
# FDA批准資料

# 510(k) Premarket Notification



| | |
|---|---|
| **Device Classification Name** | Purifier, Air, Ultraviolet, Medical |
| **510(K) Number** | K133800 |
| **Device Name** | ODOROX(R) IDU/RX (TM) IN-DUCT MODELS, ODOROX(R) IDU/RX (TM) MOBILE DISINFECTION UNITS, ODOROX(R) SLIMLINE/RX (TM) SLIMLI |
| **Applicant** | HGI INDUSTIRES<br>2055 HIGH RIDGE ROAD<br>Boynton Beach, FL 33426 |
| **Applicant Contact** | Connie Araps, Phd |
| **Correspondent** | HGI INDUSTIRES<br>2055 HIGH RIDGE ROAD<br>Boynton Beach, FL 33426 |
| **Correspondent Contact** | Connie Araps, Phd |
| **Regulation Number** | 880.6500 |
| **Classification Product Code** | FRA |
| **Date Received** | 12/13/2013 |
| **Decision Date** | 12/19/2014 |
| **Decision** | Substantially Equivalent (SESE) |
| **Regulation Medical Specialty** | General Hospital |
| **510k Review Panel** | General Hospital |
| **Summary** | Summary |
| **Type** | Traditional |
| **Reviewed By Third Party** | No |
| **Combination Product** | No |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19,2014

HGI INDUSTIRES
Dr. Connie Araps
Chairman of HGI Scientific Advisory Board.
2055 High Ridge Road
Boynton Beach, FL 33426 US

Re: K133800
Trade/Device Name: ODOROX(R) MDU/RX (TM)
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical UV Air Purifiers
Regulatory Class: II
Product Code: FRA
Dated: November 17, 2014
Received: November 19, 2014

Dear Dr. Araps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Department of Health and Human Services
Food and Drug Administration

Form Approved: OMB NO. 0910-0120
Expiration date: December 31, 2014

# Indications for Use

**510(k) Number K133800**

**Device Name**

**Odorox® MDU/Rx™**

**Indications for Use (Describe)**

The MDU/Rx™ medical model is an ultraviolet (UV) air purifying device intended for the reduction of bacteria and the MS2 and Phi-X174 virus in air in medical facilities. The MDU/Rx™ medical device is non sterile.

Type of Use: [X] Over-the-counter use (21CFR 807 Subpart C)

**Please do not write below this line – Continue on a Separate Page if needed**

**For FDA Use Only**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

# 510(k) Summary

| | |
|---|---|
| **510(k) Owner:** | **HGI Industries, Inc.**<br>**2055 High Ridge Road**<br>**Boynton Beach, FL 33426**<br>**Phone: 561-735-3701**<br>**Fax: 561-347-3824** |
| **Contact Person:** | **Connie Araps, PhD**<br>**2055 High Ridge Road**<br>**Boynton Beach, FL 33426**<br>**Phone: 561-735-3701**<br>**Fax: 561-347-3824** |
| **Date Prepared:** | **December 15, 2014** |
| **Proprietary Name(s):** | **Odorox® MDU/Rx™** |
| **Common Name:** | **Air purifier ultraviolet or ultraviolet air purifier (used interchangeably by substantially equivalent devices)** |
| **Trade Name:** | **Odorox® MDU/Rx™** |
| **Classification Name:** | **21 CFR 880-6500 Class II Medical Ultraviolet Air Purifier.** |
| **Product Code:** | **FRA** |
| **Category:** | **General Hospital** |



2055 High Ridge Road • Boynton Beach, FL 33426 • phone: 561.735.3701 • toll free: 877.735.3701 • fax: 561.735.3824 • www.hgiind.co

## 510(k) Summary

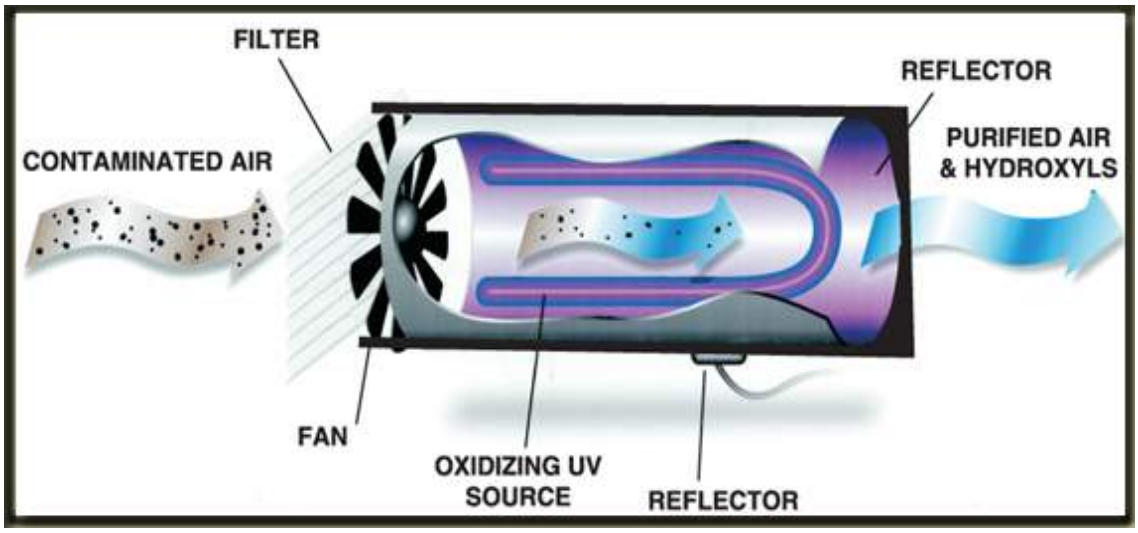
### Intended Use

The MDU/Rx™ medical model is an ultraviolet (UV) air purifying device intended for the reduction of bacteria and the MS2 and Phi-X174 virus in air in medical facilities. The MDU/Rx™ medical device is non sterile.

### Product Description

The MDU/Rx™ device purifies and sanitizes air by circulating ambient air through a filter into a chamber equipped with two ultraviolet (UV) lights (also called optics) with wavelengths in the range between ~100-285 nm, which encompasses the range of light called UV-C, as described in the general system design in Figure E-1.

**Figure E-1 MDU/Rx™ Device General System Design**




UV light in this range is commonly called germicidal. The radiation penetrates the cell walls of bacteria and virus and is absorbed by the organic structures within the cell, causing them to decompose and the cell to die.

General product information is provided below in Table E-1.

**Table E-1 MDU/Rx™ Device Ultraviolet Air Purifier Product Information**

| MODEL # | PRODUCT NAME | DESCRIPTION | # Of OPTICS | Optic Model # |
|---|---|---|---|---|
| MDURXMA00 | MDU/Rx™ | MOBILE Air DISINFECTION UNIT, 120VAC | 2 | OPT-XX-176 |

The Odorox® MDU/Rx™ system is judged to be a Class II device that falls within the FDA category:

- Common name: ultraviolet air purifier or air purifier ultraviolet
- General Hospital
- Purifier, air, ultraviolet, medical
- Regulation Number: 880.6500
- Product Code: FRA

**Substantial Equivalence**

Based on the fact that the MDU/Rx™ system uses UV light with wavelengths of 100 – 285 nm that includes the range commonly called germicidal (or UV-C) as the means by which it sanitizes, the company believes that the system is substantially equivalent to the following FDA approved, legally marketed systems:

- **ECO-Rx AIR PURIFIER WITH UV LIGHT MODEL RX-400**
  - 510(k) Number: K062716
  - Regulation Number: 21 CFR 880.6500
  - Regulation Name: Medical Ultraviolet Air Purifier
  - Regulatory Class: II
  - Product Code: FRA
  - Decision: Substantially equivalent
  - Date Approved: 10/27/2006
  - Classification: General Hospital
  - Type: Traditional
  - Combination Product: No

- **RXAir 3000**
  - 510(k) Number: K951981
  - Regulation Number: 21 CRF 880-6500
  - Regulation Name: Medical Ultraviolet Air Purifier
  - Regulatory Class II
  - Product Code: FRA
  - Decision: Substantially equivalent
  - Date Approved: 10/27/2006
  - Classification: General Hospital
  - Type: Traditional
  - Combination Product: No

All three types of devices are self-contained systems with similar quartz UV-C optics and varying types of filters. The systems use integrated fans to circulate air through the filters to remove particulates and sanitize the air by exposure to UV-C radiation, which

kills airborne microorganisms. They have similar active components, design features and intended uses. They do not incorporate any other sanitizing components such as catalysts or electrical discharge. The use of filters in the MDU/Rx™ device is primarily for the purpose of keeping the optic surfaces clean and is not intended as a means of sanitizing air.

The MDU/Rx™, RXAir 3000 and Eco RX-400 systems have the same intended use as described in Table E2. They are ultraviolet (UV) air purifying devices intended for the reduction of bacteria and specific virus in air in medical facilities. The devices are non-sterile. The construction of the devices is essentially the same in that they all circulate air through metal or plastic cases in which utilize UV-C lights (also called optics). As the air passes through the photolysis chamber and is exposed to the UV-C light, the microorganisms absorb the radiation and are killed.[1] They differ in the types of filters that are used, as described.

The RXAir 3000 uses a single "germicidal" UV-C lamp to sanitize and a five-stage filter to remove particulates, volatile organic compounds and bacteria. The ECO Rx 400 uses three UV-C lamps (also called optics) to sanitize and has a filter to remove particulates.

A comparison of the MDU/Rx™ device and available predicate product feature information is provided in Table E-2, below and compares:

- Indications for use
- Intended use
- Materials of construction
- Elements of design
- Mechanism of action

**Table E-2 Comparison of MDU/Rx™, RXAir 3000 and ECO RX-400 Features**

| Features | Odorox® Units | RXAir 3000 | ECO RX-400 |
|---|---|---|---|
| Indications for Use | UV Air sanitizer | UV Air Sanitizer | UV Air Sanitizer |
| Intended Use | Kill bacteria, virus in air | Kill bacteria, virus in air | Kill bacteria, virus in air |
| Mechanisms of action | UV light kills microorganisms | UV light kills microorganisms | UV light kills microorganisms |
| Elements of design | Fan circulates air through shielded chamber where UV light irradiates microorganisms | Fan circulates air through shielded chamber where UV light irradiates microorganisms | Fan circulates air through shielded chamber where UV light irradiates microorganisms |
| Particulate filter | Yes | Yes | Yes |
| Internal Fan | Yes | Yes | Yes |
| Germicidal UV | Yes | Yes | Yes |
| UV Optic type | Quartz UV-C | Quartz UV-C | Quartz UV-C |
| Wavelength range of UV radiation | ~100-285 nm | ~100-285 nm | ~100-285 nm |

| | | | |
|---|---|---|---|
| Catalyst coated surfaces | No | No | No |
| Electric discharge | No | No | No |
| Chemical additives | No | No | No |
| Type and Materials of Construction | Quartz UV optics, Metal or plastic structural case and fan powered by electric motor | Quartz UV optics, Metal or plastic structural case and fan powered by electric motor | Quartz UV optics, Metal or plastic structural case and fan powered by electric motor |

In summary, the available information for the predicates and data from HGI indicate that all three devices generate UV-C radiation using quartz optics. The radiation is directly absorbed by the bacteria and virus in air as they pass through the photolysis chamber. The microorganisms die as a result of radiation damage to the DNA and other organic structures within the organisms' cell wall. UV-C radiation also reacts with oxygen and water vapor in air to generate very low concentrations of hydroxyl radicals in the range of 0.1 parts per trillion to one part per billion. Hydroxyl radicals can react with the lipids and proteins in the cell walls of microorganisms (including bacteria and virus) within the radiation chamber and kills them, contributing to the sanitization process. Both mechanisms occur concurrently.

