



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

PERFORMANCE CERTIFICATION

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



Test Date:

September 2, 2022

CERTIFICATION PROCEDURES

CLEANROOMS/CLEAN ZONES

Particle Count

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

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

Test Instruments:

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

Air Flow

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

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M15523; Calibrated 6/8/22

Pressure Differential

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

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M15523; Calibrated 6/8/22

HEPA Filter Integrity Test

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

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

Test Instruments:

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

Laminar Flow Benches

Particle Count

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

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

Test Instruments:

Laser Particle Counter – Climet model 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 8/24/22

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 8/24/22

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:

9/2/22

Airflow Smoke Pattern Test

Option Care – Bakersfield

September 2, 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: 9/2/22
Arne Gjertsen

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

Cleanroom Performance Test Report

| | | | |
|-----------|-------------------------|--------------|----------------|
| Customer: | Option Care Bakersfield | Dimensions: | 98 square feet |
| Date: | 9/2/2022 | 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 | 1,942.3 Particle/M ³ |
| | | 2 | 1,447.9 Particle/M ³ |
| | | 3 | 4,308.4 Particle/M ³ |
| | | 4 | 2,542.7 Particle/M ³ |
| | | 5 | 529.7 Particle/M ³ |

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

Air Flow

| | | | | | | | |
|--------------|-------------|--------|--------|--------|----------|----------|-----|
| | | Filter | Read 1 | Read 2 | Avg. FPM | Sq. Feet | CFM |
| Air Change: | | 1 | 74 | 91 | 82.5 | 7.25 | 598 |
| Recommended= | 30.0 /hour | | | | | | |
| Actual= | 40.7 /hour | | | | | | |
| Pass/Fail | Pass | | | | | | |

Total CFM = 598

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% | No | Pass | None |

Signature: _____

Date: 9/2/22

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: | 314 square feet |
| Date: | 9/2/2022 | 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 | 812.2 Particle/M ³ |
| | | 2 | 847.6 Particle/M ³ |
| | | 3 | 459.1 Particle/M ³ |
| | | 4 | 1,553.8 Particle/M ³ |
| | | 5 | 529.7 Particle/M ³ |
| | | 6 | 1,624.5 Particle/M ³ |
| | | 7 | 20,659.1 Particle/M ³ |
| | | 8 | 1,165.4 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 | 90 | 92 | 91.0 | 7.25 | 660 |
| Recommended= | 30.0 /hour | 2 | 112 | 104 | 108.0 | 7.25 | 783 |
| Actual= | 45.3 /hour | 3 | 99 | 91 | 95.0 | 7.25 | 689 |

| | |
|-----------|-------------|
| Pass/Fail | Pass |
|-----------|-------------|

Total CFM = 2,132

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 | No |
| 2 | 26 | <0.01% | No | Pass | No |
| 3 | 29 | <0.01% | No | Pass | No |

Signature: _____



Date: _____

9/2/22

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: 9/2/2022 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 | 2,366.1 Particle/M ³ |
| 2 | 1,236.0 Particle/M ³ |
| 3 | 600.3 Particle/M ³ |
| 4 | 1,730.4 Particle/M ³ |
| 5 | 706.3 Particle/M ³ |

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

Air Flow

| Air Change: | Filter | Read 1 | Avg. FPM | Sq. Feet | CFM |
|-------------------------|--------|--------|----------|----------|-----|
| Recommended= 30.0 /hour | 1 | 70 | 70.0 | 3.25 | 228 |
| Actual= 31.0 /hour | | | | | |

Pass/Fail **Pass**

Total CFM = 228

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

| Filter# | Int. Ref. | Leak | Repaired | Pass/Fail | Prev. patch |
|---------|-----------|--------|----------|-----------|-------------|
| 1 | 89 | <0.01% | No | Pass | No |

Signature: 

Date: 9/2/22

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: 9/2/2022
 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 | 35.3 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- | 55 | 9- | 60 |
| | 2- | 56 | 6- | 58 | 10- | 60 |
| Avg. Velocity = | 3- | 58 | 7- | 60 | 11- | 62 |
| | 4- | 56 | 8- | 62 | 12- | 60 |

Pass/Fail : **Pass**

Inflow Velocity - Restricted Sash Method

| | | | | | |
|--------------|-----|----|-----|----|-----|
| Average FPM= | 279 | 1- | 290 | 5- | 266 |
| | | 2- | 296 | 6- | 279 |
| | | 3- | 260 | 7- | 284 |
| | | 4- | 279 | 8- | 278 |

Intake Velocity @ 8"sash= (279 fpm x 0.97 / 2.58) = 104.9 FPM

Required Intake Velocity- 100-120

Filter Integrity Test

Exhaust HEPA:

Int. Ref. 50
Pass/Fail : **Pass**

No scanned leaks greater than 0.01%

Supply HEPA: Combined with Exhaust Calc's

Int. Ref. 44
Pass/Fail : **Pass**

No scanned leaks greater than 0.01%

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

Signature:



Date:

9/2/22

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: 9/2/2022
 Manufacturer: Nuair #3

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

Particle Count

| Locations required: | 5 | Location | Readings: |
|-----------------------------|--|----------|------------------------------|
| Particle Size | >0.5 | 1 | 35.3 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- Pass/Fail | 3,520 Particle/M ³ Pass | | |

Air Flow

Requirement: 80-100 FPM

| Avg. Velocity = | 92.7 | FPM Readings: | | | | | |
|-------------------------------|-------------|---------------|-----|-----|-----|-----|-----|
| Pass/Fail : | Pass | 1- | 85 | 6- | 95 | 11- | 101 |
| | | 2- | 82 | 7- | 100 | 12- | 88 |
| | | 3- | 84 | 8- | 94 | 13- | 101 |
| Measured Values: Avg. +/- 20% | | 4- | 86 | 9- | 83 | 14- | 96 |
| Min. value = | 74.2 | 5- | 100 | 10- | 98 | 15- | 98 |
| Max. value = | 111.3 | | | | | | |
| 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: _____

