



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

PERFORMANCE CERTIFICATION

FOR
Crescent -Acute Care
11980 Telegraph Road
Suite 100
Santa Fe Springs, CA 90670



Test Date:

June 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 #M13678; Calibrated 9/9/21

Pressure Differential

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

Test Instruments:

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

HEPA Filter Integrity Test

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

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

Test Instruments:

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

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: _____

6/9/22

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

Cleanroom Performance Test Report

| | | | |
|-----------|-----------------------|--------------|-----------------|
| Customer: | Crescent SFS Acute | Dimensions: | 220 square feet |
| Date: | 6/9/2022 | Volume: | 1760 cubic feet |
| Room ID: | Class 5 Work Stations | Test Status: | Dynamic |
| Class: | 5 | | |

Particle Count

| | | Location | Readings: |
|---------------------|-------------------------------|----------|-----------------------------|
| Locations required: | 15 | 1 | 0.0 Particle/M ³ |
| Particle Size | >0.5 micron | 2 | 0.0 Particle/M ³ |
| | | 3 | 0.0 Particle/M ³ |
| | | 4 | 0.0 Particle/M ³ |
| | | 5 | 0.0 Particle/M ³ |
| | | 6 | 0.0 Particle/M ³ |
| | | 7 | 0.0 Particle/M ³ |
| | | 8 | 0.0 Particle/M ³ |
| | | 9 | 0.0 Particle/M ³ |
| Maximum count- | 3,520 Particle/M ³ | 10 | 0.0 Particle/M ³ |
| | | 11 | 0.0 Particle/M ³ |
| Pass/Fail | Pass | 12 | 0.0 Particle/M ³ |
| | | 13 | 0.0 Particle/M ³ |
| | | 14 | 0.0 Particle/M ³ |
| | | 15 | 0.0 Particle/M ³ |

Air Flow

| | Filter | Read 1 | Read 2 | Avg. FPM | Sq. Feet | CFM |
|------------------------------|--------|--------|--------|----------|----------|-----|
| Requirement: 72-108 FPM | 1 | 75 | 83 | 79.0 | 7.25 | 573 |
| | 2 | 103 | 92 | 97.5 | 7.25 | 707 |
| Avg. Velocity = 89 | 3 | 77 | 80 | 78.5 | 7.25 | 569 |
| Pass/Fail : Pass | 4 | 79 | 76 | 77.5 | 7.25 | 562 |
| | 5 | 84 | 91 | 87.5 | 7.25 | 634 |
| Measured Values Avg. +/- 20% | 6 | 93 | 91 | 92.0 | 7.25 | 667 |
| Min. value = 71.1 | 7 | 98 | 97 | 97.5 | 7.25 | 707 |
| Max. value = 106.7 | 8 | 87 | 87 | 87.0 | 7.25 | 631 |
| Pass/Fail : Pass | 9 | 94 | 90 | 92.0 | 7.25 | 667 |
| | 10 | 101 | 89 | 95.0 | 7.25 | 689 |
| | 11 | 83 | 74 | 78.5 | 7.25 | 569 |
| | 12 | 97 | 101 | 99.0 | 7.25 | 718 |
| | 13 | 84 | 105 | 94.5 | 7.25 | 685 |

Total CFM = 8,377

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

| Filter# | Int. Ref. | Leak | Repaired | Pass/Fail | Prev. patch |
|---------|-----------|--------|----------|-----------|-------------|
| 1 | 35 | <0.01% | N/R | Pass | None |
| 2 | 29 | <0.01% | N/R | Pass | None |
| 3 | 36 | <0.01% | N/R | Pass | None |
| 4 | 36 | <0.01% | N/R | Pass | None |
| 5 | 32 | <0.01% | N/R | Pass | Yes |
| 6 | 30 | <0.01% | N/R | Pass | Yes |
| 7 | 29 | <0.01% | N/R | Pass | None |
| 8 | 32 | <0.01% | N/R | Pass | Yes |
| 9 | 30 | <0.01% | N/R | Pass | Yes |
| 10 | 29 | <0.01% | N/R | Pass | None |
| 11 | 36 | <0.01% | N/R | Pass | Yes |
| 12 | 28 | <0.01% | N/R | Pass | Yes |
| 13 | 30 | <0.01% | N/R | Pass | None |

Signature:



Date:

6/9/22

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: | Crescent SFS Acute | Dimensions: | 305 square feet |
| Date: | 6/9/2022 | Volume: | 2440 cubic feet |
| Room ID: | Buffer Zone | Test Status: | Dynamic |
| Class: | 7 | | |