**Performance**

The MDU/Rx™ model is designed to treat areas of approximately 130 to 500 square feet that would have 8 to 10 foot ceilings (~1300 to 5,000 cubic feet of space). The system is operated by the use of an on-off switch which activates both optics and the fan. The fan is set at a fixed speed of ~150 cubic feet per minute. When in use, an indicator light on the outside of the case is lit. The recommended mode of action is to have the unit running continuously. Larger spaces require the use of longer treatment times and/or multiple machines. The unit recirculates ambient air continuously through the UV-C photolysis chamber, where it is sanitized. Operational use guidelines are provided to users in the form of an Owner's Manual and advise that the MDU/Rx™ model is intended for use in ventilated spaces of four or more exchange rates per hour. The length of time required to reach optimal sanitization varies as a function of the volume of space being treated, and the dynamics of what occurs within the treatment space including:

- Initial load of microorganisms
- Degree of contamination being introduced by patient activities, treatment etc.
- Movement of personnel/patients within the space
- Rates of ventilation

The device is intended to result in high kill rates of 4-5 log reduction of airborne bacteria and the MS2 and Phi-X174 virus of initial concentrations of 6 log 8 -10 CFU/cu ft. of air and is not intended to create a sterile environment.

The system uses commercially available 48 watt quartz optics as UV-C radiation sources. The 48 watt optic produces 10 watts of light at ~254 nm (at 100 hours of use). There is an indicator light to show that both optics are on and are functioning properly.

The fan speed is not critical to the operation of the system. Generally, operating the fan at ~ 150 cfm results in slightly faster elimination of bacteria and virus than higher fan speeds as the ambient air has increased residence time within the photolysis chamber. The device uses a washable polyester filter to remove particulates greater than 8 microns. The purpose of the filter is primarily to keep the optics clean. Placement of the units is not critical to performance. In general the unit is best placed near a wall at an angle so as to create a vortex around the room to be treated.

Intertek tested the MDU™ model (identical to the proposed MDU/Rx™ model) for compliance with the safety Standards listed below:

- Electrical safety – fans, ventilators using Standards 1 and 2
- Safety for Luminaires using Standard 3
- UV Safety using Standards 4 and 5

1. Standard for Safety for Electric Fans, UL 507-9th Edition, Dated 12/13/1000, with revisions through And including September 27, 2007.

2. Standard for Fans and Ventilators, CSA C22.2 No. 113-10. General Instruction NO 1-7, Dated March 2, 2010.
3. Standard for Safety – Luminaires – UL 1598, 3rd Edition, 9/17/2008 with revisions through and including 2/20/2009

4. UL Standard for Electrical Equipment for Measurement, Control and Laboratory use; Part 1: General requirements, UL 61010-1, 2nd Edition, dated 07/12/04 with revisions through and including 07/22/05

5. Canadian Standards Association C22.2 No. 250, 0-04, 2nd Edition, Dated 12/30/04 with revisions through and including 05/31/06

The Intertek report concluded that "…the MDU™ product covered by this report has been evaluated and found to comply with the applicable requirements" of the Standards referenced above." Based on the Intertek report, the MDU™ unit is ETL Listed (UL 507 and CSA C22.2).

Ozone and organic oxidation by-products are formed as a result of the irradiation of ambient water vapor and oxygen in air by UV-C radiation with a range of wavelengths between ~100-285 nm. Columbia Analytical Services (Simi Valley, CA) evaluated the MDU™ device (identical to the proposed MDU/Rx™ device) for the purpose of measuring the types and concentrations of organic oxidation by-products and ozone in a 1296 cubic foot test space and a 3656 cubic foot test space. Air samples were taken in hourly intervals for up to fifteen hours. In summary, the data indicated that:

- No carbon monoxide was detected above baseline levels
- Formaldehyde, acetaldehyde and other target aldehydes remained at or marginally above background concentrations
- No significant concentrations of oxidized volatile organic compounds (VOC) were formed
- Ozone reached a steady state concentration of ~19 ppb in the smaller chamber and ~14 ppb in the larger chamber. The highest oxidant levels resulted from

using both optics with the fan at the low setting. These are the settings used by the MDU/Rx™ device.

Additional ozone measurement were conducted by HGI in a range of typical, normally ventilated treatment areas (3-6 exchange rates per hour) representative of those found in medical facilities. Measurements were also made without ventilation. The spaces ranged from ~1190 to 4102 cubic feet (~130 sf to ~450 sf with 8-9 foot ceilings). Testing times varied from 3 to 24 hours. Ozone (total oxidant) levels remained below 50 ppb for all tests.

**Mode of Action**

The primary mode of action for the MDU/Rx™ unit and its predicates is to sanitize air as it passes through the photolysis chamber by direct exposure to UV radiation with wavelengths between ~100-285 nm. The primary bactericidal mode of action of UV-C radiation results from the penetration of radiation into the interior of the cell where it is absorbed by key biochemicals. The UV radiation damages the RNA, DNA and other organic moieties within the cell preventing cell replication and causing cell death.

A secondary mode of action results from the formation of hydroxyl radicals within the photolysis chamber by the action of UV-C radiation with oxygen and water vapor in ambient air. The hydroxyl radicals react rapidly (within a second) with the lipids and proteins on the surface of the cells, causing the contents of the cell to leak and the cell to die.

**MDU/Rx™ Device Effectiveness as an Air Sanitizer**

The efficacy of the MDU/Rx™ device as an air sanitizer was determined by measuring the kill rates of selected aerosolized bacteria and virus. Studies of the kill rates of the following aerosolized microorganisms by the MDU/Rx™ unit were done for HGI by Aerosol Research and Engineering Laboratories (ARE, Overland Park, Kansas). The testing was conducted in a 563 cubic foot sterile stainless steel test clean-room chamber into which specified concentrations of aerosolized bacteria and virus were introduced.

- Staphylococcus epidermidis – a gram positive bacterium used as an index organism for Staphylococcus aureus; considered as representative of its class

- Erwinia herbicola – a gram negative bacterium used as an index organism for Escherichia coli; considered as representative of its class

  (Note: E. coli was tried but it proved too fragile to remain viable in an aerosol long enough to establish a stable baseline.)

- MS2 virus – a bacteriophage that infects E.coli that is used as a surrogate for mammalian influenza

- Phi-X174 virus – a DNA based bacteriophage that infects E.coli that is used as a surrogate model for HIV, HCV

Controls were run to establish a stable baseline of aerosolized microorganisms. Kill rates were measured in triplicate at regular intervals by sampling air from the chamber

until a 4-5 log reduction in viable organism was measured. The MDU/Rx™ resulted in a 4 log or greater kill rate for all organisms tested within two hours.

**Conclusion:**
The performance testing demonstrates that the MDU/Rx™ medical device is substantially equivalent to the FDA approved claimed predicate devices, the RxAir 3000 and the ECO RX-400.

**Footnotes**

1. "The History of Ultraviolet Germicidal Irradiation for Air Disinfection", Nicholas G. Reed, Public Health Rep. 2010 Jan-Feb; 125(1): 15-27.


# ARE實驗室 - 各種病菌氣溶膠

| ODOROX® MDU/Rx™ System | |
|---|---|
| Picture: |  |
| Device Features | |
| Manufacturer: | HGI Industried Inc. |
| Model: | Mobile Disinfection Unit (MDU) |
| Notes: | Hydroxyl Air Processor |

***Figure 1:*** *ODOROX® Mobile Disinfection Unit (MDU/Rx™).*

### Bioaerosol Testing Chamber

A large sealed aerosol test chamber was used to replicate a potentially contaminated room environment and to contain any potential release of aerosols into the surrounding environment.

The aerosol test chamber is constructed of 304 stainless steel and is equipped with three viewing windows and an air-tight lockable chamber door for system setup and general ingress and egress. The test chamber internal dimensions are 9.1ft x 9.1ft x 6.8ft, with a displacement volume of 563 cubic feet, or 15,933 liters.

The chamber is equipped with filtered HEPA inlets, digital internal temperature and humidity monitor, external humidifiers (for humidity control), lighting system, multiple sampling ports, aerosol mixing fans, and an HEPA filtered exhaust system that are operated with wireless remote control. For testing, the chamber was equipped with four 3/8 inch diameter stainless steel probes for aerosol sampling, a 1 inch diameter port for bio-aerosol dissemination into the chamber using a Collison 24-jet nebulizer for the bacteriophages and vegetative cells, or a Fox dry powder eductor for the fungal spores. A ¼ inch diameter probe was used for continuous aerosol particle size monitoring via a TSI Aerodynamic Particle Sizer (APS) model 3321. All sample and dissemination ports were inserted approximately 18 inches from the interior walls of the chamber to avoid wall effects and at a height of approximately 40 inches from the floor.

The aerosol sampling and aerosol dissemination probes are stainless steel and bulk headed through the chamber walls to provide external remote access to the aerosol generator and samplers during testing.

The test chamber is equipped with two high-flow HEPA filters for the introduction of filtered purified air into the test chamber during aerosol evacuation/purging of the system between test trials and a HEPA filtered exhaust blower with a 500 $ft^3$/min rated flow capability for rapid evacuation of remaining bioaerosols.

A magnehelic gauge with a range of 0.0 +/- 0.5 inch $H_2O$ (Dwyer instruments, Michigan City IN) was used to monitor and balance the system pressure during aerosol generation, aerosol purge and testing cycles.

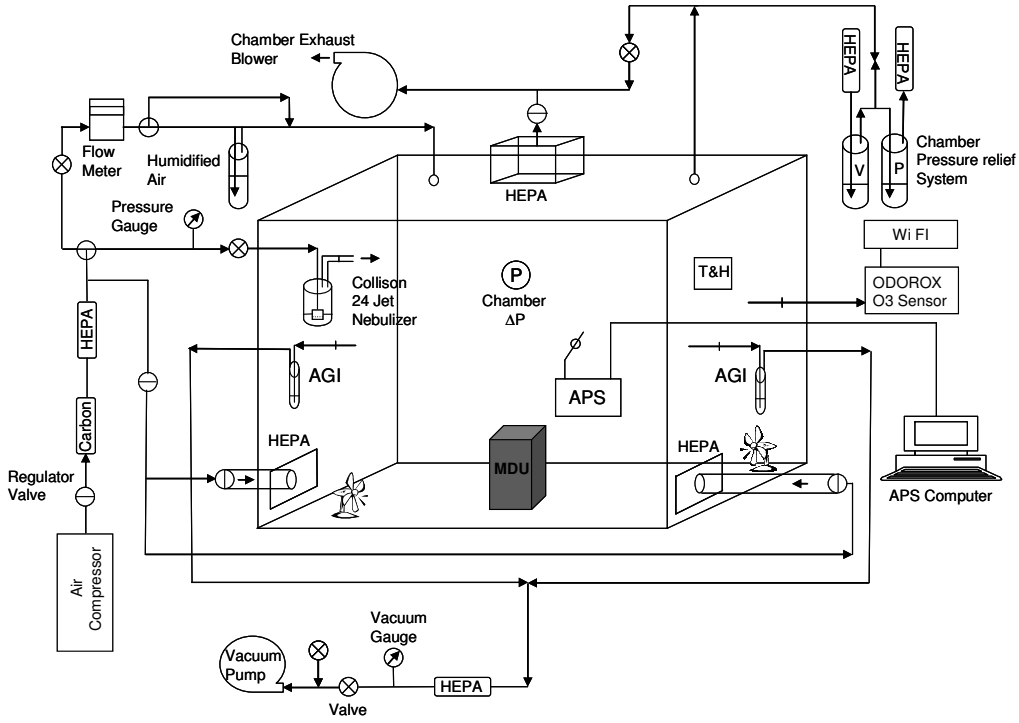



***Figure 2:*** *Bio-Aerosol Test Chamber Flow Diagram.*

## Bioaerosol Generation System

Test bacteriophage and vegetative bioaerosols were disseminated using a Collison 24 jet nebulizer (BGI Inc. Waltham MA) driven by purified filtered house air supply. A pressure regulator allowed for control of disseminated particle size, use rate and sheer force generated within the Collison nebulizer.

Prior to testing, the Collison nebulizer flow rate and use rate were characterized using an air supply pressure of approximately 28-50 psi, which obtained an output volumetric flow rate of 50-80 lpm with a fluid dissemination rate of approximately 1-2 ml/min. The Collison nebulizer was flow characterized using a calibrated TSI model 4040 mass flow meter (TSI Inc, St Paul MN).

A Fox dry powder eductor was used for the dissemination of dry *A. niger* spores using purified filtered house air. Eductor air supply pressure was regulated at 50 psi with a volumetric flow rate of 30 lpm.