9/2/22

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 | Model # | NU-301-630 |
| Date: | 9/2/2022 | Serial # | 131658070709 |
| Manufacturer: | Nuaire #1 | 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 = | 91.0 | FPM Readings: | | | | | |
| Pass/Fail : | Pass | 1- | 87 | 6- | 99 | 11- | 102 |
| | | 2- | 94 | 7- | 83 | 12- | 98 |
| | | 3- | 83 | 8- | 99 | 13- | 93 |
| Measured Values: Avg. +/- 20% | | 4- | 84 | 9- | 89 | 14- | 92 |
| Min. value = | 72.8 | 5- | 84 | 10- | 86 | 15- | 92 |
| Max. value = | 109.2 | | | | | | |
| 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: _____

9/2/22

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 | Model # | S201-830 |
| Date: | 9/2/2022 | Serial # | 168186042115 |
| Manufacturer: | Nuaire | 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 = | 92.0 | FPM Readings: | | | | | |
| Pass/Fail : | Pass | 1- | 89 | 9- | 92 | 17- | 91 |
| | | 2- | 89 | 10- | 94 | 18- | 97 |
| | | 3- | 90 | 11- | 87 | 19- | 97 |
| Measured Values: Avg. +/- 20% | | 4- | 86 | 12- | 95 | 20- | 96 |
| Min. value = | 73.6 | 5- | 89 | 13- | 100 | 21- | 96 |
| Max. value = | 110.4 | 6- | 92 | 14- | 102 | 22- | 83 |
| Pass/Fail : | Pass | 7- | 84 | 15- | 91 | 23- | 84 |
| | | 8- | 88 | 16- | 94 | 24- | 102 |

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: _____

9/2/22

See Test Summary Sheet for instrument data.

Viability Air and Surface Sampling

Option Care - Bakersfield

Viability 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 September 2, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab Reports #22036095. All of the tests were within the allowable CFU and passed except air sample locations #44, #46, #48 & #50.

Those sample locations were retested on September 12, 2022 and air sample locations #44(1) & #46(3) failed again as per Lab Report 2237147. Those locations were retested on September 23, 2022 and both locations failed as per Lab Report 22039280.

Option Care is removing the solid state refrigerator from the room and CRP will then re-certify the NPR room and Ante room and retest the Viability Sampling

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

Manufacturer – Hardy Diagnostics:

Air Sample Media

Tryptic Soy: Lot #511172P, Exp. 11/1/22; MEA: Lot #506696P, Exp. 10/6/22

Surface Sample Media

Tryptic Soy: Lot #11729P, Exp. 11/10/22; MEA: Lot #510706, Exp. 10/25/22

Signature: _____

Arne Gjertsen

Date: _____

9/28/22

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







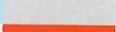
Date Collected: 9/2/2022
 Date Received: 9/2/2022
 Date Analyzed: 9/7/2022
 Date Reported: 9/8/2022
 Project ID: 22036095
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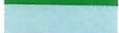

AeroMetric 797™ Results Summary Sheet

| Sample Location | Class | Matrix | Pass | Acpt | O.O.C. | Cause |
|------------------------------|-------|--------|------|------|--------|-------|
| 1: Class 5 LFB | 5 | S | | | | |
| 2: Class 5 LFB | 5 | S | | | | |
| 3: Class 5 LFB | 5 | S | | | | |
| 4: Class 5 LFB | 5 | S | | | | |
| 5: Class 5 LFB | 5 | S | | | | |
| 6: Class 5 LFB | 5 | S | | | | |
| 7: Class 5 LFB | 5 | S | | | | |
| 8: Class 5 LFB | 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 Zone | 7 | S | | | | |
| 16: Class 7 Buffer Zone | 7 | S | | | | |
| 17: Class 7 NPR | 7 | S | | | | |
| 18: Class 7 NPR | 7 | S | | | | |
| 19: Class 7 Ante Room | 7 | S | | | | |
| 20: Class 7 Ante Room | 7 | S | | | | |
| 21: Class 7 Ante Room | 7 | S | | | | |
| 22: Class 7 Ante Room | 7 | S | | | | |
| 23: Class 5 LFB Touchscreen | 5 | S | | | | |
| 24: Class 5 LFB Touchscreen | 5 | S | | | | |
| 25: Class 5 LFB Touchscreen | 5 | S | | | | |
| 26: Class 5 LFB Touchscreen | 5 | S | | | | |
| 27: Class 5 LFB Touchscreen | 5 | S | | | | |
| 28: Class 5 LFB Touchscreen | 5 | S | | | | |
| 29: Class 7 NPR Refrigerator | 7 | S | | | | |
| 30: Class 7 NPR Refrigerator | 7 | S | | | | |
| 31: Class 5 LFB | 5 | A | | | | |
| 32: Class 5 LFB | 5 | A | | | | |
| 33: Class 5 LFB | 5 | A | | | | |
| 34: Class 5 LFB | 5 | A | | | | |
| 35: Class 5 LFB | 5 | A | | | | |
| 36: Class 5 LFB | 5 | A | | | | |
| 37: Class 5 LFB | 5 | A | | | | |
| 38: Class 5 LFB | 5 | A | | | | |
| 39: Class 5 BSC | 5 | A | | | | |
| 40: Class 5 BSC | 5 | A | | | | |
| 41: Class 7 Buffer Zn | 7 | A | | | | |
| 42: Class 7 Buffer Zn | 7 | A | | | | |
| 43: Class 7 Buffer Zone | 7 | A | | | | |

