Aerobiology Laboratory Associates, Incorporated
Expertise Since 1997

43760 Trade Center Place
Suite 100
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(877) 648-9150
www.aerobiology.net

Certificate of Analysis
AIHA-LAP EMLAP# 102977

CECS, Inc. - Cincinnati
171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20161804 Cert# 124303**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035854

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 124303 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
2	Cert# 124303 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
3	L1 Cert# 124303 IV Prep ISO Class 7	7				
4	L2 Cert# 124303 IV Prep ISO Class 7	7				
5	L3 Cert# 124303 IV Prep ISO Class 7	7				

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.

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CECS, Inc. - Cincinnati
171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20161804 Cert# 124303**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035854

Client Sample #: 1/3 — Lab Sample #: 16035854-001
Sample Location: Cert# 124303 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1152, BACTERIAL AIR - USP 797 Positive (+) Control: SOP 2.2
Results: **Growth** — Air Volume: **0 (L)**

Client Sample #: 1/3 — Lab Sample #: 16035854-001
Sample Location: Cert# 124303 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1153, FUNGAL AIR - USP 797 Positive (+) Control: SOP 3.2
Results: **Growth** — Air Volume: **0 (L)**

Client Sample #: 2/4 — Lab Sample #: 16035854-002
Sample Location: Cert# 124303 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1156, BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth** — Air Volume: **0 (L)**

Client Sample #: 2/4 — Lab Sample #: 16035854-002
Sample Location: Cert# 124303 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1157, FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth** — Air Volume: **0 (L)**

Client Sample #: 5/6 — Lab Sample #: 16035854-003
Sample Location: L1 Cert# 124303 IV Prep ISO Class 7
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 — Positive Hole: **219**
Positive Hole Corrected Result: **No Growth** — Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6 — Lab Sample #: 16035854-003
Sample Location: L1 Cert# 124303 IV Prep ISO Class 7
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 — Positive Hole: **219**
Positive Hole Corrected Result: **No Growth** — Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Attn: Adam West
Project: **WO# A20161804 Cert# 124303**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035854

Client Sample #: 7/8
Lab Sample #: 16035854-004
Sample Location: L2 Cert# 124303 IV Prep ISO Class 7
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole: **219**
Positive Hole Corrected Result: **No Growth**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 7/8
Lab Sample #: 16035854-004
Sample Location: L2 Cert# 124303 IV Prep ISO Class 7
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole: **219**
Positive Hole Corrected Result: **No Growth**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 9/10
Lab Sample #: 16035854-005
Sample Location: L3 Cert# 124303 IV Prep ISO Class 7
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole: **219**
Positive Hole Corrected Result: **No Growth**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 9/10
Lab Sample #: 16035854-005
Sample Location: L3 Cert# 124303 IV Prep ISO Class 7
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole: **219**
Positive Hole Corrected Result: **No Growth**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Attn: Adam West
Project: **WO# A20161804 Cert# 124303**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035854

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
Class 5	3,520	>1	>3	>3
Class 7	352,000	>10	>5	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A

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 identification on an air or surface sample will cause the sample to be 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 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.

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 cm^2, 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/m^3, SURFACE is CFU/25cm^2, 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 of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony.Identification structure must be present for identification.

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 S. Blevins, B.S., SM (ASCP)
Laboratory Director

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Project: **WO# A20161804 Cert# 124302**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035853

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 124302 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
2	Cert# 124302 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
3	L1 Cert# 124302 AnteRoom ISO Class 8	8				
4	L2 Cert# 124302 AnteRoom ISO Class 8	8				

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.

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Attn: Adam West
Project: **WO# A20161804 Cert# 124302**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035853

Client Sample #: 1/3
Lab Sample #: 16035853-001
Sample Location: Cert# 124302 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1152, BACTERIAL AIR - USP 797 Positive (+) Control: SOP 2.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 1/3
Lab Sample #: 16035853-001
Sample Location: Cert# 124302 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1153, FUNGAL AIR - USP 797 Positive (+) Control: SOP 3.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035853-002
Sample Location: Cert# 124302 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1156, BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035853-002
Sample Location: Cert# 124302 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1157, FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 5/6
Lab Sample #: 16035853-003
Sample Location: L1 Cert# 124302 AnteRoom ISO Class 8
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Lab Sample #: 16035853-003
Sample Location: L1 Cert# 124302 AnteRoom ISO Class 8
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Project: **WO# A20161804 Cert# 124302**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035853

Client Sample #: 7/8
Lab Sample #: 16035853-004
Sample Location: L2 Cert# 124302 AnteRoom ISO Class 8
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 7/8
Lab Sample #: 16035853-004
Sample Location: L2 Cert# 124302 AnteRoom ISO Class 8
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Project: **WO# A20161804 Cert# 124302**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035853

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
Class 5	3,520	>1	>3	>3
Class 7	352,000	>10	>5	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A

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 identification on an air or surface sample will cause the sample to be 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 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.