## Bioaerosol Sampling and Monitoring System

A pair of AGI impingers (Ace Glass Inc. Vineland NJ) was used for bio-aerosol collection of viral and vegetative aerosols. The fungal spores we collected with a 47mm 0.22um Tisch Scientific MCE in line filter with sample flow rates controlled and monitored using a valved Emerson 1/3 hp rotary vane vacuum pump (Emerson Electric, St. Louis, MO) equipped with a 0-30 inHg vacuum gauge (WIKA Instruments, Lawrenceville, GA).

The AGI-30 impinger vacuum source was maintained at a negative pressure of 18 inches of Hg during all characterization and test sampling to assure critical flow conditions. The AGI-30 sample impingers were flow characterized using a calibrated TSI model 4040 mass flow meter. Filter sample flow rates were maintained and monitored at 12.5 lpm using an in line calibrated TSI model 4040 mass flow meter.

Aerosol particle size distributions and count concentrations were measured in real-time through the duration of all control and MDU/Rx™ trial runs using a model 3321 Aerodynamic Particle Sizer (APS) (TSI Inc, St Paul, MN). The APS sampled for the entire duration of all trials (2-6 hours) with 1 minute sampling intervals. A general flow diagram of the aerosol test system is shown above in Figure 2.

## Species Selection

Two vegetative bacteria were chosen for the study as simulants for a broad range of pathogenic bacteria. The first vegetative organism used for this study was *Staphylococcus epidermidis* (ATCC 12228). *Staphylococcus epidermidis* is a Gram-positive bacterium and simulant for a wider range of medically significant pathogens such as *Staphylococcus aureus*.

*Erwinia herbicola* (ATCC 39049), renamed Pantoea agglomerans, is a Gram-negative bacterium which is commonly used as a simulant for *Francisella tularensis* and *Yersinia pestis* (bubonic plague).

Two representative BSL1 viruses were chosen to evaluate the MDU/Rx™'s performance against both RNA and DNA based viruses. *MS2 bacteriophage* (ATCC 15597-B1) is positive-sense, single-stranded RNA virus that infects the bacterium Escherichia coli and other members of the Enterobacteriaceae family. MS2 is routinely used as a simulant for pathogenic RNA viruses.

*Phi-X174* (ATCC 13706-B1) *bacteriophage* is a circular single stranded DNA based virus that infects the bacterium *Escherichia coli*. Phi-X174 was selected as a simulant for DNA based pathogenic viruses.

*Aspergillus niger* (ATCC 16404) or *A. niger* is one of the most common species of the genus *Aspergillus*. *A. niger* is routinely defined as a troublesome black mold and has been attributed to many respiratory problems for infants, elderly and immune compromised individuals. Purified *A. niger* spores were obtained in bulk dry powder with an approximate concentration of 1 x $10^9$ cfu/gram.

*Bacillus subtilis* is a Gram positive bacterium found in soil and the gastrointestinal tract of ruminants and humans. *Bacillus subtilis* is a member of the genus Bacillus and is a commonly used in research as a surrogate for *B. anthracis*. *B. subtilis* is rod-shaped, and can form a tough, protective endospore, which allows it to tolerate extreme environmental conditions.

## Vegetative Cells Culture & Preparation

Pure strain seed stocks were purchased from ATCC (American Type Culture Collection, Manassas VA). Working stock cultures were prepared using sterile techniques in a class 2 biological safety cabinet and followed standard preparation methodologies. Approximately 250mL of each biological stock was prepared in tryptic soy liquid broth media, and incubated for 24 – 48 hours with oxygen infusion (1cc/min) at 37°C. Biological stock concentrations were greater than 1 x $10^9$ cfu/ml for both *Staphylococcus epidermidis* and *Erwinia herbicola* using this method.

Stock cultures were centrifuged for 20 minutes at 5000 rpm in sterile 15mL conical tubes, growth media was removed, and the cells re-suspended in sterile PBS buffer for aerosolization. Aliquots of these suspensions were enumerated on tryptic soy agar plates (Hardy Diagnostics, Cincinnati OH) for viable counts and stock concentration calculation. For each organism, test working stocks were grown in sufficient volume to satisfy use quantities for all tests conducted using the same culture stock material.

## Viral Culture & Preparation

Pure strain viral seed stock and host bacterium were obtained from ATCC. Host bacterium was grown in a similar fashion to the vegetative cells in an appropriate liquid media. The liquid media was infected during the logarithmic growth cycle with the specific bacteriophage. After an appropriate incubation time the cells were lysed and the cellular debris discharged by centrifugation. MS2 stock yields were greater than 1 x $10^{11}$ plaque forming units per milliliter (pfu/ml) with a single amplification procedure. Phi-X174, due to its much lower burst size, required multiple amplification steps to produce satisfactory viral yields. After amplification the cells were lysed and the cellular debris separated from the liquid media and discarded. Phi-X174 viral yields were plated and enumerated and yielded viable concentrations greater than 1 x $10^8$ pfu /ml in the stock used for aerosolization.

## Fungal Spore Culture & Preparation

*A. niger* fungal spores were obtained in purified bulk powder form at a concentration of 1 x $10^9$ cfu/g. To verify the bulk powder spore concentration, an aliquot of weighed dry powder was prepared in suspension in PBS + 0.005% Tween 80 at a mass: volume ratio to obtain a concentration of 1 x $10^9$ cfu/ml. The spore suspension was serial diluted, plated on TSA plates and incubated at 30°C for 48 hours.

Plates were enumerated and bulk powder spore concentration was verified to be in the range of 1 x $10^9$cfu/g. Calculations were performed to obtain mass use needed to generate aerosol test challenge chamber concentrations in the range of 1 x $10^6$cfu/L for testing the *ODOROX® MDU/Rx™ System.*

### *Bacillus Subtilis* Spore Culture & Preparation

*B. Subtilis* spores were obtained in purified bulk powder form at a concentration of 1 x $10^9$ cfu/g. To verify the bulk powder spore concentration, an aliquot of weighed dry powder was prepared in suspension in PBS + 0.005% Tween 80 at a mass: volume ratio to obtain a concentration of 1 x $10^9$ cfu/ml.

The spore suspension was serial diluted, plated on TSA plates and incubated at 30°C for 24 hours. Plates were enumerated and bulk powder spore concentration was verified to be in the range of 1 x $10^9$cfu/g. Calculations were performed to obtain mass use needed to generate aerosol test challenge chamber concentrations in the range of 1 x $10^6$cfu/L for testing the *ODOROX® MDU/Rx™ System.*

### Plating and Enumeration

Impinger and stock biological cultures were serially diluted and plated in triplicate (multiple serial dilutions) using a standard spread plate assay technique onto tryptic soy agar plates. The plated cultures were incubated for 24 hours and enumerated and recorded.

Bacteriophage samples and stock were plated using the small drop plaque assay techniques outlined by A. Mazzocco, T. Waddell, E Lingohr and R. Johnson. The plates were then incubated 8-12 hours and enumerated. All colonies and plaques counts were manually enumerated and recorded.

Bulk powder working stock *Aspergillis* spores were concentration verified prior to testing using the small drop technique. Test spore sample filters were placed in 50ml conical tubes and spores were extracted in 20 ml of sterile PBS buffer + 0.005% Tween 80. Samples were plated using the small drop technique on TSA agar plates. The plates were incubated at 30°C for 24-48 hours and enumerated.

| Trial | Run | Species (gram, description) | ATCC Ref | Target Mondispersed Particle Size | Challenge Conc. (#/ft$^3$) | Total Trial Time (min) | Impinger Sample Time (min) | Sampling |
|---|---|---|---|---|---|---|---|---|
| 1 | Control | *E. coli* | 11229 | 2.5 um | $10^4$-$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Impinger Train |
| 2 | Challenge | *(+; vegetative)* | | | | | | |
| 3 | Challenge | | | | | | | |
| 4 | Challenge | | | | | | | |
| 5 | Control | *Staphylococcus epidermidis* | 12228 | 1.5-2.0 um | $10^4$-$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Impinger Train |
| 6 | Challenge | *(+, vegetative)* | | | | | | |
| 7 | Challenge | | | | | | | |
| 8 | Challenge | | | | | | | |
| 9 | Control | *Phi-X174 phage* | 13706 | <1.0um | $10^4$-$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Impinger Train |
| 10 | Challenge | *(E. coli phage)* | | | | | | |
| 11 | Challenge | | | | | | | |
| 12 | Challenge | | | | | | | |
| 13 | Control | *MS2 bacteriophage* | 15597-B1 | <1.0um | $10^4$-$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Impinger Train |
| 14 | Challenge | *(E. coli phage)* | | | | | | |
| 15 | Challenge | | | | | | | |
| 16 | Challenge | | | | | | | |
| 17 | Control | *Aspergillis niger* | 16404 | 3.5-4.0 um | >$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Filter Samples |
| 18 | Challenge | *(mold, spore forming)* | | | | | | |
| 19 | Challenge | | | | | | | |
| 20 | Challenge | | | | | | | |
| 21 | Control | *Bacillus Subtilis* | | 2.0-3.0 um | $10^4$-$10^6$ | 120 | 0,30,60,90,120 | APS, Ozone, Impinger Train |
| 22 | Challenge | *(endospores)* | | | | | | |
| 23 | Challenge | | | | | | | |
| 24 | Challenge | | | | | | | |

***Table 1:*** *Test Matrices for all trials.*

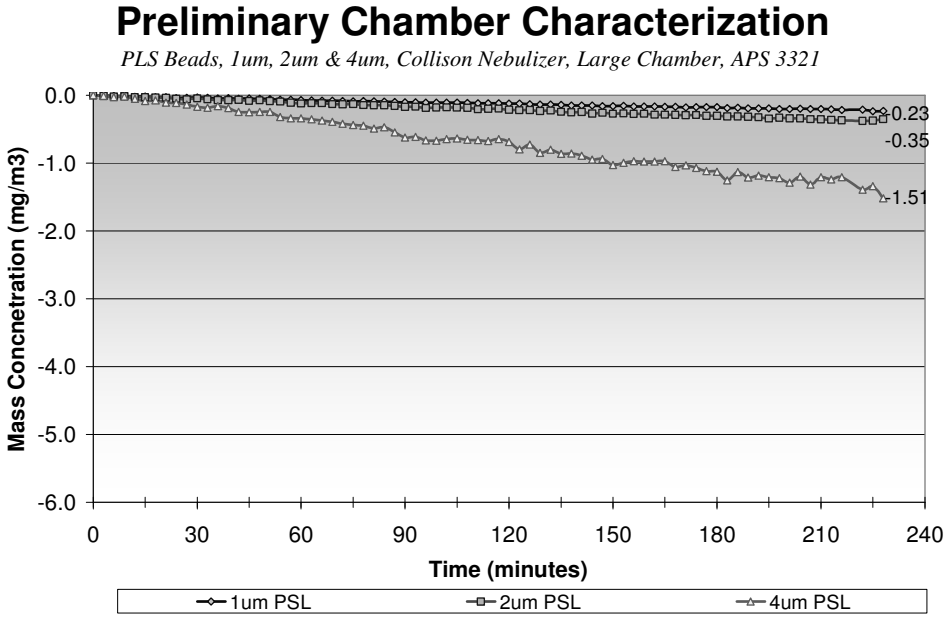



***Figure 3:*** *Chamber Characterization using various sizes of PSL beads.*

## Chamber Characterization

In order to calculate the dissemination efficiency and stability of the bioaerosol, polystyrene latex beads (PSL beads) were used to characterize the various aspects of the chamber system. PSL beads with aerodynamic diameters of 1.0µm, 2.0µm and 4.0µm were nebulized and chamber concentrations were recorded using the APS. Nebulization efficiencies, particle stability and AGI-30 collection efficiencies were used to estimate generation efficiencies, dissemination times, sample times and aerosol persistence prior to bioaerosol testing.

## Control Testing

To accurately assess the ODOROX® MDU/Rx™ unit, a test chamber pilot control test was performed with each biological over 4 to 6 hour periods without the ODORDOX® MDU/Rx™ in operation to characterize each biological challenge aerosol for particle size distribution, aerosol delivery/collection efficiency, and viable concentration over time. Control testing was performed to provide baseline comparative data in order to assess the actual reduction from MDU/Rx™ challenge testing and verify that viable bioaerosol concentrations persisted above the required concentrations over the entire pilot control test period.