Particle Count

| | Location | Readings: |
|---------------------|---------------------------------|-----------------------------------|
| Locations required: | 8 | 1 1,447.9 Particle/M ³ |
| Particle Size | >0.5 | 2 882.9 Particle/M ³ |
| | | 3 2,436.7 Particle/M ³ |
| | | 4 1,165.4 Particle/M ³ |
| | | 5 282.5 Particle/M ³ |
| | | 6 1,130.1 Particle/M ³ |
| | | 7 1,836.4 Particle/M ³ |
| Maximum count- | 352,000 Particle/M ³ | 8 459.1 Particle/M ³ |

Pass/Fail **Pass**

Air Flow

| | | Filter | Read 1 | Read 2 | Avg. FPM | Sq. Feet | CFM |
|-------------|-------------|--------|--------|--------|----------|----------|-----|
| Air Change: | | 1 | 97 | 97 | 97.0 | 7.25 | 703 |
| Specified: | 30.0 / hour | 2 | 83 | 70 | 76.5 | 7.25 | 555 |
| Actual= | 65.2 / hour | 3 | 93 | 96 | 94.5 | 7.25 | 685 |
| | | 4 | 108 | 87 | 97.5 | 7.25 | 707 |

Pass/Fail **Pass**

Total CFM = **2,650**

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

| Filter# | Int. Ref. | Leak | Repaired | Pass/Fail |
|---------|-----------|--------|----------|-----------|
| 1 | 29 | <0.01% | N/R | Pass |
| 2 | 37 | <0.01% | N/R | Pass |
| 3 | 30 | <0.01% | N/R | Pass |
| 4 | 29 | <0.01% | N/R | Pass |

Signature: _____

Date: _____

6/9/22

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: | Crescent SFS Acute | Dimensions: | 168 square feet |
| Date: | 6/9/2022 | Volume: | 1344 cubic feet |
| Room ID: | Ante room | Test Status: | Dynamic |
| Class: | 7 | | |

Particle Count

| | | Location | Readings: |
|---------------------|--------------------------------|----------|--------------------------------|
| Locations required: | 6 | 1 | 4,379.0 ParticleM ³ |
| Particle Size | >0.5 | 2 | 2,330.8 ParticleM ³ |
| | | 3 | 1,553.8 ParticleM ³ |
| | | 4 | 2,048.3 ParticleM ³ |
| | | 5 | 3,708.0 ParticleM ³ |
| Maximum count- | 352,000 ParticleM ³ | 6 | 3,566.8 ParticleM ³ |
| Pass/Fail | Pass | | |

Air Flow

| | | Filter | Read 1 | Read 2 | Avg. FPM | Sq. Feet | CFM |
|--------------|------------|--------|--------|--------|----------|----------|-----|
| Air Change: | | 1 | 62 | 67 | 64.5 | 7.25 | 468 |
| Recommended= | 30.0 /hour | 2 | 92 | N/A | 92.0 | 3.2 | 294 |
| Actual= | 34.0 /hour | | | | | | |

Pass/Fail **Pass**

Total CFM = 762

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

| Filter# | Int. Ref. | Leak | Repaired | Pass/Fail |
|---------|-----------|--------|----------|-----------|
| 1 | 43 | <0.01% | N/R | Pass |
| 2 | 23 | <0.01% | N/R | Pass |

Signature: _____

Date: _____

6/9/22

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

Airflow Smoke Pattern Test

Crescent Santa Fe Springs Acute

June 9, 2022

Objective:

To perform airflow smoke pattern tests on the Class 5 Workstation 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" above the IV bar and 6" in front and back of the work table. The pattern should be uni-directional flowing down and then splitting to the front and back of the work table and not influenced by the operators process nor equipment.

Smoke shall be generated in each of the Workstation benches to assure no reflux back up onto the work surface.

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

A DegreeC handheld Smoke Generator shall be used.

Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- Good split of air at table was observed at each work station.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of work stations.
- Table #1 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #2 Smoke study validates 1 person compounding maintains unidirectional airflow

- Table #3 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #4 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #5 Smoke study validates 1 person compounding maintains unidirectional airflow
- Table #7 Smoke study validates 2 persons compounding maintains unidirectional airflow

Conclusion:

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: 6/9/22
Arne Gjertsen

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

Weight Scale – Calibration Report

Customer: Option Care Santa Fe Springs Acute

Calibration Date: 6/9/2022

Calibration Due Date: 6/9/2023

Model # Ohaus CS-2000-001 Scale Identification # 1

Test procedure:

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

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

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

Troemner weight set calibration date: 10/7/21

Weight certificate on file

Signature:  Date: 6/9/22

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

Weight Scale – Calibration Report

Customer: Option Care Santa Fe Springs Acute

Calibration Date: 6/9/2022

Calibration Due Date: 6/9/2023

Model # Ohaus CS-2000-001 Scale Identification # 2

Test procedure:

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

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

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

Troemner weight set calibration date : 10/7/21

Weight certificate on file

Signature:  Date: 6/9/22

Crescent Acute Care
Surface and Viable Air Sampling
June 9, 2022

Surface and Viable air sampling were performed in accordance with USP<797> in order to evaluate the airborne microorganisms in the controlled Class 5 Laminar Flow Workstations, the Class 7 Buffer Zone and the Class 8 Ante Room.

