Aerobiology Laboratory Associates, Incorporated
Expertise Since 1997

43760 Trade Center Place
Suite 100
Sterling, Virginia 20166
(877) 648-9150
www.aerobiology.net

Certificate of Analysis
EMLAP# 102977

Agape Instruments Service, Inc.
171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20160774 Cert# 119791**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012223

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 119791 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
2	Cert# 119791 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
3	L1 Cert# 119791 Anteroom ISO Class 8	8				
4	L2 Cert# 119791 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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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012223

Client Sample #: 1/3
Sample Location: Cert# 119791 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012223-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 1/3
Sample Location: Cert# 119791 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012223-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119791 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012223-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119791 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012223-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 5/6
Sample Location: L1 Cert# 119791 Anteroom ISO Class 8
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012223-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Sample Location: L1 Cert# 119791 Anteroom ISO Class 8
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012223-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Attn: Adam West
Project: **WO# A20160774 Cert# 119791**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012223

Client Sample #: 7/8
Lab Sample #: 16012223-004
Sample Location: L2 Cert# 119791 Anteroom ISO Class 8
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **1 CFU/m^3**

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

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	1	1	100	Environment
	1	1	~100%	

Comments: **Acceptable**

Client Sample #: 7/8
Lab Sample #: 16012223-004
Sample Location: L2 Cert# 119791 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# A20160774 Cert# 119791**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012223

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. The positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into consideration that multiple particles can impact on the same hole. For this reason the sum of the 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°C to 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. 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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171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20160774 Cert# 119789**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012219

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 119789 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
2	Cert# 119789 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
3	L1 Cert# 119789 Envirco LAWF 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# A20160774 Cert# 119789**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012219

Client Sample #: 1/3
Sample Location: Cert# 119789 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012219-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 1/3
Sample Location: Cert# 119789 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012219-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119789 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012219-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119789 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012219-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 5/6
Sample Location: L1 Cert# 119789 Envirco LAWF ISO Class 5
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012219-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Sample Location: L1 Cert# 119789 Envirco LAWF ISO Class 5
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012219-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Project: **WO# A20160774 Cert# 119789**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012219

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. The positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into consideration that multiple particles can impact on the same hole. For this reason the sum of the 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°C to 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. 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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Agape Instruments Service, Inc.
171 Container Place
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Attn: Adam West
Project: **WO# A20160774 Cert# 119790**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012220

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 119790 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
2	Cert# 119790 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
3	L1 Cert# 119790 Envirco LAWF 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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Project: **WO# A20160774 Cert# 119790**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012220

Client Sample #: 1/3
Sample Location: Cert# 119790 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012220-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 1/3
Sample Location: Cert# 119790 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012220-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119790 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012220-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119790 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012220-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 5/6
Sample Location: L1 Cert# 119790 Envirco LAWF ISO Class 5
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012220-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Sample Location: L1 Cert# 119790 Envirco LAWF ISO Class 5
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012220-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

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Project: **WO# A20160774 Cert# 119790**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
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Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012220

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. The positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into consideration that multiple particles can impact on the same hole. For this reason the sum of the 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°C to 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. 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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Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012224

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	Cert# 119792 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
2	Cert# 119792 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16	N/A				
3	L1 Cert# 119792 IV Room ISO Class 7	7				
4	L2 Cert# 119792 IV Room ISO Class 7	7				
5	L3 Cert# 119792 IV Room 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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EMLAP# 102977

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171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20160774 Cert# 119792**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012224

Client Sample #: 1/3
Sample Location: Cert# 119792 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012224-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 1/3
Sample Location: Cert# 119792 + Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **Growth**

Lab Sample #: 16012224-001
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119792 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012224-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 2/4
Sample Location: Cert# 119792 - Control Lot# H16075 Exp. Date: 6/13/16 / Lot# H16074 Exp. Date: 6/12/16
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012224-002
Positive Hole: **219**
Air Volume: **0 (L)**
MRL: **1**

Client Sample #: 5/6
Sample Location: L1 Cert# 119792 IV Room ISO Class 7
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012224-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Client Sample #: 5/6
Sample Location: L1 Cert# 119792 IV Room ISO Class 7
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 16012224-003
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**

Aerobiology Laboratory Associates, Incorporated
Expertise Since 1997

43760 Trade Center Place
Suite 100
Sterling, Virginia 20166
(877) 648-9150
www.aerobiology.net

Certificate of Analysis
EMLAP# 102977

Agape Instruments Service, Inc.
171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20160774 Cert# 119792**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012224

Client Sample #: 7/8
Lab Sample #: 16012224-004
Sample Location: L2 Cert# 119792 IV Room 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 #: 16012224-004
Sample Location: L2 Cert# 119792 IV Room 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 #: 16012224-005
Sample Location: L3 Cert# 119792 IV Room 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 #: 16012224-005
Sample Location: L3 Cert# 119792 IV Room 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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171 Container Place
Cincinnati, Ohio 45246
Attn: Adam West
Project: **WO# A20160774 Cert# 119792**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 04/20/2016
Date Received: 04/26/2016
Date Analyzed: 05/02/2016
Date Reported: 05/03/2016
Project ID: 16012224

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. The positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into consideration that multiple particles can impact on the same hole. For this reason the sum of the 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°C to 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. 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