



U.S. Micro-Solutions, Inc. \* 302 Unity Plaza \* Latrobe, PA 15650  
 Phone: (724) 853-4047 Fax: (724) 853-4049 AIHA-LAP, LLC EMLAP #103009  
[www.usmslab.com](http://www.usmslab.com)



|                      |                                      |                 |                |
|----------------------|--------------------------------------|-----------------|----------------|
| Customer Name:       | U.S. Micro-Solution, Inc.            | Sample Date:    | March 30, 2018 |
| Customer Address:    | 302 Unity Plaza<br>Latrobe, PA 15650 | Date Received:  | March 31, 2018 |
|                      |                                      | Date of Report: | April 9, 2018  |
| Customer Phone:      | (724) 853-4047                       | Fax:            | (724) 853-4049 |
| PO Number:           |                                      | Attention:      | John Doe       |
| Project Name/Number: | USP Sample Report                    |                 |                |

Customer sample numbers below are uniquely identified by prefixing Laboratory #: 12345-18

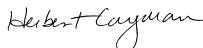
Bioaerosol Sample Set(s) for Bacterial & Fungal Analysis - Analytical Method USMS-G065

| Sample Description / Sample Number |             | Results of Microbial Analysis   |                                   | Raw CTs                         |
|------------------------------------|-------------|---|-----------------------------------|---------------------------------|
| <b>Ante Room</b>                   |             | <b>Total Microbial Count</b>  | <b>38</b>                         | <b>CFU/m<sup>3</sup> of air</b> |
|                                    | ISO Class 7 | Viable Air Level:   | <b>Count Exceeds Action Level</b> |                                 |
|                                    |             |   | No of Personnel in Room:          | 1                               |
| Bacteria                           | 1           | Total Bacterial Count:  | 36                                | CFU/m <sup>3</sup> of air       |
|                                    |             | Coagulase-negative Staphylococcus spp.  |                                   | 15                              |
|                                    |             | Micrococcus/Kocuria spp.  |                                   | 2                               |
|                                    |             | <b>Escherichia coli</b>   |                                   | <b>1</b>                        |
|                                    |             | Total Raw Count: 18<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air |                                   |                                 |
| Fungi                              | 1F          | Total Fungal Count:   | 2                                 | CFU/m <sup>3</sup> of air       |
|                                    |             | <b>*Aspergillus sydowii</b>   |                                   | <b>1</b>                        |
|                                    |             | Total Raw Count: 1<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air  |                                   |                                 |
| <b>Chemo Room</b>                  |             | <b>Total Microbial Count</b>  | <b>&lt; 2</b>                     | <b>CFU/m<sup>3</sup> of air</b> |
|                                    | ISO Class 7 | Viable Air Level:   | <b>Count Below Action Level</b>   |                                 |
|                                    |             |   | No of Personnel in Room:          | 1                               |
| Bacteria                           | 2           | Total Bacterial Count:  | < 2                               | CFU/m <sup>3</sup> of air       |
|                                    |             | No growth   |                                   |                                 |
|                                    |             | Total Raw Count: <1<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air |                                   |                                 |
| Fungi                              | 2F          | Total Fungal Count:   | < 2                               | CFU/m <sup>3</sup> of air       |
|                                    |             | No growth   |                                   |                                 |
|                                    |             | Total Raw Count: <1<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air |                                   |                                 |

| Air Sampler:  | Impaction Head (# of holes) | Lot Number:  | Exp Date: | Media             |
|---|-----------------------------|--|-----------|-------------------|
|   |                             | 287535   | 04/26/18  | TSA w/Lec Poly 80 |
|   |                             | 123456   | 05/01/18  | SDA w/Lec Poly 80 |
| Results are not pore corrected.   |                             | Viable sampling was conducted while the cleanroom was in an active or dynamic state. |           |                   |
| <b>Notation for Bolded Microbes</b>   |                             |  |           |                   |
| <b>USP&lt;797&gt; Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod in any area is considered not to be in compliance and immediate remediation and investigation into the cause must be conducted.</b> |                             |  |           |                   |

Results relate only to the samples tested. Results are reported as calculated. For biological data, the first and/or second digit should be considered significant.  
 \*Fungus (mold, yeast)

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Technical Manager:   
 Herbert Layman, BS, SM, CIEC



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 Project Name/Number: USP Sample Report

Customer sample numbers below are uniquely identified by prefixing Laboratory # 12345-18