During control runs, two low velocity fans located in the corners of the bioaerosol test chamber were turned on for the duration of impinger sampling and filter sampling to ensure that a homogenous aerosol sample was collected. The two impingers used for bacteriophage, vegetative, and bacterial endospore test sampling were pooled and mixed prior to plating and enumeration. Filter samples used for fungal spore test sampling were extracted in 20ml of PBS buffer + 0.005% Tween 80 and vortexed for 5 minutes prior to plating.

## ODOROX® MDU/Rx™ Testing

Six challenge biological organisms: *Staphylococcus epidermidis* (ATCC 12228), *Erwinia herbicola* (ATCC 39049), *MS2* bacteriophage (ATCC 15597-B1), *Phi-X174* bacteriophage (ATCC 13706-B1), *Aspergillus niger* (ATCC 16404), and *Bacillus Subtilis* were used for testing the viable reduction capacity of the ODOROX® MDU/Rx™ unit against the broad spectrum bioaerosols. Aerosol decontamination testing was performed in triplicate for each biological with the addition of a pilot control test for each organism (24 total tests). The complete test matrix for the study is shown in Table 1 (page 5).

For each control and challenge test, excluding *A. niger*, the Collison nebulizer was filled with

**General Timeline for Bioaerosol Chamber Testing**

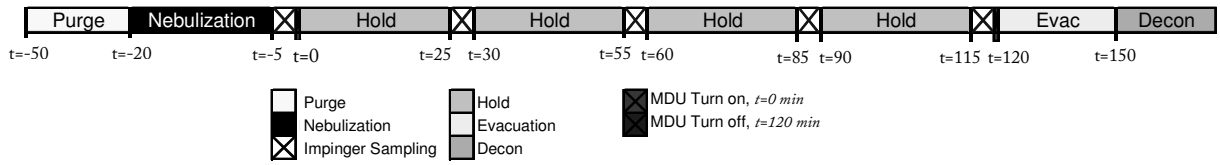



***Table 2:*** General *Trial Timeline for MDU/Rx™ Decontamination Trials.*

approximately 40 mL of biological stock and operated at 28-50 psi for a period of 20 or 25 minutes (organism dependent). For control and MDU/Rx™ trials, the impingers were filled with 20 mL of sterilized PBS (addition of 0.005% v/v Tween 80 for Phi-X174 and *B. subtilis*) for bioaerosol collection. The addition of Tween 80 was shown to increase the impinger collection efficiency of Phi-X174 and de-agglomeration of *B. subtilis*.

For *A. niger* control and MDU/Rx™ trials, the Fox eductor was filled with approximately 2 grams of gravimetrically weighed purified dry spores and operated at 50psi for 5 minutes.

Chamber mixing fans were turned on during bioaerosol dissemination to assure a homogeneous bioaerosol concentration in the test chamber prior to the first impinger or filter sample. Mixing fans were not used for subsequent MDU/Rx™ AGI or filter sampling because the MDU/Rx™ system has its own internal mixing fan.

Following bioaerosol generation, baseline bioaerosol concentrations were established for each pilot control and ODOROX® MDU/Rx™ test by sampling simultaneously with two AGI-30 impingers or filters located at opposite sides of the chamber. AGI samples were collected for 5 or 10 minutes (organism dependent) and filter samples were collected for 10 minutes with subsequent 5 or 10 minute samples taken at intervals of 30 minutes throughout the entire period. Table 2 below shows the general timeline for each MDU/Rx™ live bioaerosol challenge trial.

Collected impinger samples were pooled and mixed at each sample interval for each test, and an aliquot pulled for plating and enumeration of viable concentration. Impingers were rinsed 3x with sterile filtered water between each sampling interval, and re-filled with sterile PBS using sterile graduated pipettes for sample collection. Filter samples used for *Aspergillis* spore only aerosol collection were placed in sterile 50 ml conical tubes, extracted in 20ml of PBS + 0.005% Tween 80 and an aliquot pulled for plating and enumeration of viable concentration.

The filter holders were rinsed with isopropyl alcohol, dried with filtered compressed air, and reloaded with a sterile filter between each sample point.

For ODOROX® biological testing, the unit was turned on immediately following a time 0 baseline sample and operated for the entirety of the test (120 minutes). Subsequent impinger samples or filter samples were taken at intervals of 30 to 60 minutes and samples enumerated for viable concentration to measure the effective viable bioaerosol reduction during operation of the ODOROX® system over time.

Test chamber temperature and humidity were recorded at the initiation and completion of each test. The Collison nebulizer stock volume and use rate were also measured gravimetrically. Impingers were tared on a microbalance, and reweighed after each sample period for net collection media mass and accurate calculation of collected concentration. All samples were plated in triplicate on tryptic soy agar media over a minimum of a 3 log dilution range.

Plates were incubated for viable plaque forming units (pfu) formation for the viral phase of the study, and colony forming units (cfu) for fungal spore, and bacterial endospore phases of the study. Plates were incubated and enumerated for viable counts to calculate aerosol challenge concentrations in the chamber and reduction of viable microorganisms.

### Post-Testing Decontamination and Prep

Following each test, the chamber was air flow evacuated/purged for a minimum of twenty minutes between tests and analyzed with the APS for particle concentration decrease to baseline levels between each test. The chamber was decontaminated between live microorganism trials with vaporous hydrogen peroxide. The Collison nebulizer, impingers, and filter holders were cleaned at the conclusion of each

day of testing by soaking in a 10% bleach bath for 20 minutes. The nebulizer, impingers and filter holders were then submerged in a DI water bath, removed, and spray rinsed 10x with filtered DI water until use.

## Bioaerosol Particle Size Data

Aerosol particle size distributions were measured with the APS. The APS has a dynamic measurement range of 0.5 to 20µm and was programmed to take consecutive real time one minute aerosol samples throughout the duration of each aerosol trial.

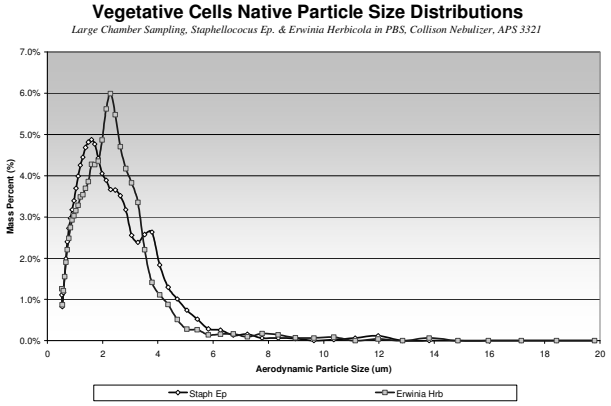



***Figure 3:*** *Vegetative Cells Particle Sized Distribution in Test Chamber.*

Data was logged in real time to an Acer laptop computer, regressed, and plotted. Aerosol particle size distributions showing each bioaerosol are shown in Figures 3 and figure 4 and 5.

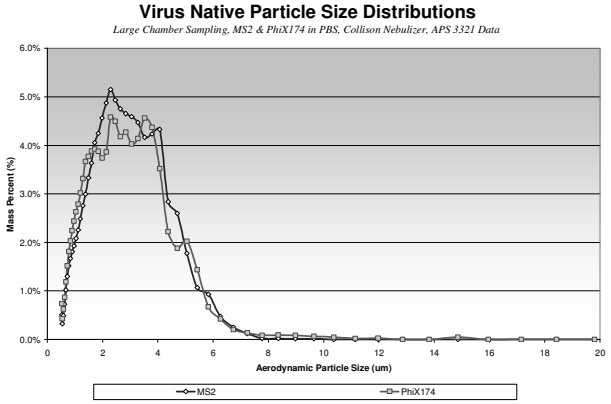



***Figure 4:*** *Viral Particle Size Distribution in Test Chamber.*

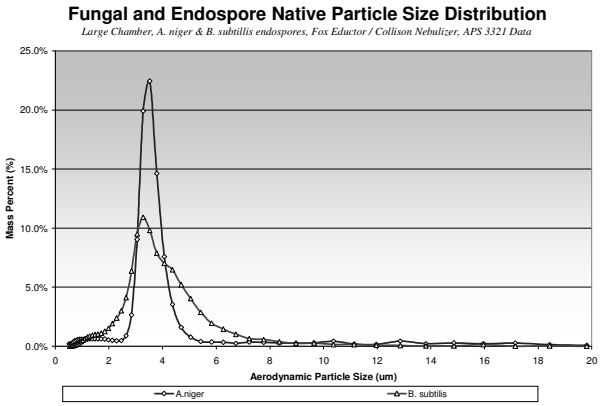



***Figure 5:*** *Fungal Spores and Endospore Particle Size Distribution in Test Chamber.*

The particle size distributions for each bioaerosol are shown to be within the respirable range for alveolar region tract lung deposition and show a low geometric standard deviation (GSD) indicating a monodispersed aerosol was generated into the test chamber. Figure 6 shows a summary of the MMAD and GSD for each challenge organism.

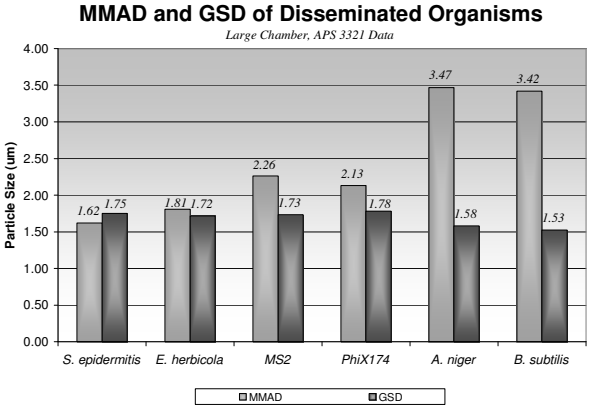



*Figure 6: MMAD and GSD of Bioaerosols*

## MDU/Rx™ Vegetative Bioaerosol Results

Results from the control trials were graphed and plotted to show natural viability loss over time in the chamber. These control runs served as the basis to determine the time required for MDU/Rx™ to achieve a 4 log reduction in viable bioaerosol above the natural losses from the control runs. The control and trial runs are plotted showing log reduction in viable bioaerosol for each organism. All data is normalized with time zero (*t=0* minutes) enumerated concentrations. Subsequent samples are normalized and plotted to show the loss of viability over time (Figures 7, 8, 9, 10, 11 and 12).

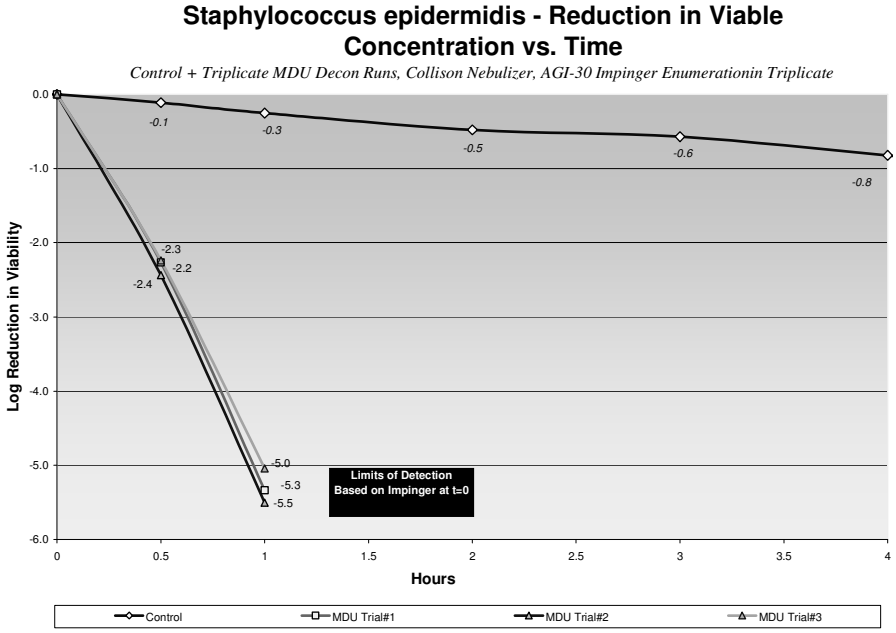



***Figure 7:*** *S. Epidermidis Control and MDU/Rx™ trial Log Reduction in Viable Concentration.*

It was demonstrated that stability for *S. epidermidis* during the control runs was excellent even at extremely high concentrations. Chamber viable aerosol concentrations were greater than 1 x $10^5$ cfu/liter or 2.8 x $10^6$ cfu/ft$^3$ for all trials.

