

Allometrics, Inc.
 2500 Bayport Blvd
 Seabrook, Texas 77586
 Attn: Technician
 Project: **Customer Name**
 Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 09/19/2017
 Date Received: 09/21/2017
 Date Analyzed: 09/26/2017
 Date Reported: 09/26/2017
 Project ID: 17031565
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AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Pass	Acpt	0.0.C.	Cause
1 BSC	5				
2 BSC	5				
3 Chemo Room	7				
4 Ante Room	7				Maximum count for Class 7 exceeded
5 BSC	5				
6 BSC	5				
7 Chemo Room	7				
8 Ante Room	7				
9 TSA Positive Control	N/A				
10 SDA Positive Control	N/A				
11 TSA Negative Control	N/A				
12 SDA Negative Control	N/A				

New Color and notification for Growth of Microorganism within USP guidelines.



- 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.
- 0.0.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.

Definitions of results and guidance

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Client Sample #: A3
 Sample Location: Chemo Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Lab Sample #: 1
 Positive Hole: **219**

Positive Hole Corrected Result: **No Growth**

Air Volume: **1000 (L)**
 MRL: **1**

Comments: **Pass**

Client Sample #: A4
 Sample Location: Ante Room
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **3 CFU/m³**

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

Organism Name:	Raw Count	CFU/m ³	% Total	Reservoirs
Coag-negative Staphylococcus species	2	2	67	Human
Micrococcus species	1	1	33	Human
	3	3	-100%	

Comments: **Acceptable**

Client Sample #: A4
 Sample Location: Ante Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **1 CFU/m³**

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

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	MRL
Non-sporulating colony	1	1	100	1

Comments: **Out Of Compliance**

Notification of results (color coded to match description).

Client Sample #: S1
 Sample Location: BSC
 Test: 1104, USP 797 Culture, Surface, Bacterial Counts with ID: SOP 2.23

Lab Sample #: 1

Results: **No Growth** Area: **25 (cm²)**
 MRL: **1**

Comments: **Pass**

Client Sample #: _____
Sample Location: Buffer Room
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **15 CFU/m³**

Lab Sample #: 0000000
Positive Hole: **219**
Air Volume: **1000 (L)**
MRL: **1**

CFU Counts and Reservoirs.

Organism Name:	Raw Count	CFU/m ³	% Total	Reservoirs
Bacillus species	1	1	7	Environment
Coag-negative Staphylococcus species	3	3	21	Human
Micrococcus species	10	10	71	Human
	14	14	~100%	

Comments: **O.O.C.**

Explanation of reporting

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

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