For Surface sampling- Tryptic Soy Agar and Malt Extract Agar were used for each location.

For Viable Air sampling-Tryptic Soy Agar and Malt Extract Agar were used for each location.

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

The test samples were taken on June 9, 2022 and delivered to Aerobiology Laboratory for analysis.

The results are attached, in Lab report # 22021915. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics

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

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

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

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

Signature: _____

Arne Gjertsen

Date: _____

6/14/22

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

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 1 of 14

AeroMetric 797™ Results Summary Sheet

| Sample Location | Class | Matrix | Pass | Acpt | O.O.C. | Cause |
|--|-------|--------|------|------|--------|-------|
| 1: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 2: Class 5 LAFW Touchscreen | 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 Touchscreen | 5 | S | | | | |
| 8: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 9: Class 5 LAFW | 5 | S | | | | |
| 10: Class 5 LAFW | 5 | S | | | | |
| 11: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 12: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 13: Class 5 LAFW | 5 | S | | | | |
| 14: Class 5 LAFW | 5 | S | | | | |
| 15: Class 7 Buffer Zone | 7 | S | | | | |
| 16: Class 7 Buffer Zone | 7 | S | | | | |
| 17: Class 5 LAFW | 5 | S | | | | |
| 18: Class 5 LAFW | 5 | S | | | | |
| 19: Class 7 Buffer Zone | 7 | S | | | | |
| 20: Class 7 Buffer Zone | 7 | S | | | | |
| 21: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 22: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 23: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 24: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 25: Class 5 LAFW | 5 | S | | | | |
| 26: Class 5 LAFW | 5 | S | | | | |
| 27: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 28: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 29: Class 5 LAFW | 5 | S | | | | |
| 30: Class 5 LAFW | 5 | S | | | | |
| 31: Class 5 LAFW | 5 | S | | | | |
| 32: Class 5 LAFW | 5 | S | | | | |
| 33: Class 5 LAFW | 5 | S | | | | |
| 34: Class 5 LAFW | 5 | S | | | | |
| 35: Class 7 Ante Room | 7 | S | | | | |
| 36: Class 7 Ante Room | 7 | S | | | | |
| 37: Class 7 Ante Room | 7 | S | | | | |
| 38: Class 7 Ante Room | 7 | S | | | | |
| 39: Class 5 LAFW | 5 | S | | | | |
| 40: Class 5 LAFW | 5 | S | | | | |
| 41: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 42: Class 5 LAFW Touchscreen | 5 | S | | | | |
| 43: Control Lot #507373 Exp: 08/25/2022 | NA | S | | | | |

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

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915




Page 2 of 14

44: Control Lot #506482 Exp: NA S
08/11/2022

| | | |
|-------------------------|---|---|
| 45: Class 5 LAFW | 5 | A |
| 46: Class 5 LAFW | 5 | A |
| 47: Class 5 LAFW | 5 | A |
| 48: Class 5 LAFW | 5 | A |
| 49: Class 5 LAFW | 5 | A |
| 50: Class 5 LAFW | 5 | A |
| 51: Class 5 LAFW | 5 | A |
| 52: Class 5 LAFW | 5 | A |
| 53: Class 5 LAFW | 5 | A |
| 54: Class 5 LAFW | 5 | A |
| 55: Class 5 LAFW | 5 | A |
| 56: Class 5 LAFW | 5 | A |
| 57: Class 7 Buffer Zone | 7 | A |
| 58: Class 7 Buffer Zone | 7 | A |
| 59: Class 7 Buffer Zone | 7 | A |
| 60: Class 7 Buffer Zone | 7 | A |
| 61: Class 7 Buffer Zone | 7 | A |
| 62: Class 7 Buffer Zone | 7 | A |
| 63: Class 7 Buffer Zone | 7 | A |
| 64: Class 7 Buffer Zone | 7 | A |
| 65: Class 7 Ante Room | 7 | A |
| 66: Class 7 Ante Room | 7 | A |
| 67: Class 7 Ante Room | 7 | A |
| 68: Class 7 Ante Room | 7 | A |

69: Control Lot #504874 Exp: NA A
07/13/2022

70: Control Lot #504698P Exp: NA A
07/11/2022

-  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 - Santa Fe Springs**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 3 of 14

Client Sample #: 1
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-001

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

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

Lab Sample #: 22021915-002

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 #: 22021915-003

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 #: 22021915-004

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 #: 22021915-005

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 #: 22021915-006

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

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

Lab Sample #: 22021915-007

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

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

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 4 of 14

Client Sample #: 8
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-008

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 9
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 #: 22021915-009

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 10
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 #: 22021915-010

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 11
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-011

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 12
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-012

