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
AIHA-LAP EMLAP# 102977

Aerobiology Sample Report
43760 Trade Center Place
Sterling, Virginia 20166
Attn: John Doe
Project: **Fingertip Challenge**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 05/21/2018
Date Received: 05/22/2018
Date Analyzed: 05/24/2018
Date Reported: 05/25/2018
Project ID: 18005655

Client Sample #: Fingertip 1
Lab Sample #: 18005655-001
Sample Location: Fingertip of Hand
Test: 1109, USP 797 Culture, GLOVE FINGERTIP (L + R) Bacterial Counts Only
Results: **No Growth**
Area: **Plate**
MRL: **1**

Client Sample #: Fingertip 2
Lab Sample #: 18005655-002
Sample Location: Fingertip of Robotic Hand
Test: 1109, USP 797 Culture, GLOVE FINGERTIP (L + R) Bacterial Counts Only
Results: **No Growth**
Area: **Plate**
MRL: **1**

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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	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

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