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 cm^2, 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/m^3, SURFACE is CFU/25cm^2, 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 of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony.Identification structure must be present for identification.

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%.

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Laboratory Director

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Project: **WO# A20161804 Cert# 124300**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035850

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 124300 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
2	Cert# 124300 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
3	L1 Cert# 124300 Envirco LAFCB (IV Prep) ISO Class 5	5				

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.

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Attn: Adam West
Project: **WO# A20161804 Cert# 124300**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035850

Client Sample #: 1/3
Lab Sample #: 16035850-001
Sample Location: Cert# 124300 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1152, BACTERIAL AIR - USP 797 Positive (+) Control: SOP 2.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 1/3
Lab Sample #: 16035850-001
Sample Location: Cert# 124300 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1153, FUNGAL AIR - USP 797 Positive (+) Control: SOP 3.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035850-002
Sample Location: Cert# 124300 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1156, BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035850-002
Sample Location: Cert# 124300 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1157, FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 5/6
Lab Sample #: 16035850-003
Sample Location: L1 Cert# 124300 Envirco LAFCB (IV Prep) ISO Class 5
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Lab Sample #: 16035850-003
Sample Location: L1 Cert# 124300 Envirco LAFCB (IV Prep) ISO Class 5
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Project: **WO# A20161804 Cert# 124300**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035850

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
Class 5	3,520	>1	>3	>3
Class 7	352,000	>10	>5	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A

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 identification on an air or surface sample will cause the sample to be 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 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.

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 cm^2, 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/m^3, SURFACE is CFU/25cm^2, 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 of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony.Identification structure must be present for identification.

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%.

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Laboratory Director

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171 Container Place
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Attn: Adam West
Project: **WO# A20161804 Cert# 124301**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035851

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 124301 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
2	Cert# 124301 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16	N/A				
3	L1 Cert# 124301 Envirco LAFCB (IV Prep) ISO Class 5	5				

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.

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Attn: Adam West
Project: **WO# A20161804 Cert# 124301**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 10/19/2016
Date Received: 10/26/2016
Date Analyzed: 11/01/2016
Date Reported: 11/02/2016
Project ID: 16035851

Client Sample #: 1/3
Lab Sample #: 16035851-001
Sample Location: Cert# 124301 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1152, BACTERIAL AIR - USP 797 Positive (+) Control: SOP 2.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 1/3
Lab Sample #: 16035851-001
Sample Location: Cert# 124301 + Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1153, FUNGAL AIR - USP 797 Positive (+) Control: SOP 3.2
Results: **Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035851-002
Sample Location: Cert# 124301 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1156, BACTERIAL AIR - USP 797 Negative (-) Control: SOP 2.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 2/4
Lab Sample #: 16035851-002
Sample Location: Cert# 124301 - Control TSA Lot# H16260 Exp: 12/15/16 / MEA Lot# H16257 Exp: 12/12/16
Test: 1157, FUNGAL AIR - USP 797 Negative (-) Control: SOP 3.2
Results: **No Growth**
Air Volume: **0 (L)**

Client Sample #: 5/6
Lab Sample #: 16035851-003
Sample Location: L1 Cert# 124301 Envirco LAFCB (IV Prep) ISO Class 5
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Lab Sample #: 16035851-003
Sample Location: L1 Cert# 124301 Envirco LAFCB (IV Prep) ISO Class 5
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Expertise Since 1997

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Certificate of Analysis
AIHA-LAP EMLAP# 102977

CECS, Inc. - Cincinnati
171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20161804 Cert# 124301**
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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
Class 5	3,520	>1	>3	>3
Class 7	352,000	>10	>5	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A

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 identification on an air or surface sample will cause the sample to be 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 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.

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 cm^2, 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/m^3, SURFACE is CFU/25cm^2, 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 of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony.Identification structure must be present for identification.

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 S. Blevins, B.S., SM (ASCP)
Laboratory Director