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 13
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 #: 22021915-013

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 14
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 #: 22021915-014

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 5 of 14

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 #: 22021915-015

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 #: 22021915-016

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 17
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 #: 22021915-017

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 18
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 #: 22021915-018

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 19
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 #: 22021915-019

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 20
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 #: 22021915-020

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22021915-021

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915

Page 6 of 14

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

Lab Sample #: 22021915-022

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22021915-023

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Lab Sample #: 22021915-024

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 25
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 #: 22021915-025

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 26
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 #: 22021915-026

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 27
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-027

Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 28
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-028

Area: **25 cm²**
MRL: **1 CFU/25cm²**

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Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 7 of 14

Client Sample #: 29
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 #: 22021915-029
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 30
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 #: 22021915-030
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 31
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 #: 22021915-031
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 32
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 #: 22021915-032
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 33
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 #: 22021915-033
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 34
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 #: 22021915-034
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 35
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 #: 22021915-035
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 8 of 14

Client Sample #: 36
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 #: 22021915-036
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 37
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 #: 22021915-037
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 38
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 #: 22021915-038
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 39
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 #: 22021915-039
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 40
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 #: 22021915-040
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 41
Sample Location: Class 5 LAFW Touchscreen
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-041
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 42
Sample Location: Class 5 LAFW Touchscreen
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-042
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 9 of 14

Client Sample #: 43
Sample Location: Control Lot #507373 Exp: 08/25/2022
Test: 1158 BACTERIAL SURFACE - USP 797 Negative (-) Control: 2.2
Results: **No Growth**

Lab Sample #: 22021915-043

Client Sample #: 44
Sample Location: Control Lot #506482 Exp: 08/11/2022
Test: 1159 FUNGAL SURFACE - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22021915-044

Client Sample #: 45
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 #: 22021915-045

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

Client Sample #: 46
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 #: 22021915-046

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

Client Sample #: 47
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 #: 22021915-047

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

Client Sample #: 48
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 #: 22021915-048

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

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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 10 of 14

Client Sample #: 49
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-049

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 #: 50
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-050

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 #: 51
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-051

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 #: 52
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-052

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 #: 53
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-053

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 #: 54
Sample Location: Class 5 LAFW

Lab Sample #: 22021915-054

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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Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 11 of 14

Client Sample #: 55
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 #: 22021915-055
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 56
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 #: 22021915-056
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 57
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 #: 22021915-057
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 58
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-058
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 59
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 #: 22021915-059
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 60
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-060
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 12 of 14

Client Sample #: 61
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 #: 22021915-061
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 62
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-062
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 63
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 #: 22021915-063
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 64
Sample Location: Class 7 Buffer Zone
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-064
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 65
Sample Location: Class 7 Ante Room
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-065
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 66
Sample Location: Class 7 Ante Room
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-066
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915
Page 13 of 14

Client Sample #: 67
Sample Location: Class 7 Ante Room
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-067

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

Client Sample #: 68
Sample Location: Class 7 Ante Room
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**
Comments: **Pass**

Lab Sample #: 22021915-068

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

Client Sample #: 69
Sample Location: Control Lot #504874 Exp: 07/13/2022
Test: 1156 BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**

Lab Sample #: 22021915-069

Client Sample #: 70
Sample Location: Control Lot #504698P Exp: 07/11/2022
Test: 1157 FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**

Lab Sample #: 22021915-070

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Date Collected: 6/9/2022
Date Received: 6/10/2022
Date Analyzed: 6/14/2022
Date Reported: 6/14/2022
Project ID: 22021915

Page 14 of 14

USP 797 Class and Action Levels

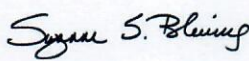
| ISO Clean Room Classification | ISO, 0.5 u/m ³ Particulate | Viable Air Sampling 400-1000 CFU/m ³ | Surface Contact CFU/plate | Gloved Fingertip CFU/plate | Gloved Fingertip CFU/plate Gown Validation |
|-------------------------------|---------------------------------------|---|---------------------------|----------------------------|--|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