The viable concentration within the aerosol chamber decreased over a period of 4 hours and showed a loss in viable aerosol of approximately 0.8 logs for the control run. In contrast, the MDU/Rx™ trials showed a viable bioaerosol reduction of 5.0, 5.3 and 5.3 logs for each trial in 1 hour.

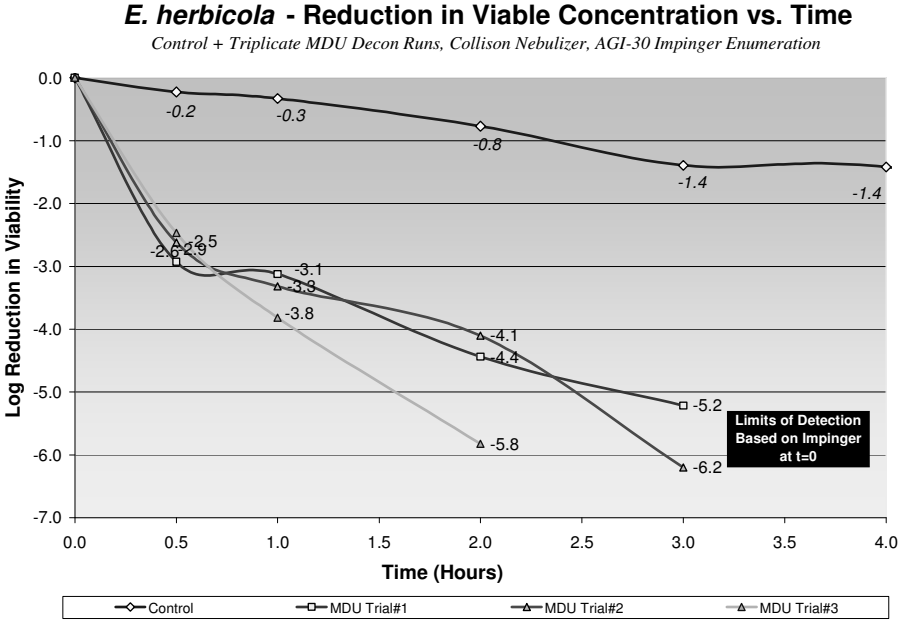



***Figure 8:*** *E. herbicola Control and MDU/Rx™ trial Log Reduction in Viable Concentration.*

After 1 hour all subsequent impinger samples (t=90 and 120 minutes) plated neat showed no colony growth. Total viable reduction of airborne *S. epidermidis* was 5.0 +/ 0.2 logs (Avg. +/- STdev) above the control run at 1 hour. Limits of detection were not able to resolve the continued reduction at the 90 and 120 minute mark. Figure 7, shows the results of the control and triplicate Staphylococcus MDU/Rx™ trial runs.

*E. herbicola* stability was similar to that of the *S. epidermidis*. The control run showed that over a 4 hour period, approximately 1.4 log reduction in viable aerosol was observed. Chamber initial aerosol concentrations were high for all MDU/Rx™ trials and averaged 3.62 x $10^5$ cfu/l or 1.02 x $10^7$ cfu/$ft^3$ for the t=0 impinger sample.

The triplicate MDU/Rx™ trials showed a viable *E. herbicola* reduction of 6.2, 5.2 and 5.8 logs within 90-120 minutes. Figure 8, shows the results of the control and triplicate *Erwinia herbicola* MDU/Rx™ trial runs. The MDU/Rx™ unit was able to reduce the viable bioaerosol concentrations 5.0 +/-0.5 logs (Avg +/- STdev) over the control runs in approximately 180 minutes..

### MDU/Rx™ Viral Bioaerosol Results

Results from the control trials were graphed and plotted in a similar fashion to vegetative cell bioaerosol testing with the control runs plotted alongside the MDU/Rx™ live challenge triplicate runs.

Testing results with MS2 bacteriophage (figure 9) showed that the MDU/Rx™ showed viable reductions of 6.2, 5.9 and 6.6 log for the triplicate trials. This was in contrast to the control run which showed a 0.9 log reduction after 3 hours. The adjusted viable reduction after subtracting the control run reduction showed that the MDU/Rx™ reduced the viable MS2 aerosol by 4.9 +/- 0.3 logs (Avg. +/- STdev) in the 90-180 minutes timeframe.

Similar results were observed for the DNA phage Phi-X174. The MDU/Rx™ trials (figure 10) showed a 5.0, 5.1 and 5.1 log reduction in 2 hours compared to the control which had a 1.1 log reduction in the same timeframe. MDU/Rx™ showed a net of 4.0 +/- 0.1 log (Avg. +/- STdev) reduction above the baseline control trial.

