



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

PERFORMANCE CERTIFICATION

FOR
Option Care – Hawaii
550 Paiea Street # 236
Honolulu, HI 96819



Test Date:
January 4, 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 CI150T, serial #131729; calibrated 3/4/21

Air Flow

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

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M15523; Calibrated 4/1/21

Pressure Differential

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

Test Instruments:

AirData Multimeter – Shortridge Model ADM-860C, serial #M15523; Calibrated 4/1/21

HEPA Filter Integrity Test

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

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

Test Instruments:

Photometer - ATI Model TDA-2i, serial #23806; Calibrated 1/29/21

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 CI150T, serial #131729; calibrated 3/4/21

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 1/29/21

Aerosol Generator – ATI Model TDA-4BL (calibration not required)

PAO was used as the aerosol

Air Flow

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

Test Instruments:

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

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: _____

1/4/22

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

Cleanroom Performance Test Report

Customer:	Option Care Hawaii	Dimensions:	214 square feet
Date:	1/4/2022	Volume:	1712 cubic feet
Room ID:	Buffer Zone	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	6	Location	Readings:
Particle Size	>0.5 micron	1	459.1 Particle/M ³
		2	0.0 Particle/M ³
		3	0.0 Particle/M ³
		4	70.6 Particle/M ³
		5	2,012.9 Particle/M ³
		6	2,683.9 Particle/M ³

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

Air Flow

		Filter	Read 1	Read 2	Avg. FPM	Sq. Feet	CFM
Air Change:		1	79	87	83.0	7.25	602
Recommended=	30.0 /hour	2	158	169	163.5	7.25	1185
Actual=	62.6 /hour						

Pass/Fail **Pass**

Total CFM = 1,787

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail
1	22	<0.01%	N/R	Pass
2	11	<0.01%	N/R	Pass

Signature: 

Date: 1/4/22

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 Hawaii	Dimensions:	79 square feet
Date:	1/4/2022	Volume:	632 cubic feet
Room ID:	Ante room	Test Status:	Dynamic
Class:	7		

Particle Count

Locations required:	5		
Particle Size	>0.5	Location	Readings:
		1	3,107.7 Particle/M ³
		2	2,401.4 Particle/M ³
		3	1,024.1 Particle/M ³
		4	1,165.4 Particle/M ³
		5	1,801.0 Particle/M ³

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

Air Flow

Air Change:		Filter	Read 1	Avg. FPM	Sq. Feet	CFM
Recommended=	30.0 /hour	1	101	101.0	3.2	323
Actual=	30.7 /min					
Pass/Fail	Pass					

Total CFM = 323

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Filter#	Int. Ref.	Leak	Repaired	Pass/Fail	Prev. patch
1	42	<0.01%	N/R	Pass	None

Signature: _____

Date: _____

1/4/22

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

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

Clean Flow Hood Performance Test Report

Customer: Option Care Hawaii
Date: 1/4/2022
Manufacturer: Nuaire
Occupancy rate: 1

Model # NU-201-630
Serial # 166186120114
Class: 5
Status: Dynamic

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	70.6 Particle/M ³
2	35.3 Particle/M ³
3	35.3 Particle/M ³
4	0.0 Particle/M ³
5	0.0 Particle/M ³

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

Air Flow

Requirement: 80-100 FPM

Avg. Velocity = 95.2 FPM Readings:
Pass/Fail : **Pass**

1-	88	6-	100	11-	100
2-	89	7-	99	12-	100
3-	86	8-	89	13-	99
4-	97	9-	89	14-	99
5-	95	10-	100	15-	98

Measured Values: Avg. +/- 20%
Min. value = 76.2
Max. value = 114.2
Pass/Fail : **Pass**

1171 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail
12	<0.01%	N/R	Pass

Signature: _____

Date: _____

1/4/22

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 Hawaii
Date: 1/4/2022
Manufacturer: Nuaire
Occupancy rate: 1

Model # NU-201-630
Serial # 170929102715
Class: 5
Status: Dynamic

Particle Count

Locations required: 5
Particle Size >0.5

Location	Readings:
1	0.0 Particle/M ³
2	0.0 Particle/M ³
3	0.0 Particle/M ³
4	0.0 Particle/M ³
5	0.0 Particle/M ³