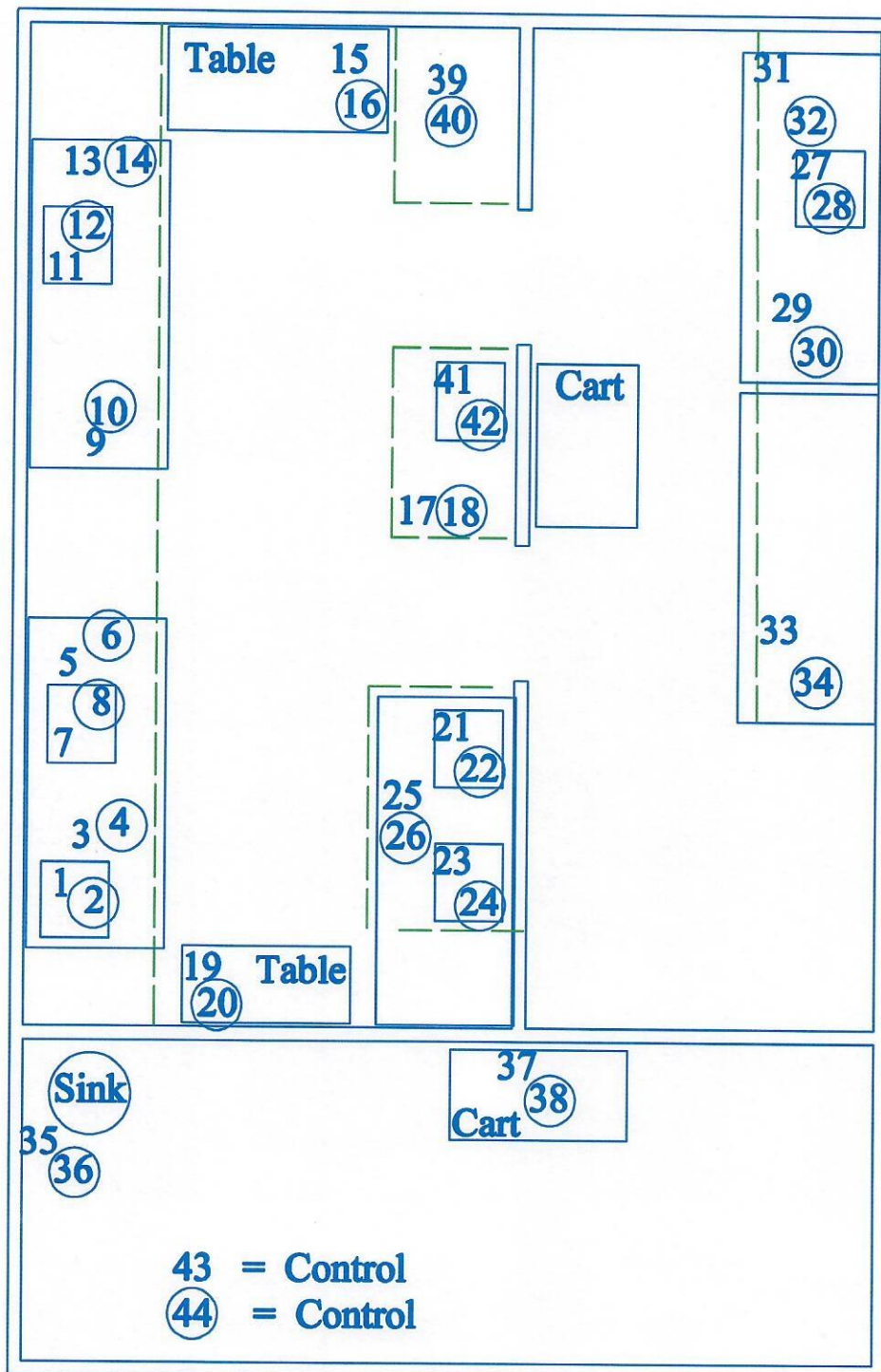
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Source PIC/S, 2007