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

Date Collected: 9/2/2022
 Date Received: 9/2/2022
 Date Analyzed: 9/7/2022
 Date Reported: 9/8/2022
 Project ID: 22036095
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| | | | | |
|---|----|---|--|---------------------------------------|
| 44: Class 7 Buffer Zone | 7 | A |  | Presence of actionable microorganisms |
| 45: Class 7 Buffer NPR | 7 | A |  | |
| 46: Class 7 Buffer NPR | 7 | A |  | Presence of actionable microorganisms |
| 47: Class 7 Ante Room | 7 | A |  | |
| 48: Class 7 Ante Room | 7 | A |  | Presence of actionable microorganisms |
| 49: Class 7 Ante Room | 7 | A |  | |
| 50: Class 7 Ante Room | 7 | A |  | Presence of actionable microorganisms |
| 51: Control / Operator Handling Lot#511172P, Exp: 11-1-22 | NA | A | | |
| 52: Control Lot#509696P, Exp: 10-6-22 | NA | A | | |
| 53: Control Lot#511729P, Exp: 11-10-22 | NA | S | | |
| 54: Control Lot#510706, Exp: 10-25-22 | 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 Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 9/2/2022
Date Received: 9/2/2022
Date Analyzed: 9/7/2022
Date Reported: 9/8/2022
Project ID: 22036095
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Client Sample #: 1
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 #: 22036095-001
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 2
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 #: 22036095-002
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 3
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 #: 22036095-003
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 4
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 #: 22036095-004
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 5
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 #: 22036095-005
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 6
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 #: 22036095-006
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 7
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 #: 22036095-007
Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Client Sample #: 8
Sample Location: Class 5 LFB

Lab Sample #: 22036095-008

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 #: 9
Sample Location: Class 5 BSC

Lab Sample #: 22036095-009

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

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 10
Sample Location: Class 5 BSC

Lab Sample #: 22036095-010

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 #: 11
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22036095-011

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

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 12
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22036095-012

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 #: 13
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22036095-013

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

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 14
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22036095-014

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

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Client Sample #: 15
 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 #: 22036095-015
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 16
 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 #: 22036095-016
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 17
 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 #: 22036095-017
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 18
 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 #: 22036095-018
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 19
 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 #: 22036095-019
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 20
 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 #: 22036095-020
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

Client Sample #: 21
 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 #: 22036095-021
 Area: **25 cm2**
 MRL: **1 CFU/25cm2**

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Client Sample #: 22
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 #: 22036095-022
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 #: 22036095-023
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 #: 22036095-024
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 25
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 #: 22036095-025
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 26
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 #: 22036095-026
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 27
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 #: 22036095-027
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 28
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 #: 22036095-028
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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Client Sample #: 29
 Sample Location: Class 7 NPR Refrigerator
 Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22036095-029

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

Client Sample #: 30
 Sample Location: Class 7 NPR Refrigerator
 Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22036095-030

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

Client Sample #: 31
 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 #: 22036095-031

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

Client Sample #: 32
 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 #: 22036095-032

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

Client Sample #: 33
 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 #: 22036095-033

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

Client Sample #: 34
 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 #: 22036095-034

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

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Client Sample #: 35
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 #: 22036095-035
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 36
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 #: 22036095-036
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 37
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 #: 22036095-037
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 38
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 #: 22036095-038
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 39
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 #: 22036095-039
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 40
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 #: 22036095-040
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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

Lab Sample #: 22036095-041
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 42
 Sample Location: Class 7 Buffer Zn
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Results: **No Growth**
 Comments: **Pass**

Lab Sample #: 22036095-042
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 43
 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 #: 22036095-043
 Air Volume: **1000 L**
 Positive Hole: **219**
 MRL: **1 CFU/m3**

Client Sample #: 44
 Sample Location: Class 7 Buffer Zone
 Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **1 CFU/m3**

Lab Sample #: 22036095-044
 Air Volume: **1000 L**
 Positive Hole: **219**

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|------------------------|-----------|--------|---------|----------|
| Aspergillus versicolor | 1 | 1 | 100 | 1 CFU/m3 |

Comments: **D.O.C** **1** **1** **~100%**

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Client Sample #: 45
 Sample Location: Class 7 Buffer NPR

Lab Sample #: 22036095-045

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **5 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | Reservoirs |
|--------------------------------------|-----------|--------|---------|--------------------|
| Bacillus species | 3 | 3 | 60 | Environment |
| Coag-negative Staphylococcus species | 1 | 1 | 20 | Human |
| Corynebacterium-like | 1 | 1 | 20 | Human, Environment |

5 **5** **~100%**

Comments: **Acceptable**

Client Sample #: 46
 Sample Location: Class 7 Buffer NPR

Lab Sample #: 22036095-046

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **2 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|------------------------|-----------|--------|---------|----------|
| Aspergillus versicolor | 1 | 1 | 50 | 1 CFU/m3 |
| Penicillium species | 1 | 1 | 50 | 1 CFU/m3 |

2 **2** **~100%**

Comments: **O.O.C**

Client Sample #: 47
 Sample Location: Class 7 Ante Room

Lab Sample #: 22036095-047

Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **3 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | Reservoirs |
|-----------------------|-----------|--------|---------|------------|
| Micrococcus species | 3 | 3 | 100 | Human |

3 **3** **~100%**

Comments: **Acceptable**

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Client Sample #: 48
 Sample Location: Class 7 Ante Room

Lab Sample #: 22036095-048

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **2 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|------------------------|-----------|--------|---------|----------|
| Non-sporulating colony | 1 | 1 | 50 | 1 CFU/m3 |
| Verticillium species | 1 | 1 | 50 | 1 CFU/m3 |

Comments: **O.O.C.** **2** **2** **~100%**

Client Sample #: 49
 Sample Location: Class 7 Ante Room

Lab Sample #: 22036095-049

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

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | Reservoirs |
|--------------------------------------|-----------|--------|---------|-------------|
| Bacillus species | 3 | 3 | 75 | Environment |
| Coag-negative Staphylococcus species | 1 | 1 | 25 | Human |