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

Air Flow

Requirement: 80-100 FPM

Avg. Velocity = 97.9 FPM Readings:
Pass/Fail : **Pass**

1-	96	6-	100	11-	97
2-	98	7-	98	12-	100
3-	94	8-	98	13-	100
4-	99	9-	96	14-	99
5-	100	10-	96	15-	98

Measured Values: Avg. +/- 20%
Min. value = 78.3
Max. value = 117.5
Pass/Fail : **Pass**

1224 CFM

Filter Integrity Test

No scanned leaks shall be greater than 0.01%

Int. Ref.	Leak	Repaired	Pass/Fail
11	<0.01%	N/R	Pass

Signature: _____

Date: _____

1/4/22

See Test Summary Sheet for instrument data.

Airflow Smoke Pattern Test

Option Care – Hawaii

January 4, 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 work table 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.

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

Smoke study comments:

- Good unidirectional airflow was observed at each workstation location.
- No reflux was observed at front edge of panels.
- No reflux was observed at back side of work stations.
- No reflux around perimeter nor over operators head was observed

Conclusion:

PEC: NuAire # 166186120114 Smoke Study validates 1 person compounding maintains unidirectional flow.

PEC: NuAire # 170929102715 Smoke Study validates 1 person compounding maintains unidirectional flow.

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

Signed: _____


Arne Gjertsen

Date: 1/4/22

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

Weight Scale – Calibration Report

Customer: Option Care Hawaii

Calibration Date: 1/4/2022

Calibration Due Date: 1/4/2023


Model # Ohaus CS-2000 Scale Identification # Cleanroom

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.

Signature:  Date: 1/4/22

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

Weight Scale – Calibration Report

Customer: Option Care Hawaii

Calibration Date: 1/4/2022

Calibration Due Date: 1/4/2023

Model # Ohaus CS-2000 Scale Identification # Pharmacy

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.

Signature:  Date: 1/4/22

Viable Air and Surface Sampling

Option Care - Hawaii

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

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

A SAS 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 January 4, 2022. and delivered January 5, 2022 to Aerobiology Laboratory for analysis.

The results are attached, in Lab Report #22000290. All of the tests were within the allowable CFU and passed.

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

Manufacturer – Hardy Diagnostics

(Air) Malt Plates – Lot #497097; expires 3/4/22

(Air) Tryptic Soy Plates – Lot #497536; expires 3/13/22

(Surface) Malt Plates- Lot #496300; expires 2/17/22

(Surface) Tryptic Soy Plates- Lot #495131; expires 1/30/22

Signature: _____

Arne Gjertsen

Date: _____


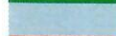



1/11/22

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 1 of 9

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Matrix	Pass	Acpt	O.O.C.	Cause
1: Class 5 LFB	5	A				
2: Class 5 LFB	5	A				
3: Class 5 LFB	5	A				
4: Class 5 LFB	5	A				
5: Class 7 Buffer Zone	7	A				
6: Class 7 Buffer Zone	7	A				
7: Class 7 Buffer Zone	7	A				
8: Class 7 Buffer Zone	7	A				
9: Class 7 Ante Room	7	A				
10: Class 7 Ante Room	7	A				
11: Class 7 Ante Room	7	A				
12: Class 7 Ante Room	7	A				
13: Control / Op. Handling Lot #497536 , Ex: 03/13/2022	NA	A				
14: Control Lot #497097 , Ex: 03/04/2022	NA	A				
15: Class 5 LFB	5	S				
16: Class 5 LFB	5	S				
17: Class 5 LFB	5	S				
18: Class 5 LFB	5	S				
19: Class 7 Buffer Zone	7	S				
20: Class 7 Buffer Zone	7	S				
21: Class 7 Buffer Zone	7	S				
22: Class 7 Buffer Zone	7	S				
23: Class 7 Ante Room	7	S				
24: Class 7 Ante Room	7	S				
25: Class 7 Ante Room	7	S				
26: Class 7 Ante Room	7	S				
27: Class 5 LFB Touchscreen	5	S				
28: Class 5 LFB Touchscreen	5	S				
29: Control Lot #495131 , Ex: 01/30/2022	NA	S				
30: Control Lot #496300 , Ex: 02/17/2022	NA	S				
31: Class 5 LFB Touchscreen	5	S				
32: Class 5 LFB Touchscreen	5	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 Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 2 of 9