Bioaerosol Sample(s) for Microbial Analysis - Analytical Method USMS-G065

| Sample Number   | Sample Description   | Results of Microbial Analysis  | Raw CTs |
|---|--|--|---------|
| A7  | ISO Class 7<br>Viable Air Level: <b>Count Exceeds Action Level</b><br>Ante - Ante Room | No of Personnel in Room: 1<br>Total Microbial Count 36 CFU/m <sup>3</sup> of air                     | 1       |
|   |  | Coagulase-negative Staphylococcus spp. 15<br>Micrococcus/Kocuria spp. 2<br><b>Escherichia coli 1</b> |         |
| Total Raw Count: 18<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air |  |  |         |
| A8  | ISO Class 7<br>Viable Air Level: <b>Count Below Action Level</b><br>Ante - Ante Room   | No of Personnel in Room: 1<br>Total Microbial Count 4 CFU/m <sup>3</sup> of air                      | 1       |
|   |  | Coagulase-negative Staphylococcus spp. 1<br>Bacillus spp. 1  |         |
| Total Raw Count: 2<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air  |  |  |         |
| A9  | ISO Class 7<br>Viable Air Level: <b>Count Below Action Level</b><br>Chemo - Chemo Room | No of Personnel in Room: 1<br>Total Microbial Count < 2 CFU/m <sup>3</sup> of air                    | 1       |
|   |  | No growth  |         |
| Total Raw Count: <1<br>Total Volume: 500 liters of air<br>Analytical Sensitivity: 2 CFU/m <sup>3</sup> of air |  |  |         |

| Air Sampler:   | Impaction Head (# of holes) | Media: TSA w/Lec Poly 80   |           |
|--|-----------------------------|--|-----------|
|  |                             | Lot Number:  | Exp Date: |
|  |                             | 287535   | 4/26/18   |
| Results are not pore corrected.  |                             | Viable sampling was conducted while the cleanroom was in an active or dynamic state. |           |
| <b>Notation for Bolded Microbes</b>  |                             |  |           |
| <b>USP&lt;797&gt; Pharmaceutical Compounding-Sterile Preparations states recovery of any mold, yeast, coagulase-positive Staphylococcus, or gram-negative rod requires immediate remediation and investigation into the cause.</b> |                             |  |           |

Results relate only to the samples tested. Results are reported as calculated. For biological data, the first and/or second digit should be considered significant.

\*Fungus (mold, yeast)

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Technical Manager: *Herbert Layman*

Herbert Layman, BS, SM, CIEC



**U.S. MICRO-SOLUTIONS INC.**  
AN ENVIRONMENTAL MICROBIOLOGY LAB

**RECOMMENDED ACTION LEVELS FOR MICROBIAL CONTAMINATION**

USP 797 states that the tables of recommended action levels are intended to be used as guidelines only, and "Action levels are determined on the basis of CFU data gathered at each sampling location and trended over time." "Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive *Staphylococcus*, molds, and yeasts)...must be immediately remedied, regardless of CFU count."

| Action Level for BIOAEROSOL Samples |                              |
|-------------------------------------|------------------------------|
| CLASSIFICATION                      | Total CFU per m <sup>3</sup> |
| ISO Class 5                         | >1                           |
| ISO Class 6                         | >10                          |
| ISO Class 7                         | >10                          |
| ISO Class 8 or worse                | >100                         |

| Action Level for GLOVED FINGERTIP Samples |         |           |
|---|---------|-----------|
| Total CFU for both hands                  |         |           |
|   | Gowning | Post Fill |
|   | >0      | >3        |

| Action Level for SURFACE Samples |  |
|----------------------------------|--|
| CLASSIFICATION                   | Total CFU per plate, swab, or area sampled |
| ISO Class 5                      | >3   |
| ISO Class 6                      | >5   |
| ISO Class 7                      | >5   |
| ISO Class 8 or worse             | >100                                       |

**USP <797> Standard Operating Procedure**

- **Incubation**
  - Samples are placed in the incubator on the day that they are received in the laboratory.
  - Bacterial agar plates: 30-35°C for 48-72 hours.
  - Fungal agar plates: 26-30°C for 5-7 days.
  - Single plate method agar plates: 30-35°C for 48-72 hours (bacteria) and then 26-30°C for 5-7 days (fungi).
  - Media fill vials: 20-25°C for 7 days and then 30-35°C for 7 days.
  - Cultures are examined daily (Mon – Sat).
  - Incubator temperatures are monitored 24/7 via a wireless temperature monitoring and alert system.
- **Growth Promotion** - performed with the following organisms when requested:
  - *Staphylococcus aureus* ATCC 25923
  - *Pseudomonas aeruginosa* ATCC 9027
  - *Bacillus subtilis* ATCC 6633
  - *Candida albicans* ATCC 10231
  - *Aspergillus brasiliensis* NCPF 2275
- **Accreditation**
  - ISO/IEC 17025:2017 accreditation for bacterial and fungal analysis through the American Industrial Hygiene Association (AIHA-LAP, LLC #103009).

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