Comments: **Acceptable** **4** **4** **~100%**

Client Sample #: 50
 Sample Location: Class 7 Ante Room

Lab Sample #: 22036095-050

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

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|-----------------------|-----------|--------|---------|----------|
| Aspergillus sydowii | 1 | 1 | 100 | 1 CFU/m3 |

Comments: **O.O.C.** **1** **1** **~100%**

Client Sample #: 51
 Sample Location: Control / Operator Handling Lot#511172P, Exp: 11-1-22

Lab Sample #: 22036095-051

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

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Client Sample #: 52
Sample Location: Control Lot#509696P, Exp: 10-6-22
Test: 1157 FUNGAL AIR - Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22036095-052

Client Sample #: 53
Sample Location: Control Lot#511729P, Exp: 11-10-22
Test: 1158 BACTERIAL SURFACE - Negative (-) Control: 2.2
Results: **No Growth**

Lab Sample #: 22036095-053

Client Sample #: 54
Sample Location: Control Lot#510706, Exp: 10-25-22
Test: 1159 FUNGAL SURFACE - Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22036095-054

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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 S. Blevins
Suzanne Blevins
Laboratory Director

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Condition of Sample(s) Upon Receipt: Acceptable

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GLOSSARY

Aspergillus sydowii: Aspergillus is one of the most common fungi worldwide, occurring on a large number of substrates. A. sydowii is a common soil fungus but has been isolated from a wide variety of indoor and outdoor surfaces. This species can be an opportunistic pathogen to humans.

Aspergillus versicolor: Aspergillus is one of the most common fungi worldwide, occurring on a large number of substrates. A. versicolor is commonly found in soil, many kinds of dry food products, and a variety of indoor environmental sources. This organism is a common cause of the old musty odor in damp, warm indoor environments. This species produces the mycotoxin Sterigmatocystin, produces allergy-like symptoms in people, and is considered an opportunistic pathogen to humans.

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

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.

Corynebacterium-like: The majority of bacteria in this group are irregularly shaped, non spore-forming, gram-positive rods. Many species are part of the normal microbiota of the skin and mucous membranes of mammals. Some species are found in the environment. Some corynebacterium cause infection, particularly Corynebacterium diphtheriae.

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.

Non-sporulating colony: For microscopic identification of fungi, spores and/or spore-bearing structures need to be present. This colony has not sporulated, therefore the analyst cannot make a proper identification. There are a variety of reasons colonies do not produce spores, including plate overcrowding and nutrient-rich media.

Penicillium species: Penicillium is one of the most common fungi worldwide, occurring on a very large number of substrates. There are about 250 species, some of which can grow at low temperatures. They produce unicellular, usually globose, hydrophobic spores, in unbranched chains on distinctive broom-shaped structures. The spores are usually green-blue, greenish or grey green in mass. Some species may cause infections of humans, particularly in immunocompromised patients. Some species produce mycotoxins, and some may be allergenic. The spores, when present without the diagnostic structures that produce them, are impossible to differentiate visually from those of Aspergillus.




Verticillium species: Verticillium is a fungus known as a mold. It occurs worldwide on decaying vegetation and soil. Some species may be pathogenic to arthropods, plants, and other fungi. It produces tiny, microscopic, colorless, slimy spores in droplets at the end of specialized cells. These spores are not commonly found in buildings, and would be almost impossible to identify unless cultured. It may occasionally cause skin irritation (keratitis) in humans, but is not notably allergenic, pathogenic (except to plants), or toxigenic.

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

Date Collected: 9/12/2022
 Date Received: 9/12/2022
 Date Analyzed: 9/19/2022
 Date Reported: 9/20/2022
 Project ID: 22037147
 Page 1 of 4

AeroMetric 797™ Results Summary Sheet

| Sample Location | Class | Matrix | Pass | Acpt | O.O.C. | Cause |
|--|-------|--------|------|------|--------|-------|
| 1: Class 7 Ante Rm | 7 | A | | | | |
| 2: Class 7 Ante Rm | 7 | A | | | | |
| 3: Class 7 NPR | 7 | A | | | | |
| 4: Class 7 Buffer Zone | 7 | A | | | | |
| 5: Control / OP. Handling , #Lot: 509696P, Exp Date : 10/06/22 | NA | A | | | | |

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

Matrix* - A: Air S: Surface

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

Date Collected: 9/12/2022
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 Date Analyzed: 9/19/2022
 Date Reported: 9/20/2022
 Project ID: 22037147
 Page 2 of 4

Client Sample #: 1
 Sample Location: Class 7 Ante Rm

Lab Sample #: 22037147-001

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

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|-----------------------|-----------|--------|---------|----------|
| Penicillium species | 1 | 1 | 100 | 1 CFU/m3 |
| | 1 | 1 | ~100% | |

Comments: **O.O.C**

Client Sample #: 2
 Sample Location: Class 7 Ante Rm

Lab Sample #: 22037147-002

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 7 NPR

Lab Sample #: 22037147-003

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **2 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|-----------------------|-----------|--------|---------|----------|
| Penicillium species | 2 | 2 | 100 | 1 CFU/m3 |
| | 2 | 2 | ~100% | |

Comments: **O.O.C**

Client Sample #: 4
 Sample Location: Class 7 Buffer Zone

Lab Sample #: 22037147-004

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

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

Comments: **Pass**

Client Sample #: 5
 Sample Location: Control / OP. Handling , #Lot: 509696P, Exp Date : 10/06/22

Lab Sample #: 22037147-005

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

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

Date Collected: 9/12/2022
Date Received: 9/12/2022
Date Analyzed: 9/19/2022
Date Reported: 9/20/2022
Project ID: 22037147

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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 |

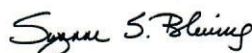
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Source PIC/S, 2007

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

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

Date Collected: 9/12/2022
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Project ID: 22037147

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GLOSSARY






Penicillium species: Penicillium is one of the most common fungi worldwide, occurring on a very large number of substrates. There are about 250 species, some of which can grow at low temperatures. They produce unicellular, usually globose, hydrophobic spores, in unbranched chains on distinctive broom-shaped structures. The spores are usually green-blue, greenish or grey green in mass. Some species may cause infections of humans, particularly in immunocompromised patients. Some species produce mycotoxins, and some may be allergenic. The spores, when present without the diagnostic structures that produce them, are impossible to differentiate visually from those of Aspergillus.