Client Sample #: 1
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 #: 22000290-001
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 2
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 #: 22000290-002
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 3
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 #: 22000290-003
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 4
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 #: 22000290-004
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 5
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 #: 22000290-005
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 6
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 #: 22000290-006
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 3 of 9

Client Sample #: 7
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 #: 22000290-007

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

Client Sample #: 8
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 #: 22000290-008

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

Client Sample #: 9
Sample Location: Class 7 Ante Room
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **3 CFU/m3**

Lab Sample #: 22000290-009

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

Organism(s) Isolated:	Raw Count	CFU/m3	% Total
Bacillus species	1	1	33
Micrococcus species	2	2	67
	3	3	~100%

Comments: **Acceptable**

Client Sample #: 10
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 #: 22000290-010

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

Client Sample #: 11
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 #: 22000290-011

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

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 4 of 9

Client Sample #: 12
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 #: 22000290-012
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 13
Sample Location: Control / Op. Handling Lot #497536 , Ex: 03/13/2022
Test: 1107 USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Results: **No Growth**

Lab Sample #: 22000290-013
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 14
Sample Location: Control Lot #497097 , Ex: 03/04/2022
Test: 1108 USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Results: **No Growth**

Lab Sample #: 22000290-014
Air Volume: **1000 L**
Positive Hole: **219**
MRL: **1 CFU/m3**

Client Sample #: 15
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 #: 22000290-015
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 16
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 #: 22000290-016
Area: **25 cm2**
MRL: **1 CFU/25cm2**

Client Sample #: 17
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 #: 22000290-017
Area: **25 cm2**
MRL: **1 CFU/25cm2**

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 5 of 9

Client Sample #: 18
Sample Location: Class 5 LFB

Lab Sample #: 22000290-018

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 #: 19
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22000290-019

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 #: 20
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22000290-020

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 #: 21
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22000290-021

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 #: 22
Sample Location: Class 7 Buffer Zone

Lab Sample #: 22000290-022

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 #: 23
Sample Location: Class 7 Ante Room

Lab Sample #: 22000290-023

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 #: 24
Sample Location: Class 7 Ante Room

Lab Sample #: 22000290-024

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**

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 6 of 9

Client Sample #: 25
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 #: 22000290-025
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 26
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 #: 22000290-026
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 #: 22000290-027
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 #: 22000290-028
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 29
Sample Location: Control Lot #495131, Ex: 01/30/2022
Test: 1104 USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23
Results: **No Growth**

Lab Sample #: 22000290-029
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 30
Sample Location: Control Lot #496300, Ex: 02/17/2022
Test: 1106 USP 797 Culture, Surface, Fungal Counts with ID: SOP 3.9
Results: **No Growth**

Lab Sample #: 22000290-030
Area: **25 cm²**
MRL: **1 CFU/25cm²**

Client Sample #: 31
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 #: 22000290-031
Area: **25 cm²**
MRL: **1 CFU/25cm²**

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 7 of 9

Client Sample #: 32
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 #: 22000290-032

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

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

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 8 of 9

USP 797 Class and Action Levels

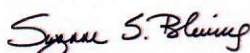
ISO Clean Room Classification	ISO, 0.5 u/m ³ Particulate	Viable Air Sampling 400-1000 CFU/m ³	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

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 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