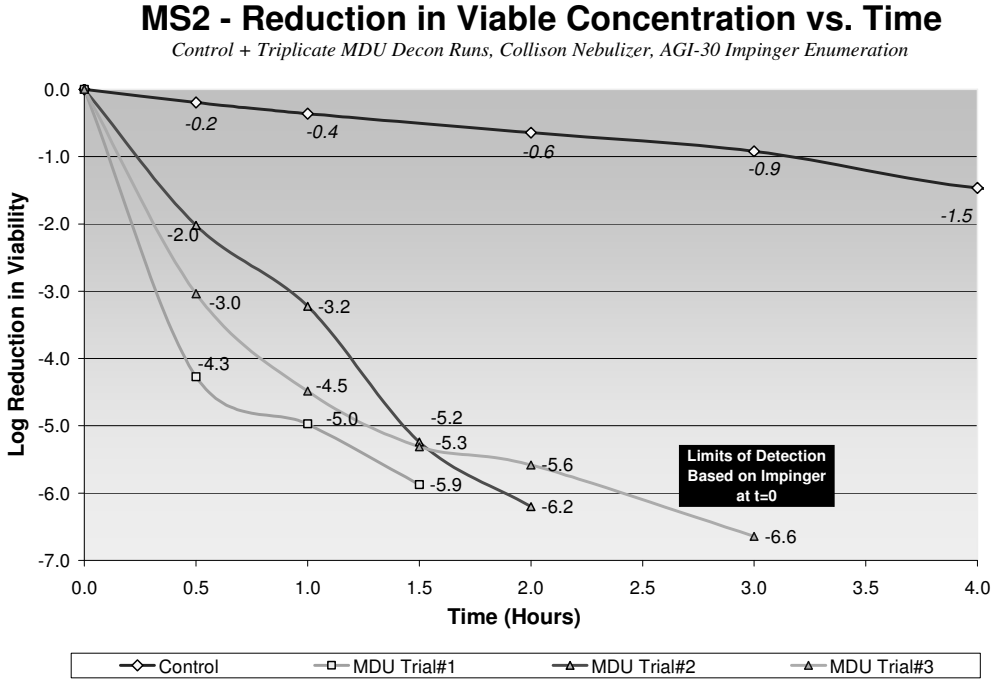



***Figure 9:*** *Bacteriophage MS2 Control and MDU/Rx™ trial Log Reduction in Viable Concentration.*

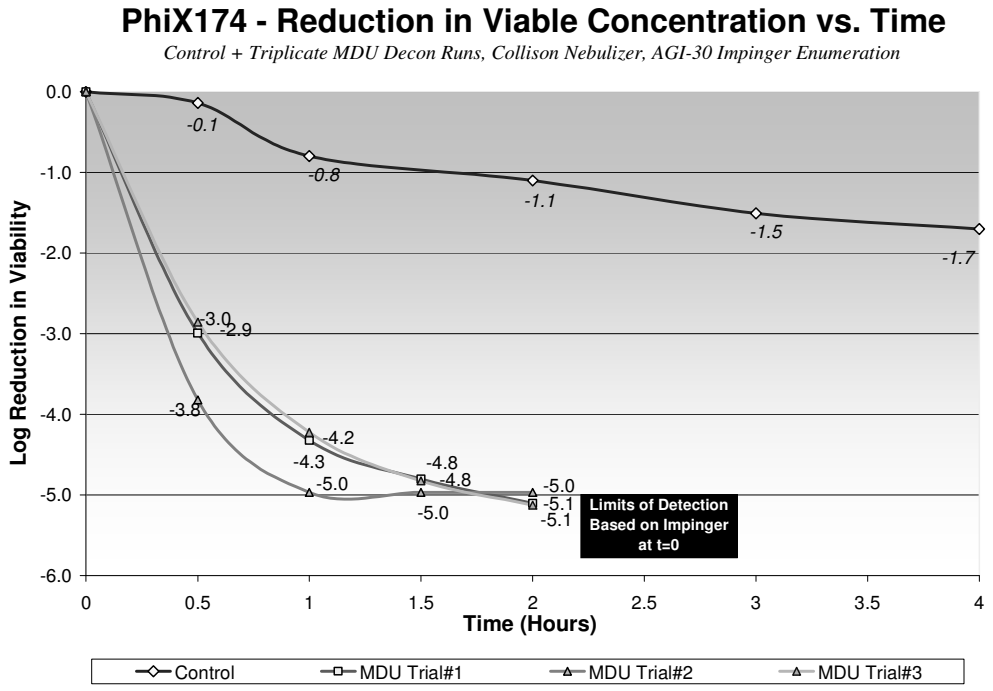



***Figure 10:*** *Bacteriophage MS2 Control and MDU/Rx™ trial Log Reduction in Viable Concentration.*

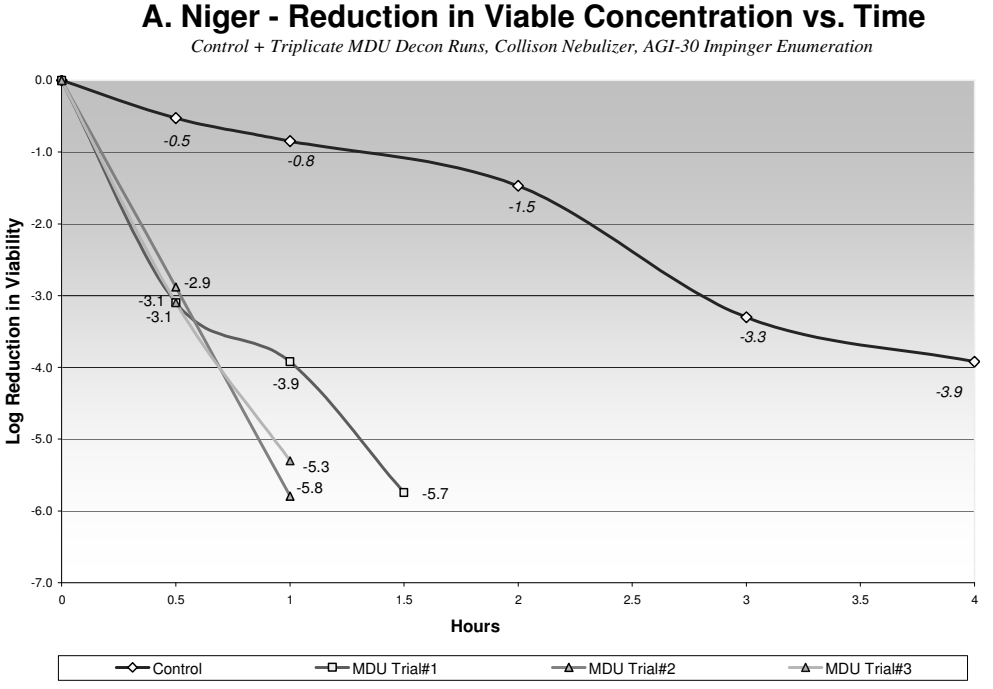



***Figure 11:*** *Aspergillus niger spores Control and MDU/Rx™ trial Log Reduction in Viable Concentration.*

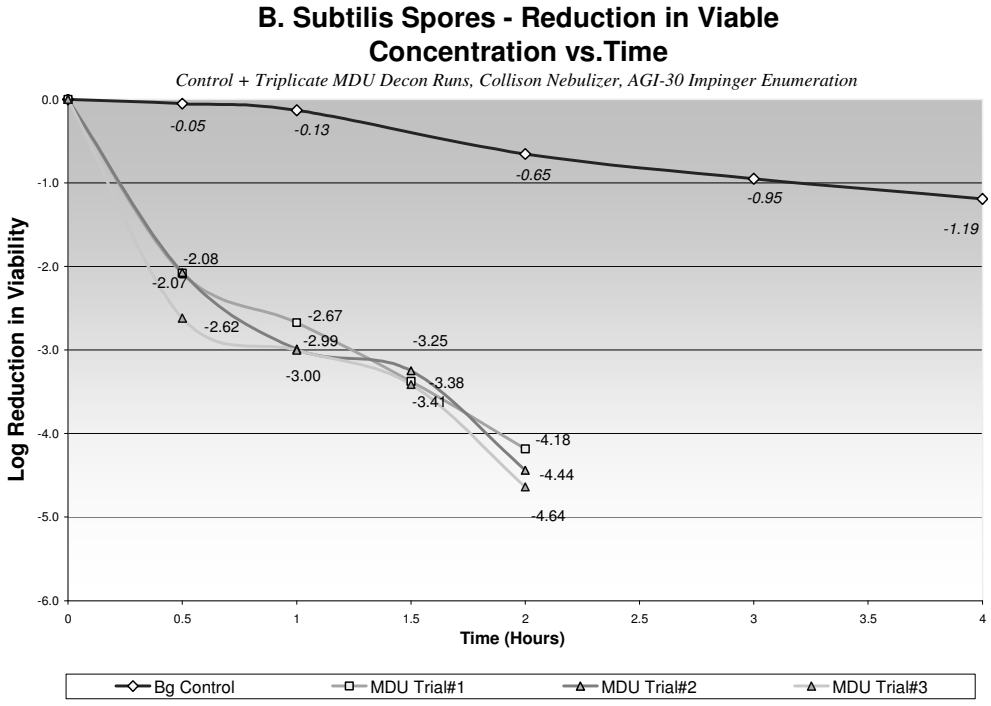



***Figure 12:*** B. Subtilis *Control and MDU/Rx™ Trial Log Reduction in Viable Concentration.*

## MDU/Rx™ Aspergillus Spore Bioaerosol Results

*A. niger* stability was poor over the 4 control a loss of 3.9 log was measured in the chamber. This could possibly be due to a net surface charge on the bioaerosol due to the dry powder dissemination technique. However, stability in under 2 hours was adequate to show the 4 log net reduction during the MDU trials. Chamber initial aerosol concentrations were high for all MDU/Rx™ trials and averaged 5.62 x $10^5$ cfu/l for the t=0 impinger sample.

Test results shown in figure 11 for *A. niger* reflect the MDU/Rx™ trials showed a 5.8, 5.3 and 5.7 log reduction in 1.5 hours or less compared to the control which had a 1.1 log reduction in the same timeframe. MDU/Rx™ testing showed a net of 4.7 +/- 0.3 log (Avg. +/- STdev) reduction above the baseline control trial.

## MDU/Rx™ Endospore Bioaerosol Results

*B. subtilis endospore* stability was excellent over the 4 hour control run period. The control run showed that over a 4 hour period, approximately 1.19 log reduction in viable aerosol was observed. Chamber initial aerosol concentrations were high for all MDU/Rx™ trials and averaged 1.27 x $10^5$ cfu/l for the t=0 impinger samples.

Test results shown in figure 12 for *B. Subtilis* reflect the MDU/Rx™ trials showed a 4.18, 4.44 and 4.64 log reduction in 2.0 hours or less compared to the control which had a 0.65 log reduction in the same timeframe. MDU/Rx™ testing showed a net of 3.8 +/- 0.2 log (Avg. +/- STdev) reduction above the baseline control trial.

## Summary of Findings

Test results show that the ODOROX® MDU/Rx™ system was extremely effective at reducing viability of bioaerosols in all conducted trials. Results from the control baseline viability tests show very stable viable aerosol persistence in the chamber with minimal losses in viability related to environmental conditions or chamber deposition.

MDU/Rx™ System's efficacy of reduction of *S. epidermidis* viability, after correcting for control run losses were 5.0 +/- 0.2 logs (average +/- standard deviation) in 2 hours or less.

MDU/Rx™ System's efficacy against *E. herbicola* bioaerosol, after correcting for control run viability losses, were 5.0 +/- 0.5 log (Avg +/- STdev) in 2 hours or less.

MS2's reduction in viable bioaerosol concentrations within the chamber, after correcting for control run viability losses, were 4.9 +/ 0.3 logs (Avg +/- STdev) in 2 hours or less. A single MDU/Rx™ trial was also ran for 3 hours and this showed a viability loss of 5.7 logs after correcting for control run losses.

PhiX174's reduction in viable aerosol, correcting for control run losses, yielded 4.0 +/- 0.1 logs (Avg +/- STdev) in 2 hours.

*A. niger* reduction in viable aerosol, correcting for control run losses, yielded 4.7 +/- 0.3 logs (Avg +/- STdev) in 1.5 hours.

*B. Subtilis* reduction in viable aerosol, correcting for control run losses, yielded 3.8 +/- 0.2 logs (Avg +/- STdev) in 2.0 hours.

In summary the ODOROX® MDU/Rx™ showed 4 logs or greater reduction in viable bioaerosols for all biological challenges in 3 hours or less for all tested organisms. Although a 4 log reduction for *B. subtilis* was not achieved in the 2.0 hour disinfection testing period as compared to the other organisms, extrapolation of the data to 2.5 hours would result in a greater than 4 log reduction in viability for all tests. Figure 12 shows the net log reduction in all bioaerosols after correction for control run viability losses.

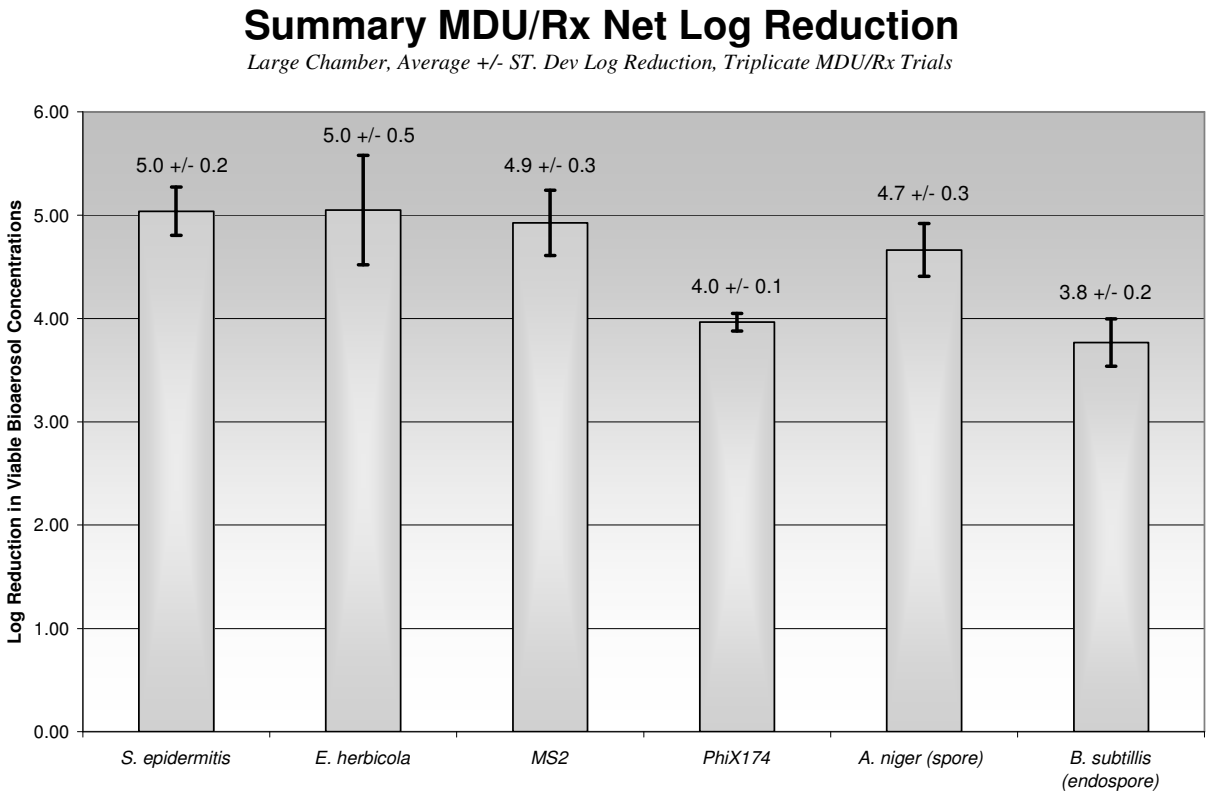



***Figure 12:*** *Summary of Net log reduction of Viable Bioaerosol concentration for MDU/Rx™.*

## References

T. Reponen, K. Willeke, V. Ulevicius et al. *Techniques of Dispersion of Microorganisms in Air.* Aerosol Science and Technology. 27: 1997. pp. 405-421.

Ding and Wing. *Effects of Sampling Time on the Total Recovery rate of AGI-30 Impingers for E. coli.* Aerosol and Air Quality Research, Vol. 1, No. 1, 2001, pp. 31-36.

Flint et al. *Principles of Virology.* Principles of Virology (ASM). Chapter 2 Virological Methods. Vol. 2. 2008.

J.F. Heildelberg et al. *Effects of Aerosolization on Culturabilty and Viability of Gram-Negative Bacteria.* Applied and Environmental Microbiology. Sept 1997, p 3585-3588.

A. Mazzocco et al. *Enumeration of Bacteriophages Using the Small Drop Plaque Assay System.* Bacteriophages: Methods and Protocols, Vol. 1: Isolation, Characterization and Interactions. vol. 501. 2009. pp. 81-95.

P Hyman et al. *Practical Methods for Determining Phage Growth Parameters.* Bacteriophages: Methods and Protocols, Vol. 1*: Isolation, Characterization and Interactions.* vol. 501. 2009. pp. 175-201.

A. Furiga, G. Pierre, et al. *Effects of Ionic Strength on Bacteriophage MS2 Behavior and Their Implications of the Assessment of Virus Retention.* University of Toulouse. 2007.

## Analytical Testing Facility

Aerosol Research and Engineering Labs, Inc.
10870 Benson Drive Suite 2120
Overland Park, KS 66210

## Project #

10805.1

## Study Director

Jamie Balarashti
Aerosol Research and Engineering Laboratories

## GLP Statement

We, the undersigned, herby certify that the work described herein was conducted by Aerosol Research and Engineering Laboratories in compliance with FDA Good Laboratory Practices (GLP) as defined in 40 CFR, Part 160.

**Study Director:**

Jamie D. Balarashti
Study Director
ARE Labs, Inc.

04/21/2015
Date

**Principal Investigator:**

Richard S. Tuttle
Principal Investigator
ARE Labs, Inc.

04/21/2015
Date

# Appendix A: Calculations

To evaluate the viable aerosol delivery efficiency and define operation parameters of the system, calculations based on (theoretical) 100% efficacy of aerosol dissemination were derived using the following steps:

- Plating and enumeration of the biological to derive the concentration of the stock suspension ($C_s$) in pfu/mL or cfu/mL, or cfu/g for dry powder.
- Collison 24 jet nebulizer use rate ($R_{neb}$) (volume of liquid generated by the nebulizer/time) at 28 psi air supply pressure = 1.0 ml/min.
- Collison 24 jet Generation time ($t$) = 20 or 30 minutes, test dependent.
- Chamber volume ($V_c$) = 15,993 Liters

Assuming 100% efficiency, the quantity of aerosolized viable particles ($V_P$) per liter of air in the chamber for a given nebulizer stock concentration ($C_s$) is calculated as:

Nebulizer: $V_P = \frac{C_s \cdot R_{neb}}{V_c} t$

Plating and enumeration of the biological to derive the concentration of the dry powder ($C_p$) in cfu/g.

- Eductor use rate ($M_p$) (Mass of powder generated by the eductor in grams)
- Chamber volume ($V_c$) = 15,993 Liters

Assuming 100% efficiency, the quantity of aerosolized viable particles ($V_P$) per liter of air in the chamber for a given dry powder stock concentration ($C_p$) is calculated as:

Eductor: $V_P = \frac{C_p \cdot M_p}{V_c}$

AGI – 30 impinger or 47mm filter collection calculation:

- Viable aerosol concentration collection ($C_a$) = cfu or pfu/L of chamber air.
- Viable Impinger concentration collection ($C_{Imp}$) = cfu or pfu/mL from enumeration of impinger sample or filter sample.
- Impinger sample collection volume ($I_{vol}$) = 20 mL collection fluid/impinger, or extraction fluid for filter.
- AGI–30 impinger or filter sample flow rate ($Q_{imp}$) = 12.5 L/min.
- AGI–30 impinger or filter sample time ($t$) = 5 or 10 minutes, test dependent.