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

Date Collected: 9/23/2022
 Date Received: 9/23/2022
 Date Analyzed: 9/28/2022
 Date Reported: 9/28/2022
 Project ID: 22039280
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AeroMetric 797™ Results Summary Sheet

| Sample Location | Class | Matrix | Pass | Acpt | O.O.C. | Cause |
|---------------------------|-------|--------|------|------|--------|---------------------------------------|
| 1: Class 7 Ante Rm | 7 | A | | | | |
| 2: Class 7 NPR | 7 | A | | | | Presence of actionable microorganisms |
| 3: Control / Op Handling | NA | A | | | | Presence of actionable microorganisms |
| Lot#509696P, Exp: 10-6-22 | | | | | | |

-  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 Bakersfield**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 9/23/2022
Date Received: 9/23/2022
Date Analyzed: 9/28/2022
Date Reported: 9/28/2022
Project ID: 22039280
Page 2 of 4

Client Sample #: 1
Sample Location: Class 7 Ante Rm

Lab Sample #: 22039280-001

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

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|-----------------------|-----------|--------|---------|----------|
| Penicillium species | 1 | 1 | 100 | 1 CFU/m3 |

Comments: **O.O.C** 1 1 ~100%

Client Sample #: 2
Sample Location: Class 7 NPR

Lab Sample #: 22039280-002

Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **10 CFU/m3**

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

| Organism(s) Isolated: | Raw Count | CFU/m3 | % Total | MRL |
|------------------------|-----------|--------|---------|----------|
| Aspergillus versicolor | 1 | 1 | 10 | 1 CFU/m3 |
| Penicillium species | 9 | 9 | 90 | 1 CFU/m3 |

Comments: **O.O.C** 10 10 ~100%

Client Sample #: 3
Sample Location: Control / Op Handling Lot#509696P, Exp: 10-6-22

Lab Sample #: 22039280-003

Test: 1157 FUNGAL AIR - Negative (-) Control: SOP 3.2
Results: **Growth**

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

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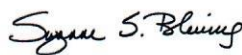
USP 797 Class and Action Levels

| 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 |

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Source PIC/S, 2007

Footnotes and Additional Report Information

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Suzanne Blevins
Laboratory Director

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

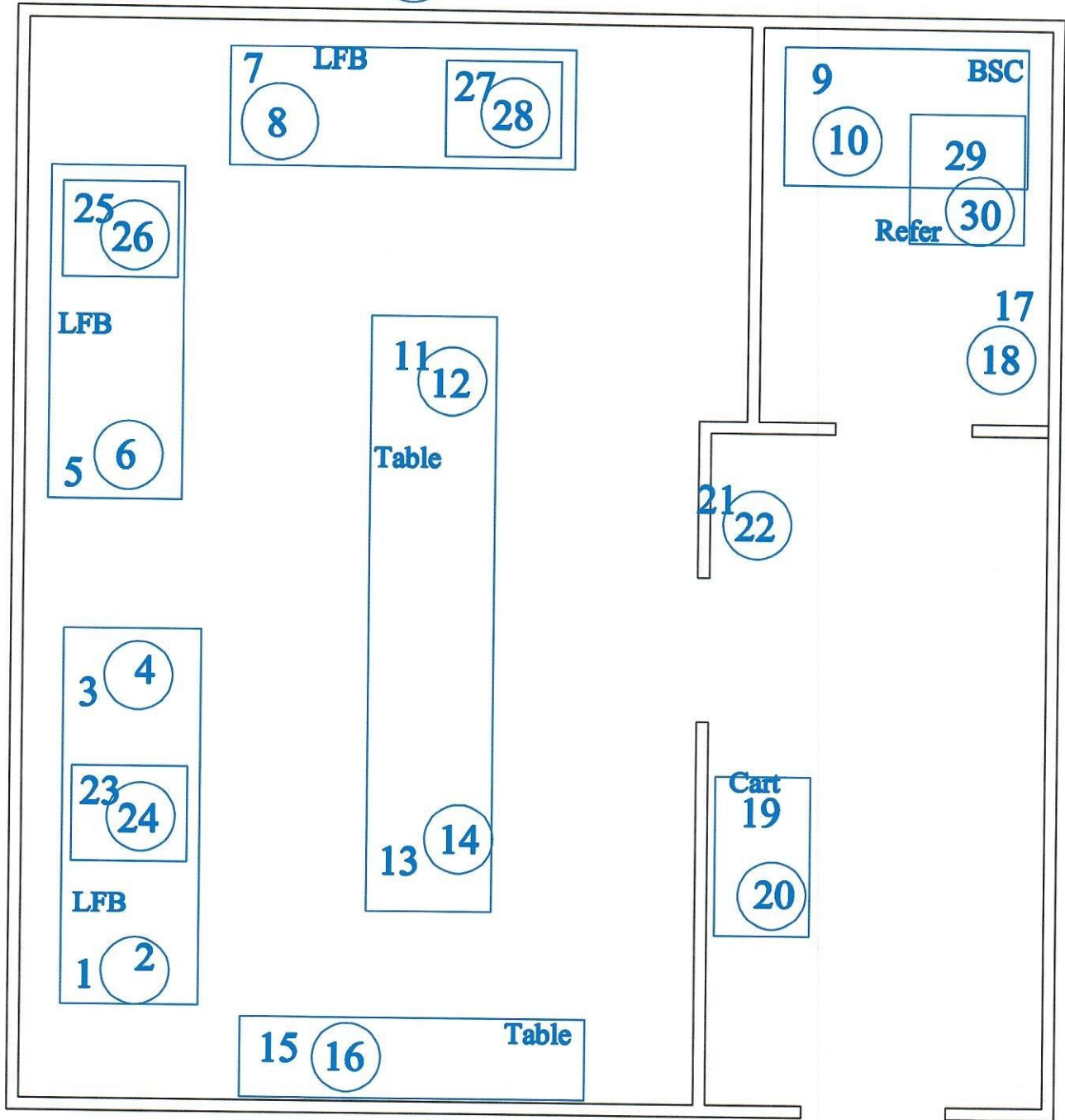
Date Collected: 9/23/2022
Date Received: 9/23/2022
Date Analyzed: 9/28/2022
Date Reported: 9/28/2022
Project ID: 22039280
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GLOSSARY