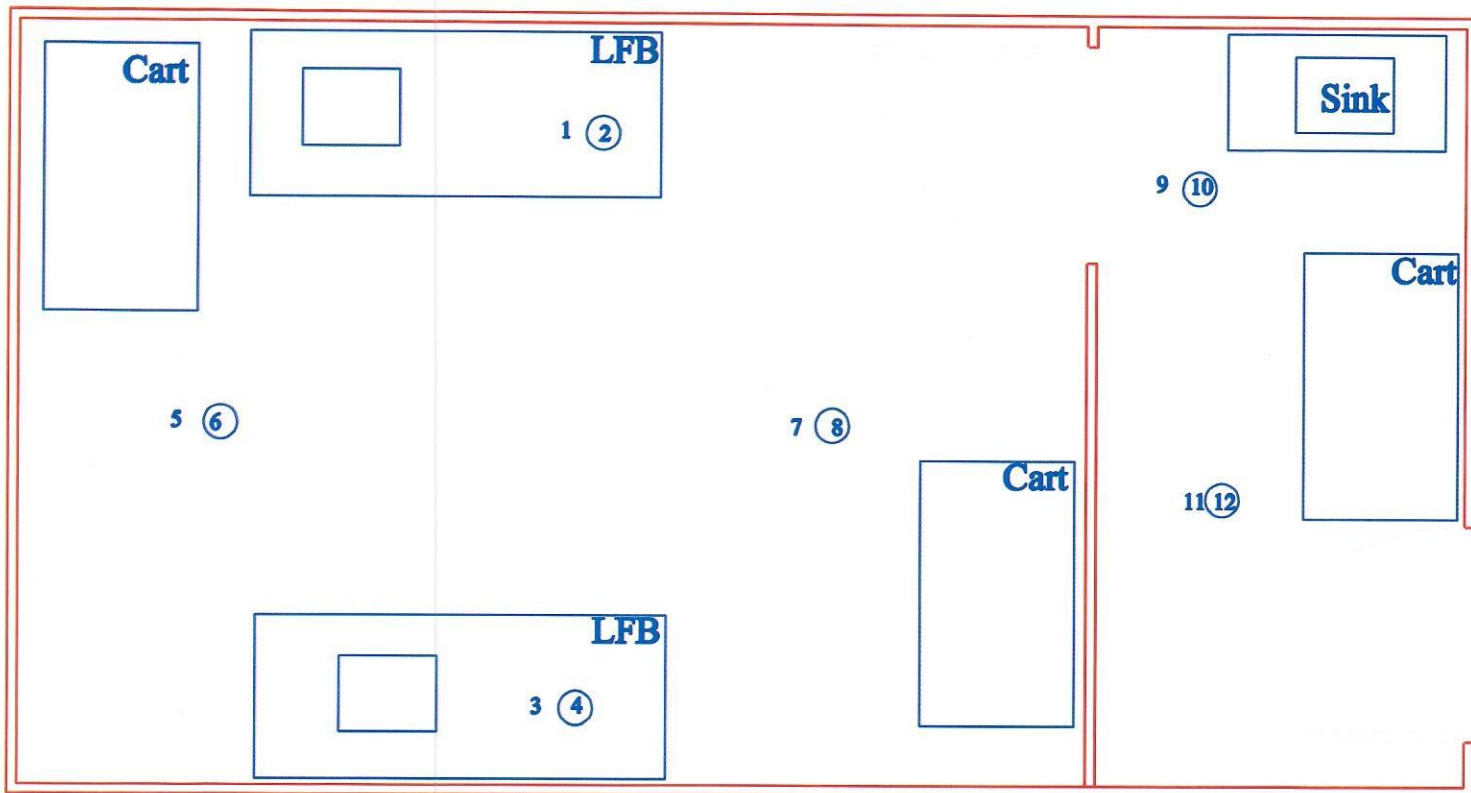
Cleanrooms Plus
1587 Sim Place
Anaheim CA, 92802
Attn: Arne Gjertsen
Project: **Option Care Hawaii**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 1/4/2022
Date Received: 1/5/2022
Date Analyzed: 1/10/2022
Date Reported: 1/11/2022
Project ID: 22000290
Page 9 of 9

GLOSSARY

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.

Micrococcus species: Micrococcus are non-spore-forming, Gram-positive cocci. They are typically non-pathogenic, and considered normal inhabitants of the human body. Micrococci are frequently isolated from air samples and are widespread in nature.

