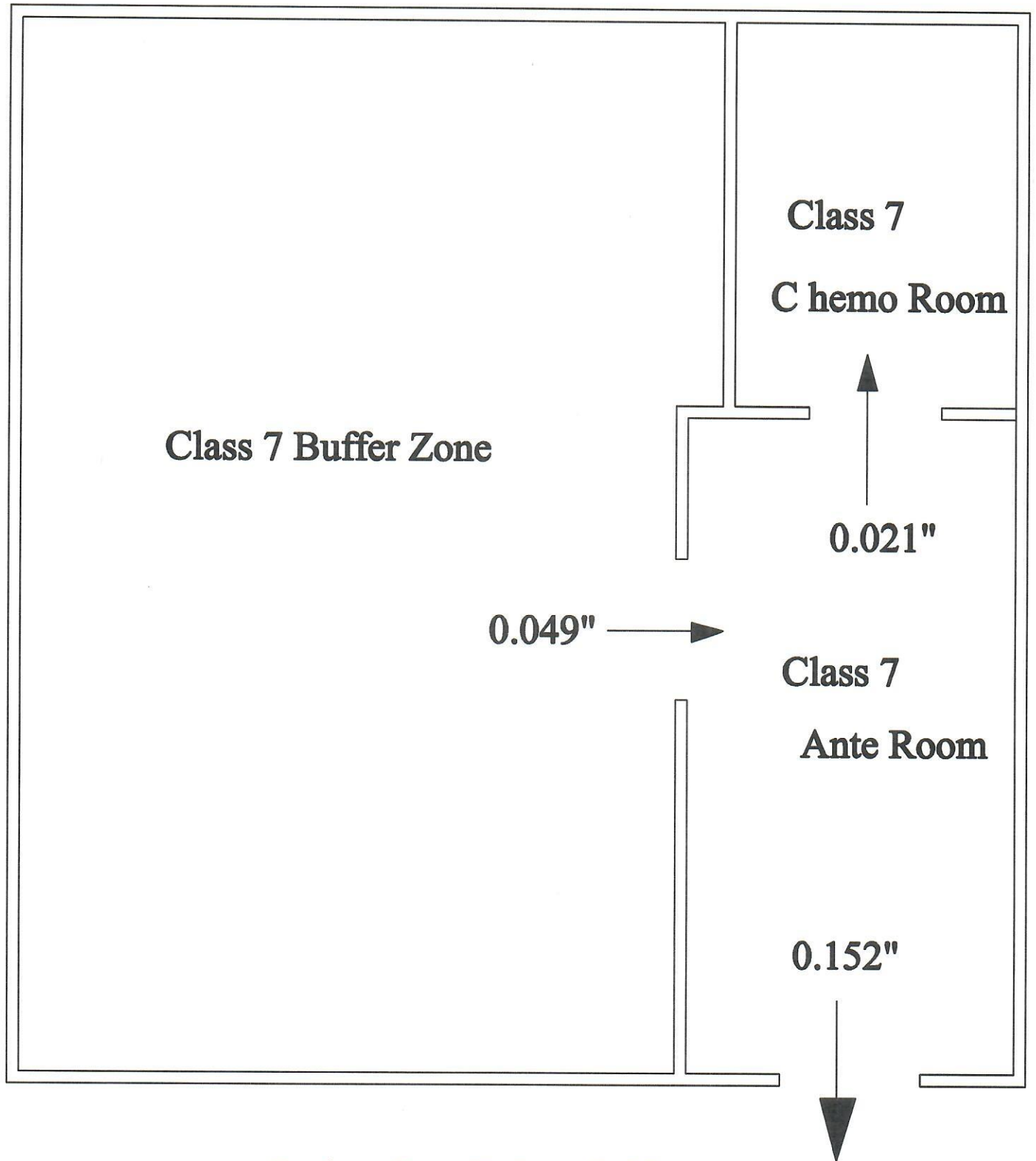
= TSA Media Sample
= MEA Media Sample



**Option Care Bakersfield
HEPA Filter Locations**



Option Care Bakersfield
Particle Count Locations



Option Care Bakersfield

Pressure Gradients