Aspergillus versicolor: Aspergillus is one of the most common fungi worldwide, occurring on a large number of substrates. A. versicolor is commonly found in soil, many kinds of dry food products, and a variety of indoor environmental sources. This organism is a common cause of the old musty odor in damp, warm indoor environments. This species produces the mycotoxin Sterigmatocystin, produces allergy-like symptoms in people, and is considered an opportunistic pathogen to humans.

Penicillium species: Penicillium is one of the most common fungi worldwide, occurring on a very large number of substrates. There are about 250 species, some of which can grow at low temperatures. They produce unicellular, usually globose, hydrophobic spores, in unbranched chains on distinctive broom-shaped structures. The spores are usually green-blue, greenish or grey green in mass. Some species may cause infections of humans, particularly in immunocompromised patients. Some species produce mycotoxins, and some may be allergenic. The spores, when present without the diagnostic structures that produce them, are impossible to differentiate visually from those of Aspergillus.

53 = Control
54 = Control



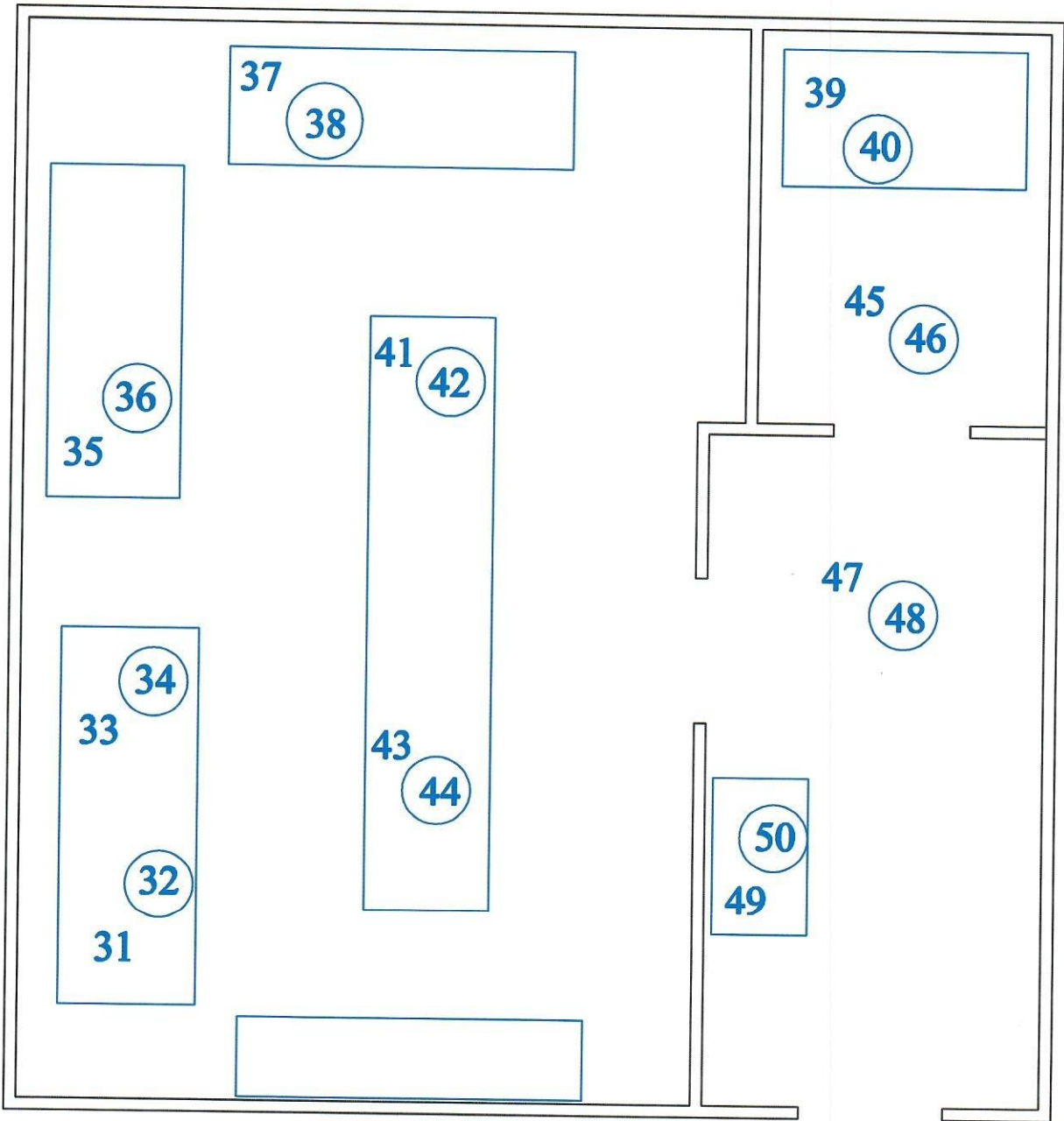
Option Care Bakersfield Surface Sample Locations