For viable impinger or filter aerosol concentration collection ($C_a$) = cfu or pfu/L of chamber air:

$$C_a = \frac{C_{Imp} \cdot I_{vol}}{Q_{imp}} t$$

The aerosol system viable delivery efficiency (expressed as %) is:

$$Efficiency = \frac{C_a}{V_p} \cdot 100$$

# Appendix B

# Plating and Enumeration Tables

# S. Epidermidis Stock and Control Run Plating Results

**Staph, Large Chamber Control, 10/14/2014 Data**

***Stock Enumeration Results***

| Sample hour AGI | Plate dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Actual concentration cfu/mL | Total Chamber Volume Liters | 100% eff Chamber Theoretical Concentration (t=0) \ | Averaged Chamber Measured Concentration (t=0) cfu/L | Average Chamber Dissemination Effeciency (t=0) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Generation Stock | 6x | TNTC | TNTC | TNTC | | 0 | 0.00E+00 | 15936 | 3.90E+06 | 8.11E+04 | 2.08% |
| | 7x | 52 | 55 | 53 | 53 | 533 | 5.33E+09 | | | | |
| | 8x | 3 | 4 | 4 | 4 | 37 | 3.67E+08 | | | | |
| | | | | | *Average* | | *2.85E+09* | | | | |

***Impinger Enumeration Results***

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 331 | 353 | 296 | 327 | 3267 | 3.27E+05 | 6.53E+06 | 1.0E+05 | | |
| | 4x | 39 | 40 | 21 | 33 | 333 | 3.33E+05 | 6.67E+06 | 1.1E+05 | | |
| | 5x | 0 | 3 | 0 | 1 | 10 | 1.00E+05 | 2.00E+06 | 3.2E+04 | | |
| | | | | | | | *Average* | ***5.07E+06*** | ***8.11E+04*** | ***100.0%*** | |
| 0.5 | 2x | TNTC | TNTC | TNTC | N/A | N?A | N/A | N/A | N/A | N/A | |
| | 3x | 206 | 148 | 168 | 174 | 1740 | 1.74E+05 | 3.48E+06 | 5.6E+04 | 68.7% | |
| | 4x | 19 | 28 | 18 | 22 | 217 | 2.17E+05 | 4.33E+06 | 6.9E+04 | 85.5% | |
| | | | | | | | *Average* | ***3.91E+06*** | ***6.25E+04*** | **77.1%** | **-0.11** |
| 1 | 2x | TNTC | TNTC | TNTC | | | | | | | |
| | 3x | 96 | 128 | 122 | 115 | 1153 | 1.15E+05 | 2.31E+06 | 3.7E+04 | 45.5% | |
| | 4x | 14 | 16 | 20 | 17 | 167 | 1.67E+05 | 3.33E+06 | 5.3E+04 | 65.8% | |
| | | | | | | | *Average* | ***2.82E+06*** | ***4.51E+04*** | **55.7%** | **-0.25** |
| 2 | 2x | TNTC | TNTC | TNTC | | | | | | | |
| | 3x | 87 | 99 | 86 | 91 | 907 | 9.07E+04 | 1.81E+06 | 2.9E+04 | 35.8% | |
| | 4x | 7 | 8 | 8 | 8 | 77 | 7.67E+04 | 1.53E+06 | 2.5E+04 | 30.3% | |
| | | | | | | | *Average* | ***1.67E+06*** | ***2.68E+04*** | **33.0%** | **-0.48** |
| 3 | 2x | TNTC | TNTC | TNTC | | | | | | | |
| | 3x | 62 | 74 | 42 | 59 | 593 | 5.93E+04 | 1.19E+06 | 1.9E+04 | 23.4% | |
| | 4x | 5 | 11 | 7 | 8 | 77 | 7.67E+04 | 1.53E+06 | 2.5E+04 | 30.3% | |
| | | | | | | | *Average* | ***1.36E+06*** | ***2.18E+04*** | **26.8%** | **-0.57** |
| 4 | 2x | TNTC | TNTC | TNTC | | | | | | | |
| | 3x | 33 | 46 | accident | 40 | 395 | 3.95E+04 | 7.90E+05 | 1.3E+04 | 15.6% | |
| | 4x | 2 | 4 | 5 | 4 | 37 | 3.67E+04 | 7.33E+05 | 1.2E+04 | 14.5% | |
| | | | | | | | *Average* | ***7.62E+05*** | ***1.22E+04*** | **15.0%** | **-0.82** |
| 5 | 2x | TNTC | TNTC | TNTC | | | | | | | |
| | 3x | 15 | 21 | 25 | 20 | 203 | 2.03E+04 | 4.07E+05 | 6.5E+03 | 8.0% | |
| | 4x | 2 | 3 | 2 | 2 | 23 | 2.33E+04 | 4.67E+05 | 7.5E+03 | 9.2% | |
| | | | | | | | *Average* | ***4.37E+05*** | ***6.99E+03*** | **8.6%** | **-1.06** |
| 6 | 2x | 123 | 121 | 111 | 118 | 1183 | 1.18E+04 | 2.37E+05 | 3.8E+03 | 4.7% | |
| | 3x | 11 | 9 | accident | 10 | 100 | 1.00E+04 | 2.00E+05 | 3.2E+03 | 3.9% | |
| | 4x | 1 | 1 | 1 | 1 | 10 | 1.00E+04 | 2.00E+05 | 3.2E+03 | 3.9% | |
| | | | | | | | *Average* | ***2.12E+05*** | ***3.40E+03*** | **4.2%** | **-1.38** |

# S. Epidermidis MDU/RX Trial #1 Plating Results

*Staph Ep. - MDU Trial #1 - Impinger Enumeration Results*

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 296 | 282 | 355 | 311 | 3110 | 3.11E+05 | 6.22E+06 | 1.0E+05 | | |
| | 4x | 42 | 41 | 28 | 37 | 370 | 3.70E+05 | 7.40E+06 | 1.2E+05 | | |
| | 5x | 4 | 3 | 5 | 4 | 40 | 4.00E+05 | 8.00E+06 | 1.3E+05 | | |
| | | | | | | | *Average* | ***7.21E+06*** | ***1.15E+05*** | ***100.0%*** | |
| 0.5 | 1x | 206 | 148 | 168 | 174 | 1740 | 1.74E+03 | 3.48E+04 | 5.6E+02 | 0.5% | |
| | 2x | 19 | 28 | 18 | 22 | 217 | 2.17E+03 | 4.33E+04 | 6.9E+02 | 0.6% | |
| | | | | | | | | | | | |
| | | | | | | | *Average* | ***3.91E+04*** | ***6.25E+02*** | **0.542%** | **-2.27** |
| 1 | Neat | 1 | 0 | 1 | 1 | 7 | 6.67E+00 | 1.33E+02 | | | |
| | 1x | 1 | 0 | 0 | 0 | 3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***6.67E+01*** | ***5.33E-01*** | **0.0005%** | **-5.33** |
| 2 | Neat | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | | | | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.0000%** | **N/A** |

# S. Epidermidis MDU/RX Trial #2 Plating Results

***Staph Ep. - MDU Trial #2 - Impinger Enumeration Results***

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 316 | 343 | 352 | 337 | 3370 | 3.37E+05 | 6.74E+06 | 1.1E+05 | | |
| | 4x | 34 | 41 | 36 | 37 | 370 | 3.70E+05 | 7.40E+06 | 1.2E+05 | | |
| | 5x | | | | | | | | | | |
| | | | | | | | *Average* | ***7.07E+06*** | ***1.13E+05*** | ***100.0%*** | 0 |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 1x | 146 | 138 | 127 | 137 | 1370 | 1.37E+03 | 2.74E+04 | 4.4E+02 | 0.4% | |
| | 2x | 11 | 14 | 11 | 12 | 120 | 1.20E+03 | 2.40E+04 | 3.8E+02 | 0.3% | |
| | | 2 | 1 | 0 | 1 | | | | | | |
| | | | | | | | *Average* | ***2.57E+04*** | ***4.11E+02*** | **0.3635%** | **-2.44** |
| 1 | Neat | 0 | 0 | 1 | 0 | 3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***2.22E+01*** | ***3.56E-01*** | **0.0003%** | **-5.50** |
| 2 | Neat | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | | | | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.0000%** | **#NUM!** |

# S. Epidermidis MDU/RX Trial #3 Plating Results

***Staph Ep. - MDU Trial #3 - Impinger Enumeration Results***

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 256 | 289 | 315 | 287 | 2.87E+05 | 5.73E+06 | 9.2E+04 | | |
| | 4x | 27 | 20 | 14 | 20 | 2.03E+05 | 4.07E+06 | 6.5E+04 | | |
| | 5x | | | | | | | | | |
| | | | | | | *Average* | ***4.90E+06*** | ***7.84E+04*** | ***100.0%*** | 0 |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 1x | 209 | 185 | 167 | 187.0 | 1.87E+03 | 3.74E+04 | 6.0E+02 | 0.8% | |
| | 2x | 16 | 14 | 11 | 13.7 | 1.37E+03 | 2.73E+04 | 4.4E+02 | 0.6% | |
| | 3x | 2 | 1 | 0 | 1.0 | 1.00E+03 | 2.00E+04 | 3.2E+02 | 0.4% | |
| | | | | | | *Average* | ***2.82E+04*** | ***4.52E+02*** | **0.5764%** | **-2.24** |
| 1 | Neat | 1 | 0 | 1 | 0.7 | 6.67E+00 | 1.33E+02 | 2.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | *Average* | ***4.44E+01*** | ***7.11E-01*** | **0.0009%** | **-5.04** |
| 2 | Neat | 0 | 0 | 0 | 0.0 | 0.00E+00 | | | | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.0000%** | **#NUM!** |

# E. herbicola Control Run Plating Results

| Erwinia Large chamber control<br>STOCK Enumeration | | | | | | | | Total Chamber Volume Liters | 100% eff Chamber Theoretical Concentration (t=0) \ | Averaged Chamber Measured Concentration (t=0) cfu/L | Chamber Dissemination Effeciency (t=0) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Sample hour AGI | Plate dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Actual concentration cfu/mL | | | | |
| Generation Stock | 6x | 71 | 86 | 68 | 75 | 750 | 7.50E+08 | 15936 | 2.00E+06 | 2.23E+04 | 1.11% |
| | 7x | 13 | 11 | 14 | 13 | 127 | 1.27E+09 | | | | |
| | 8x | 2 | 1 | 2 | 2 | 17 | 1.67E+09 | | | | |
| | | | | | Average | | 1.47E+09 | | | | |