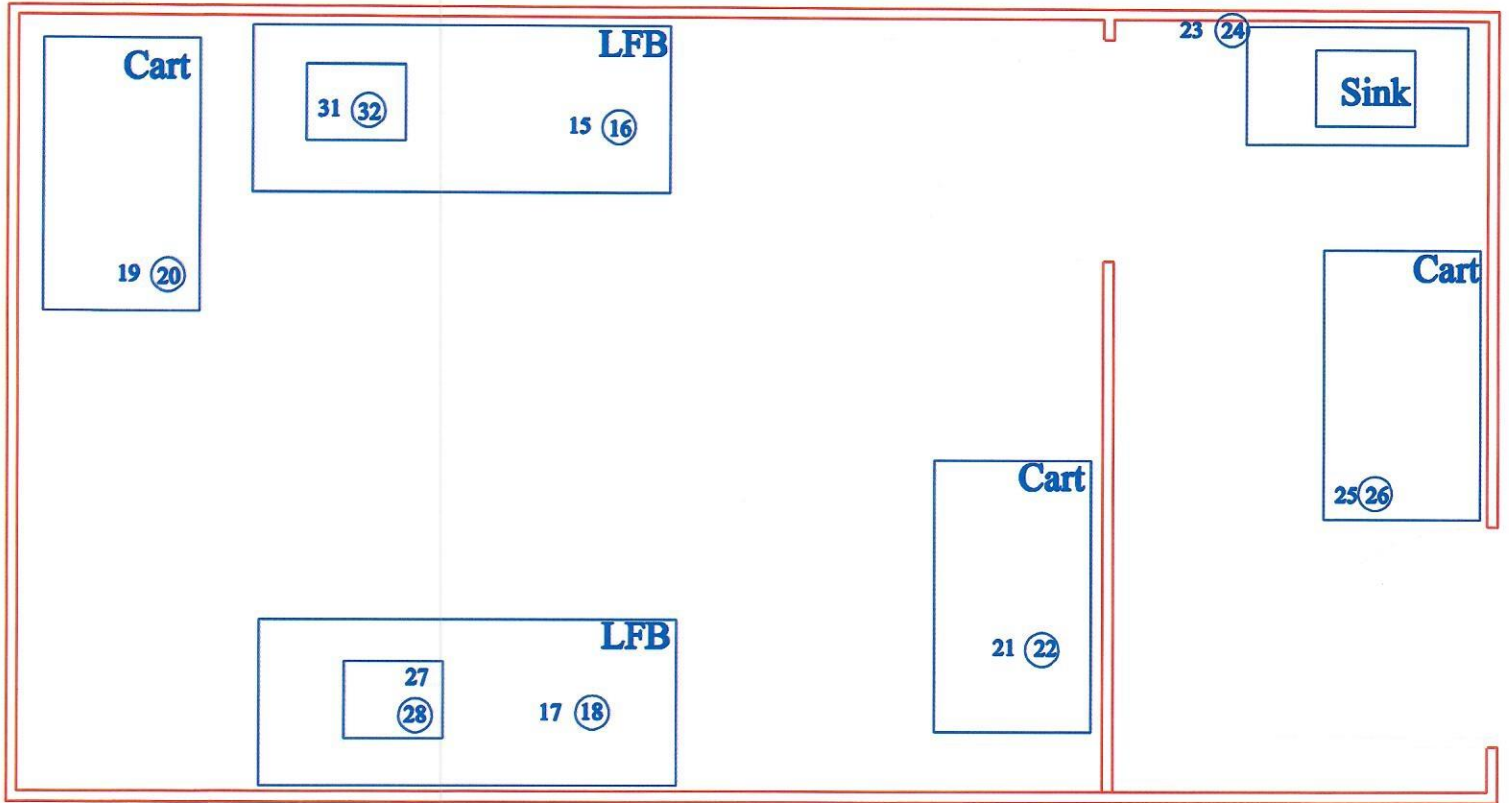


Option Care - Hawaii

Air Sample Plan

13 Control

14 Control

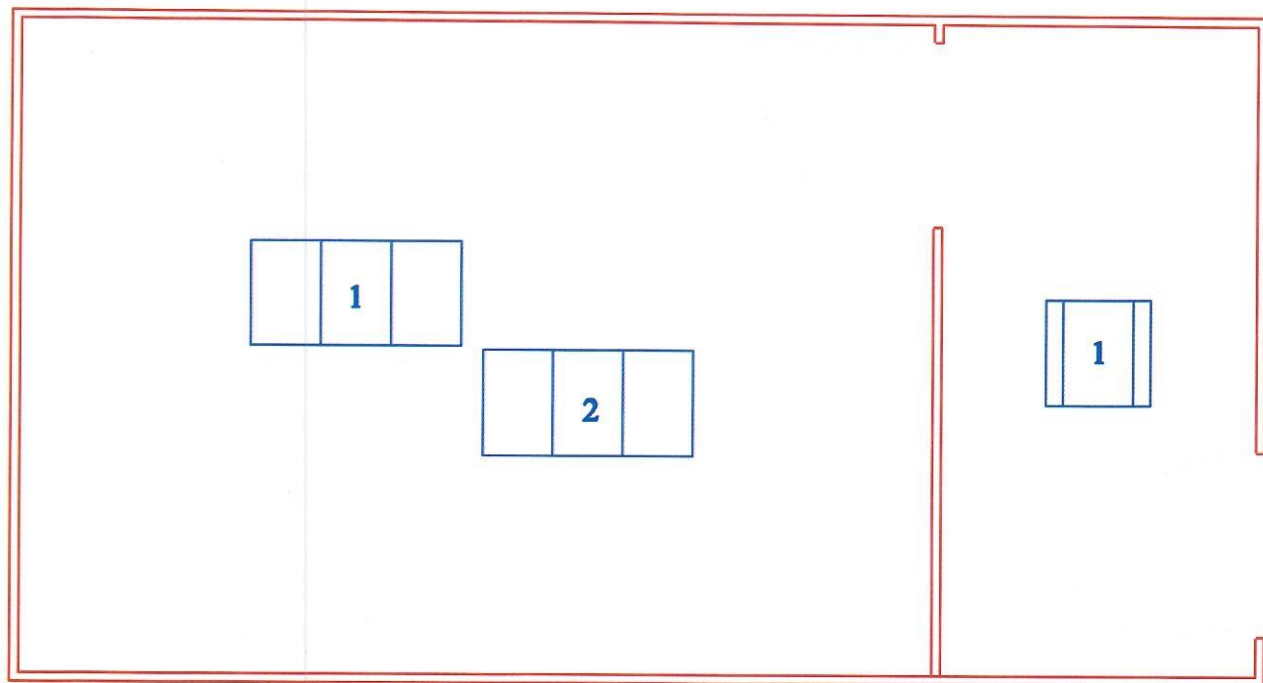