Footnotes and Additional Report Information

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

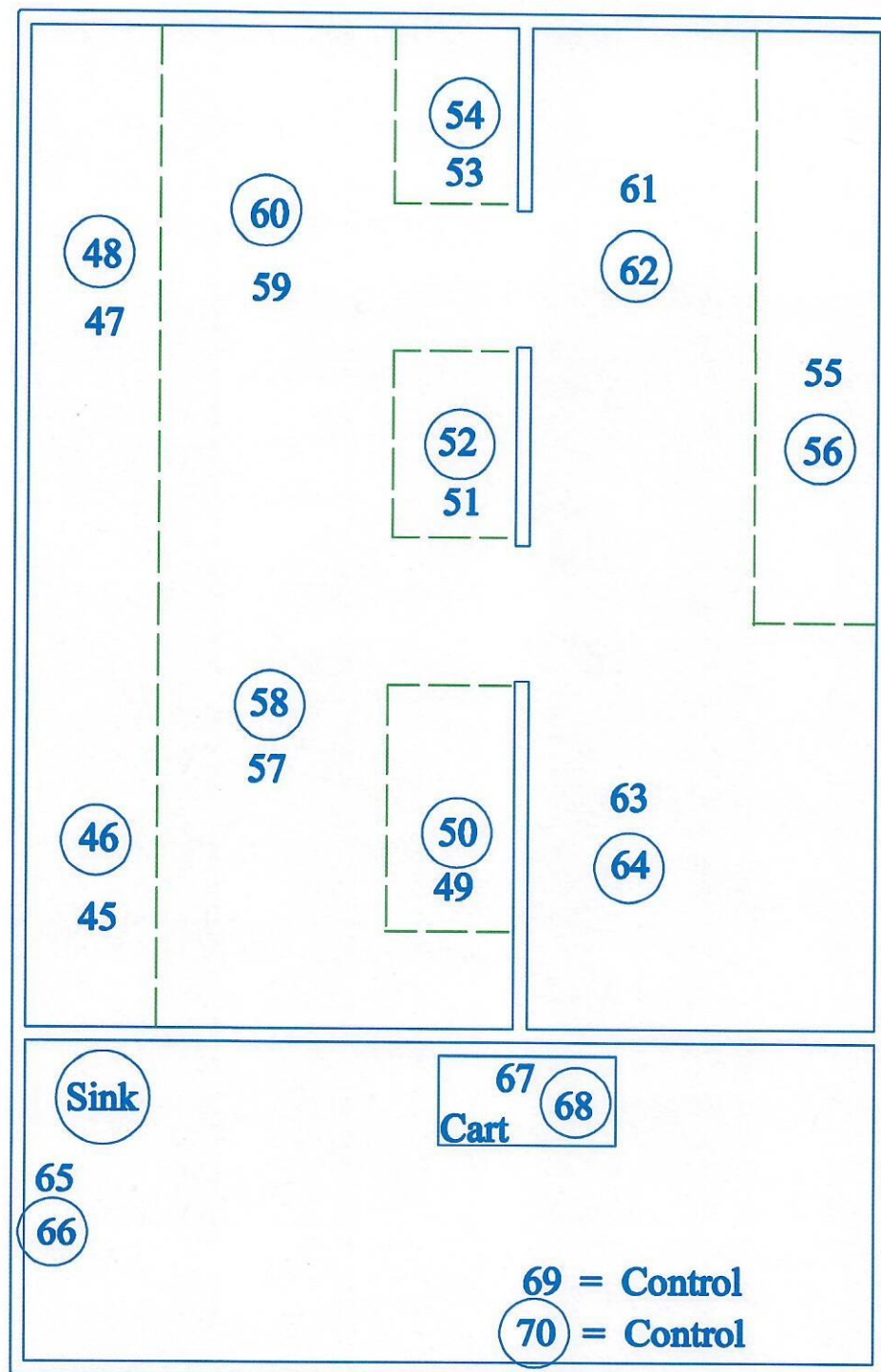

Suzanne Blevins
Laboratory Director