= TSA Media Sample

= MEA Media Sample

51 - Control/ Operator Handling

52 - Control

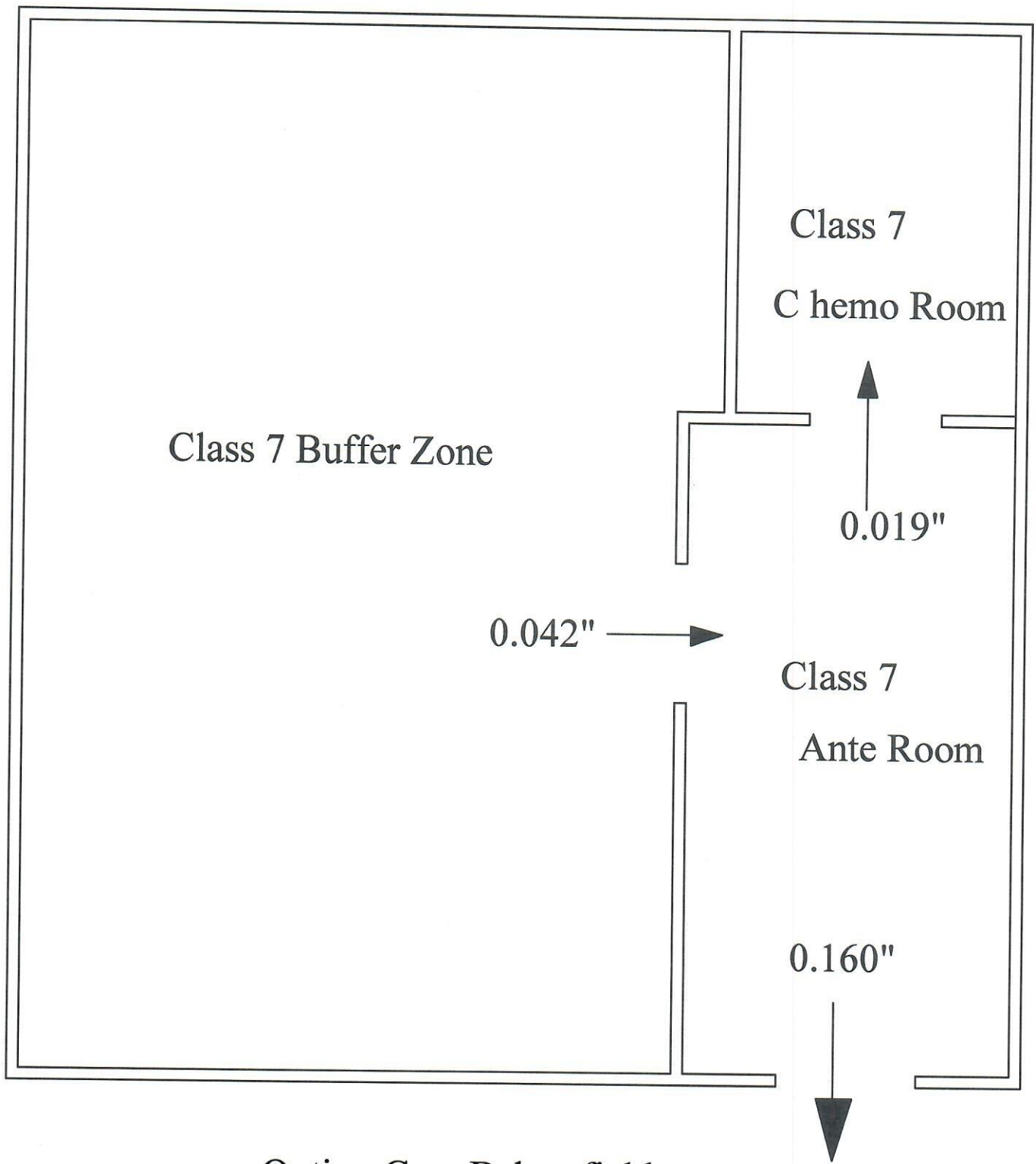


Option Care Bakersfield

Viable Air Sample Locations

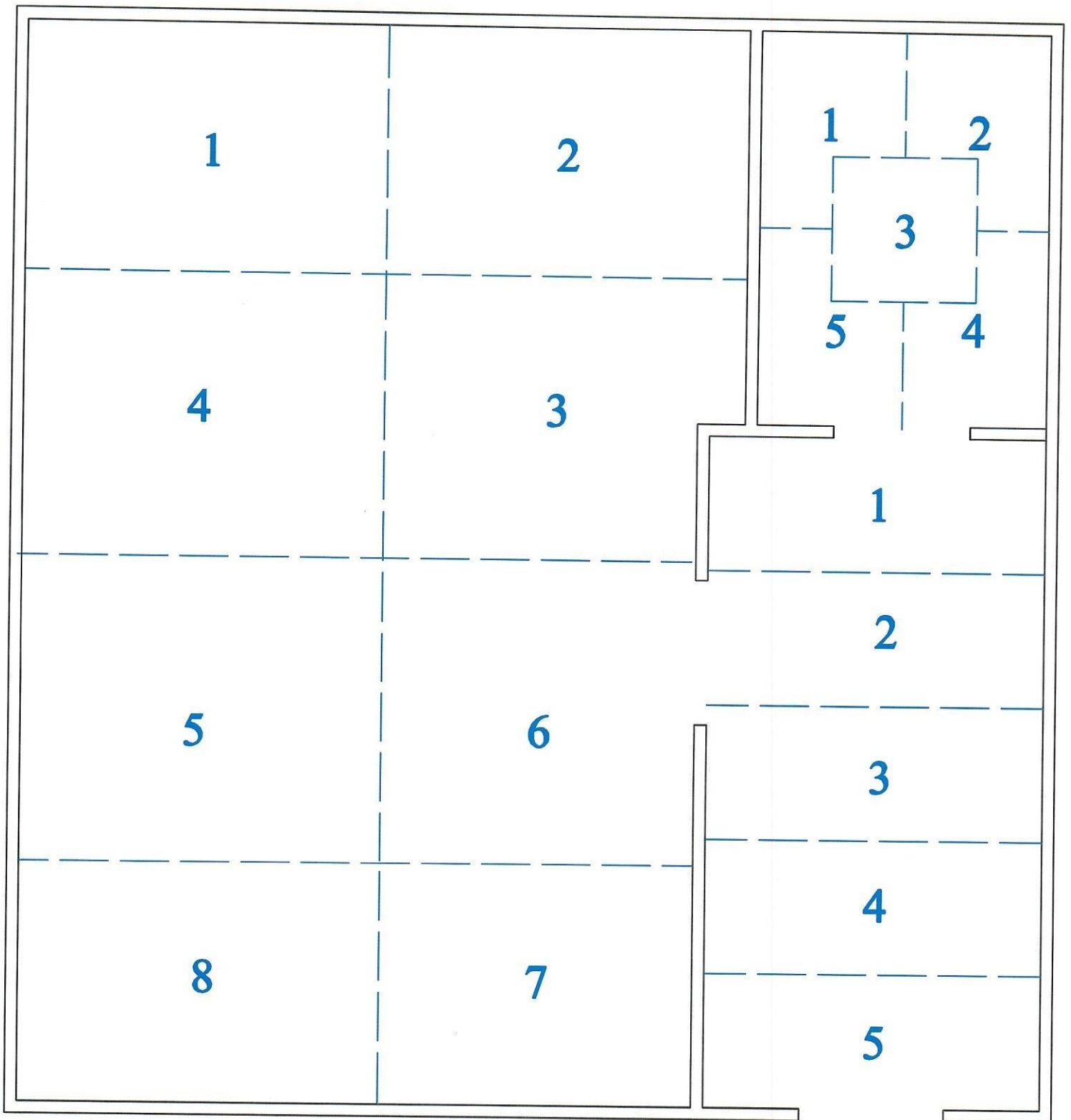