Option Care - Hawaii

Surface Sample Plan

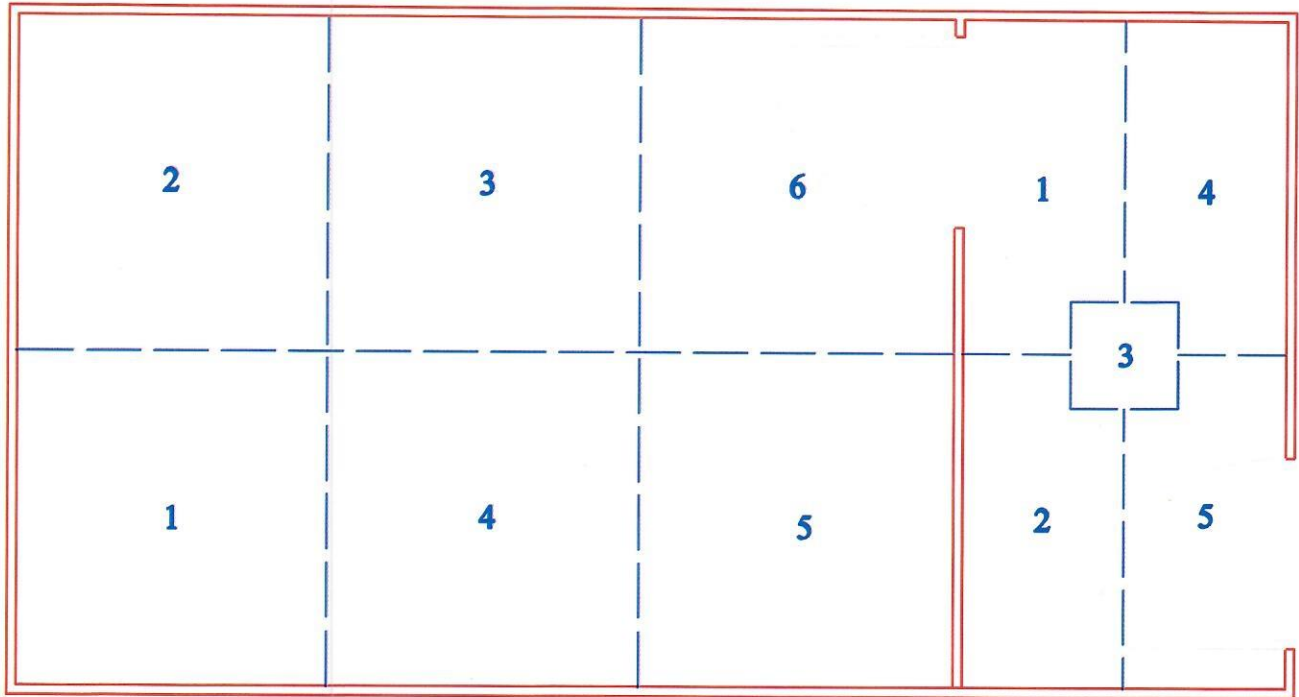
29 Control

30 Control



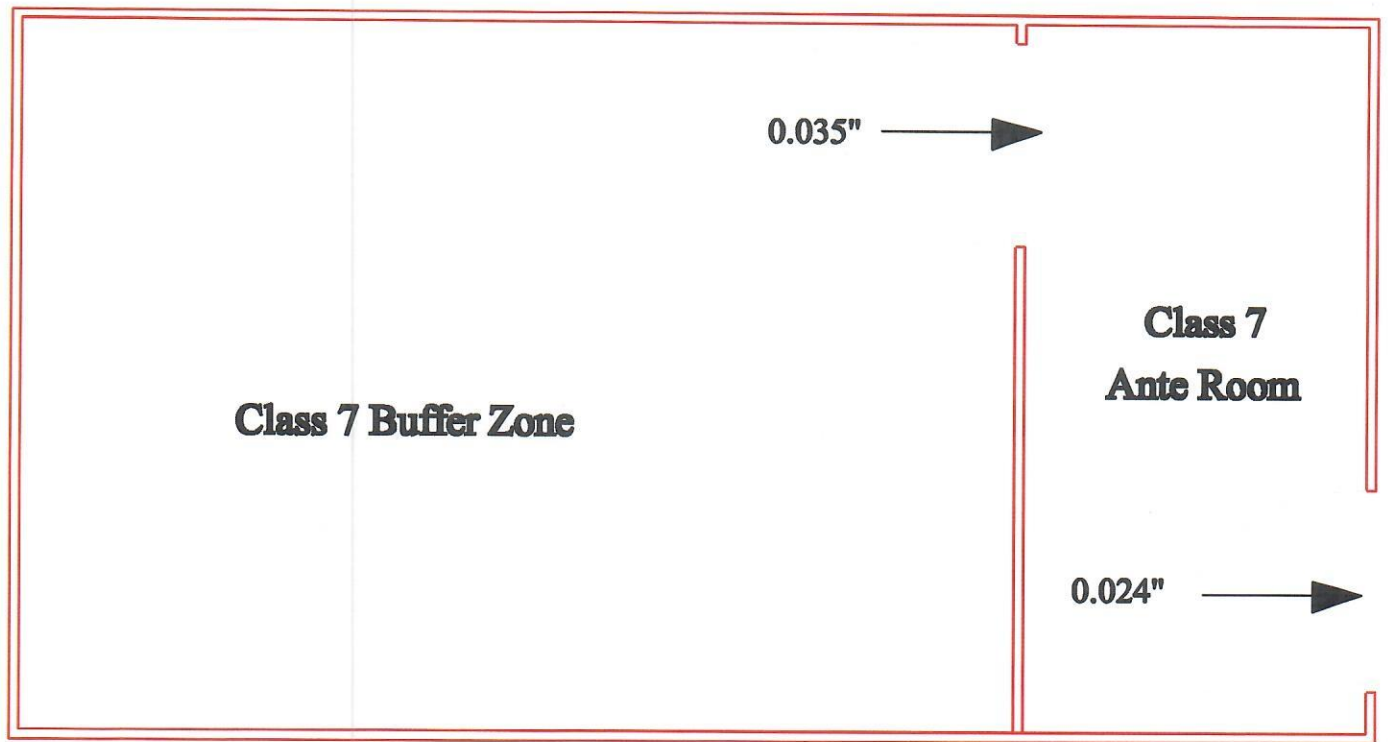
Option Care - Hawaii

HEPA Filter Locations



Option Care - Hawaii

Particle Count Locations



Option Care - Hawaii

Pressure Gradients