Crescent Sante Fe Springs Acute CR

Surface Sample Locations

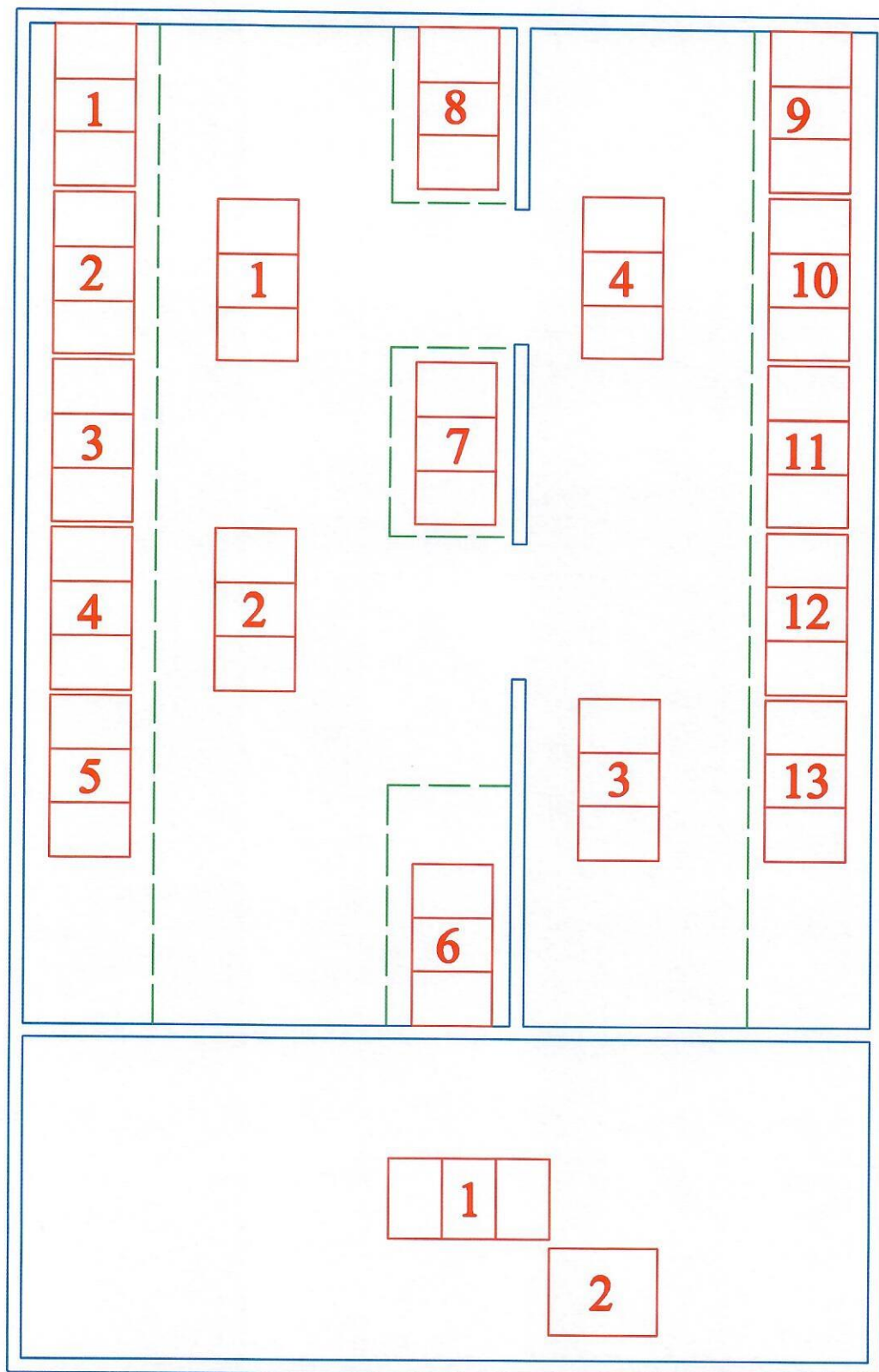
- # = TSA Media (Bacterial)
- # = MEA Media (Fungal)