= TSA Media Sample

Ⓝ = MEA Media Sample

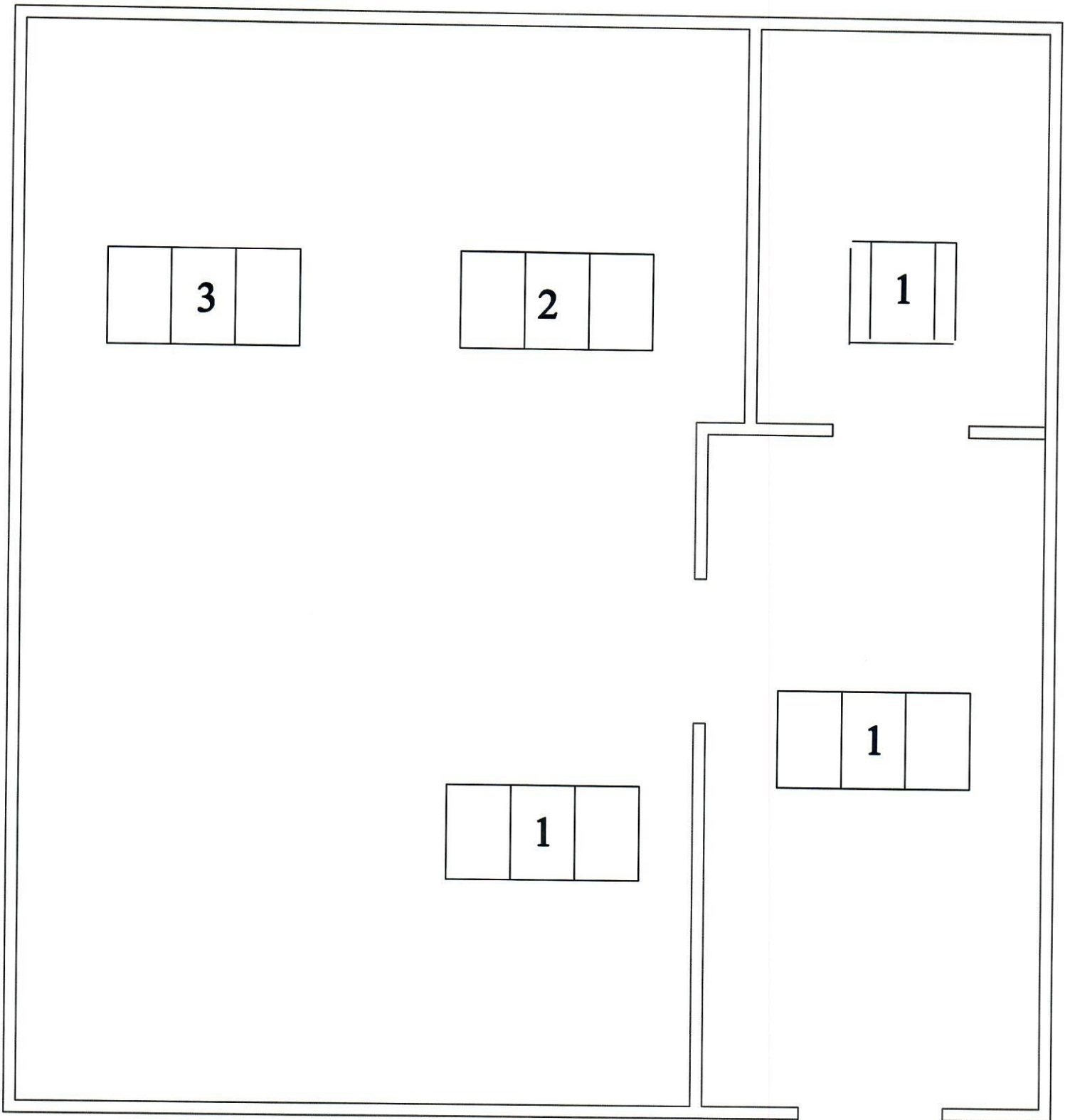


Option Care Bakersfield

Pressure Gradients



Option Care Bakersfield
Particle Count Locations



**Option Care Bakersfield
HEPA Filter Locations**