Crescent Sante Fe Springs Acute CR

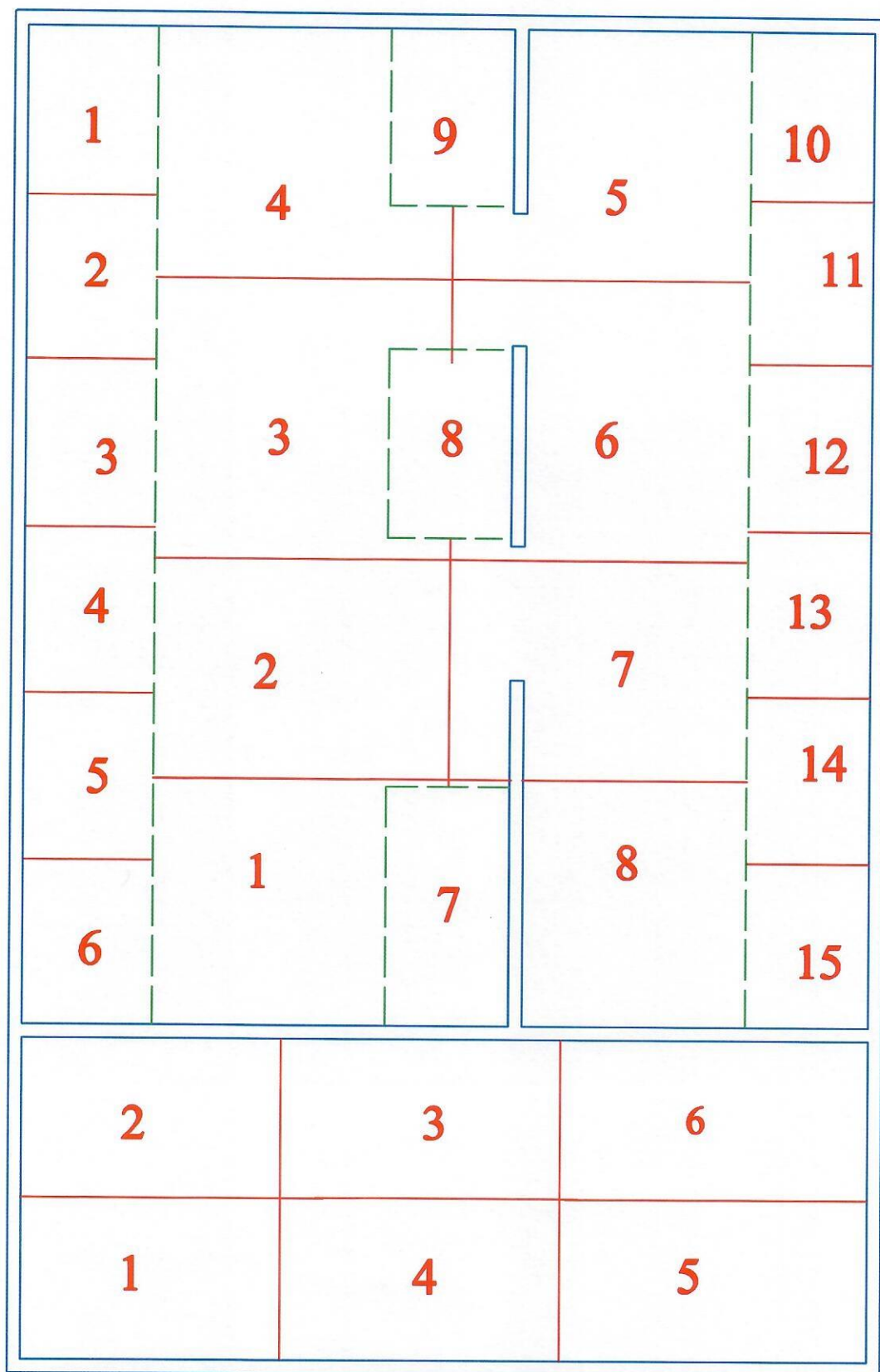
Viable Sample Locations

- # = TSA Media (Bacterial)
- # = Mea Media (Fungal)

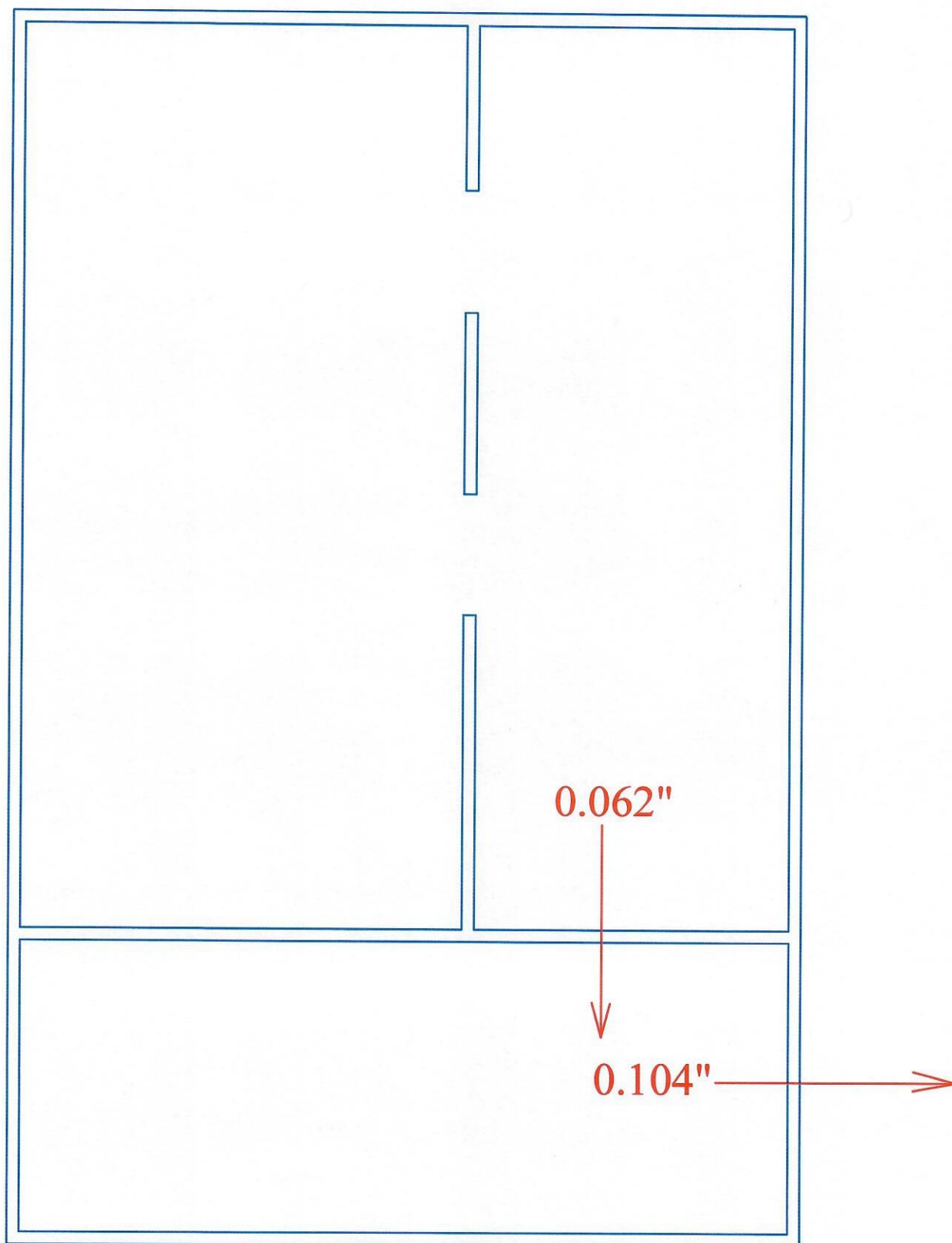


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HEPA Filter Locations



Crescent Sante Fe Springs Acute CR
Particle Count Locations



Option Care Sante Fe Springs

Pressure Differentials