**Impinger Enumeration**

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 62 | 10 | 66 | 46 | 460 | 4.60E+04 | 9.20E+05 | 1.5E+04 | |
| | 4x | 8 | 11 | 10 | 10 | 97 | 9.67E+04 | 1.93E+06 | 3.1E+04 | |
| | 5x | 0 | 1 | 1 | 1 | 7 | 6.67E+04 | 1.33E+06 | 2.1E+04 | |
| | | | | | | | Average | ***1.40E+06*** | ***2.23E+04*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 2x | TNTC | TNTC | TNTC | N/A | N/A | N/A | N/A | N/A | N/A | |
| | 3x | 39 | 34 | 36 | 36 | 36333 | 3.63E+04 | 7.27E+05 | 1.2E+04 | 52.1% | |
| | 4x | 5 | 4 | 5 | 5 | 46667 | 4.67E+04 | 9.33E+05 | 1.5E+04 | 66.9% | |
| | | | | | | | Average | ***8.30E+05*** | ***1.33E+04*** | **59.5%** | **-0.23** |
| 1 | 2x | 320 | 352 | 295 | 322 | 32233 | 3.22E+04 | 6.45E+05 | | | |
| | 3x | 35 | 34 | 38 | 36 | 35667 | 3.57E+04 | 7.13E+05 | 1.1E+04 | 51.1% | |
| | 4x | 3 | 2 | 4 | 3 | 30000 | 3.00E+04 | 6.00E+05 | 9.6E+03 | 43.0% | |
| | | | | | | | Average | ***6.53E+05*** | ***1.05E+04*** | **47.1%** | **-0.33** |
| 2 | 2x | 134 | 145 | 152 | 144 | 14367 | 1.44E+04 | 2.87E+05 | | | |
| | 3x | 19 | 15 | 17 | 17 | 17000 | 1.70E+04 | 3.40E+05 | 5.4E+03 | 24.4% | |
| | 4x | 0 | 1 | 1 | 1 | 6667 | 6.67E+03 | 1.33E+05 | 2.1E+03 | 9.6% | |
| | | | | | | | Average | ***2.54E+05*** | ***3.79E+03*** | **17.0%** | **-0.77** |
| 3 | 2x | 68 | 75 | 81 | 75 | 7467 | 7.47E+03 | 1.49E+05 | | | |
| | 3x | 4 | 7 | 6 | 6 | 5667 | 5.67E+03 | 1.13E+05 | 1.8E+03 | 8.1% | |
| | 4x | 0 | 0 | 0 | 0 | | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | Average | ***8.76E+04*** | ***9.07E+02*** | **4.1%** | **-1.39** |
| 4 | 2x | 35 | 25 | 44 | 35 | 3467 | 3.47E+03 | 6.93E+04 | | | |
| | 3x | 3 | 1 | accident | 2 | 2000 | 2.00E+03 | 4.00E+04 | 6.4E+02 | 2.9% | |
| | 4x | 1 | 0 | 0 | 0 | 3333 | 3.33E+03 | 6.67E+04 | 1.1E+03 | 4.8% | |
| | | | | | | | Average | ***5.87E+04*** | ***8.53E+02*** | **3.8%** | **-1.42** |
| 5 | 2x | | | | | | | | | | |
| | 3x | | | | | | | | | | |
| | 4x | | | | | | | | | | |
| | | | | | | | | | | | |
| 6 | 1x | 37 | 46 | 43 | 42 | 420 | 4.20E+02 | 8.40E+03 | 1.3E+02 | 0.6% | |
| | 2x | 5 | 4 | 5 | 5 | 467 | 4.67E+02 | 9.33E+03 | 1.5E+02 | 0.7% | |
| | 3x | | | | | | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | Average | ***5.91E+03*** | ***9.46E+01*** | **0.4%** | **-2.37** |

# E. herbicola MDU/Rx Trial #1 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 28 | 35 | 39 | 34 | 340 | 3.40E+05 | 6.80E+06 | 1.1E+05 | |
| | 4x | 14 | 15 | 10 | 13 | 130 | 1.30E+06 | 2.60E+07 | 4.2E+05 | |
| | 5x | | | | | 0 | | | | |
| | | | | | | | *Average* | ***1.64E+07*** | ***2.62E+05*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 153 | 194 | 184 | 177 | 1770 | 1.77E+03 | 3.54E+04 | 5.7E+02 | 0.2% | |
| | 1x | 16 | 16 | 19 | 17 | 170 | 1.70E+02 | 3.40E+03 | 5.4E+01 | 0.0% | |
| | 2x | 1 | 2 | 0 | 1 | 10 | | | | | |
| | | | | | | | *Average* | ***1.94E+04*** | ***3.10E+02*** | **0.118%** | **-2.93** |
| 1 | Neat | - | - | - | - | - | - | - | | | |
| | 1x | 8 | 11 | 10 | 10 | 97 | 9.67E+02 | 1.93E+04 | 3.1E+02 | 0.1% | |
| | 2x | 5 | 1 | 2 | 3 | 27 | 2.67E+02 | 5.33E+03 | 8.5E+01 | 0.0% | |
| | | | | | | | *Average* | ***1.23E+04*** | ***1.97E+02*** | **0.075%** | **-3.12** |
| 2 | Neat | 8 | 12 | 7 | 9 | 90 | 9.00E+01 | 1.80E+03 | 2.9E+01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***6.00E+02*** | ***9.60E+00*** | **0.004%** | **-4.44** |
| 3 | Neat | 0 | 0 | 3 | 1 | 10 | 1.00E+01 | 2.00E+02 | 3.2E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | | | | | | |
| | | | | | | | *Average* | ***1.00E+02*** | ***1.60E+00*** | **0.001%** | **-5.21** |

# E. herbicola MDU/Rx Trial #2 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 316 | 343 | 352 | 337 | 3370 | 3.37E+05 | 6.74E+06 | 1.1E+05 | |
| | 4x | 34 | 41 | 36 | 37 | 370 | 3.70E+05 | 7.40E+06 | 1.2E+05 | |
| | 5x | | | | | | | | | |
| | | | | | | | *Average* | ***7.07E+06*** | ***1.13E+05*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 84 | 70 | 77 | 77 | 770 | 7.70E+02 | 1.54E+04 | 2.5E+02 | 0.2% | |
| | 1x | 11 | 8 | 9 | 9 | 933 | 9.33E+02 | 1.87E+04 | 3.0E+02 | 0.3% | |
| | | | | | | | | | | | |
| | | | | | | | *Average* | ***1.70E+04*** | ***2.73E+02*** | **0.241%** | **-2.62** |
| 1 | Neat | 11 | 11 | 10 | 11 | 107 | 1.07E+02 | 2.13E+03 | 3.4E+01 | 0.0% | |
| | 1x | 2 | 3 | 2 | 2 | 233 | 2.33E+02 | 4.67E+03 | 7.5E+01 | 0.1% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | | | | | |
| | | | | | | | *Average* | ***3.40E+03*** | ***5.44E+01*** | **0.048%** | **-3.32** |
| 2 | Neat | 8 | 11 | 6 | 8 | 83 | 8.33E+01 | 1.67E+03 | 2.7E+01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | *Average* | ***5.56E+02*** | ***8.89E+00*** | **0.008%** | **-4.10** |
| 3 | Neat | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | | | | | | |
| | | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.000%** | **#NUM!** |

# E. herbicola MDU/Rx Trial #3 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 3x | 256 | 264 | 232 | 251 | 2.51E+06 | 5.01E+07 | 8.0E+05 | |
| | 4x | 16 | 20 | 22 | 19 | 1.93E+06 | 3.87E+07 | 6.2E+05 | |
| | 5x | - | - | - | - | | | | |
| | | | | | | *Average* | ***4.44E+07*** | ***7.10E+05*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 1x | 41 | 39 | 44 | 41.3 | 4.13E+03 | 8.27E+04 | 1.3E+03 | 0.2% | |
| | 2x | 11 | 14 | 8 | 11.0 | 1.10E+04 | 2.20E+05 | 3.5E+03 | 0.5% | |
| | | | | | | *Average* | ***1.51E+05*** | ***2.42E+03*** | **0.341%** | **-2.47** |
| 1 | Neat | 33 | 42 | 28 | 34.3 | 3.43E+02 | 6.87E+03 | 1.1E+02 | 0.0% | |
| | 1x | 3 | 6 | 1 | 3.3 | 3.33E+02 | 6.67E+03 | 1.1E+02 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***6.77E+03*** | ***1.08E+02*** | **0.015%** | **-3.82** |
| 2 | Neat | 0 | 0 | 1 | 0.3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | - | - | - | - | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***6.67E+01*** | ***1.07E+00*** | **0.0002%** | **-5.82** |
| 3 | | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.0000%** | **#NUM!** |

# MS2 Control Run Plating Results

| MS2 Large chamber control | | | | | | | Total Chamber | 100% eff Chamber | Averaged Chamber | Chamber |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample hour AGI | Plate dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average pfu/100ul | Actual concentration pfu/mL | Volume Liters | Theoretical Concentration (t=0) \ | Measured Concentration (t=0) pfu/L | Dissemination Effeciency (t=0) |
| Generation Stock | 9x | 14 | 15 | 18 | 16 | 1.57E+11 | 15936 | 1.82E+08 | 7.95E+05 | 0.44% |
| | 10x | 1 | 2 | 1 | 1 | 1.33E+11 | | | | |
| | | | | | Average | 1.33E+11 | | | | |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average pfu/100ul | Enumerated Concentration pfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 4x | 27 | 22 | 30 | 26 | 2.63E+06 | 5.27E+07 | 8.4E+05 | |
| | 5x | 4 | 1 | 2 | 2 | 2.33E+06 | 4.67E+07 | 7.5E+05 | |
| | | - | - | - | | | | | |
| | | | | | Average | 4.97E+07 | 7.95E+05 | 100.0% | |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul on Plate 1 | 2 | 3 | Average Plate Count | Enumerated Concentration pfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 3x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 4x | 19 | 23 | 23 | 22 | 2.17E+06 | 4.33E+07 | 6.9E+05 | 87.2% | |
| | 5x | 1 | 0 | 2 | 1 | 1.00E+06 | 2.00E+07 | 3.2E+05 | 40.3% | |
| | | | | | Average | 3.17E+07 | 5.07E+05 | 63.8% | -0.20 | |
| 1 | 3x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 4x | 12 | 14 | 19 | 15 | 1.50E+06 | 3.00E+07 | 4.8E+05 | 60.4% | |
| | 5x | 1 | 1 | 0 | 1 | 6.67E+05 | 1.33E+07 | 2.1E+05 | 26.8% | |
| | | | | | Average | 2.17E+07 | 3.47E+05 | 43.6% | -0.36 | |
| 2 | 3x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 4x | 5 | 4 | 8 | 6 | 5.67E+05 | 1.13E+07 | 1.8E+05 | 22.8% | |
| | 5x | 0 | 0 | 0 | 0 | - | - | - | - | |
| | | | | | Average | 1.13E+07 | 1.81E+05 | 22.8% | -0.64 | |
| 3 | 3x | 38 | 30 | 41 | 36 | 3.63E+05 | 7.27E+06 | 1.2E+05 | 14.6% | |
| | 4x | 3 | 2 | 2 | 2 | 2.33E+05 | 4.67E+06 | 7.5E+04 | 9.4% | |
| | 5x | 0 | 0 | 0 | 0 | - | - | - | - | |
| | | | | | Average | 5.97E+06 | 9.55E+04 | 12.0% | -0.92 | |
| 4 | 2x | - | - | - | - | - | - | - | - | |
| | 3x | 11 | 14 | 6 | 10 | 1.03E+05 | 2.07E+06 | 3.3E+04 | 4.2% | |
| | 4x | 2 | 0 | 0 | 1 | 6.67E+04 | 1.33E+06 | 2.1E+04 | 2.7% | |
| | | | | | Average | 1.70E+06 | 2.72E+04 | 3.4% | -1.47 | |
| 5 | 2x | 59 | 72 | 63 | 65 | 6.47E+04 | 1.29E+06 | 2.1E+04 | 2.6% | |
| | 3x | 7 | 7 | 6 | 7 | 6.67E+04 | 1.33E+06 | 2.1E+04 | 2.7% | |
| | 4x | 0 | 0 | 0 | 0 | - | - | - | - | |
| | | | | | Average | 1.31E+06 | 2.10E+04 | 2.6% | -1.58 | |

# MS2 MDU/Rx Trial #1 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 4x | 10 | 11 | 14 | 12 | 1.17E+06 | 2.33E+07 | 3.7E+05 | |
| | 5x | 1 | 2 | 1 | 1 | 1.33E+06 | 2.67E+07 | 4.3E+05 | |
| | 6x | - | - | - | | | | | |
| | | | | | | *Average* | ***2.50E+07*** | ***4.00E+05*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 12 | 13 | 15 | 13 | 1.33E+02 | 2.67E+03 | 4.3E+01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | | | | | |
| | | | | | | *Average* | ***1.33E+03*** | ***2.13E+01*** | **0.005%** | **-4.27** |
| 1 | Neat | 1 | 2 | 1 | 1 | 1.33E+01 | 2.67E+02 | 4.3E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | - | - | - | - | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***2.67E+02*** | ***4.27E+00*** | **0.001%** | **-4.97** |
| 1.5 | Neat | 0 | 1 | 0 | 0 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.0001%** | **-5.88** |
| 2 | Neat | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***0.00E+00*** | ***0.00E+00*** | **0.0000%** | **#NUM!** |

# MS2 MDU/Rx Trial #2 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 4x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 5x | 9 | 13 | 12 | 11 | 113 | 1.13E+07 | 2.27E+08 | 3.6E+06 | |
| | 6x | 2 | 1 | 2 | 2 | 17 | 1.67E+07 | 3.33E+08 | 5.3E+06 | |
| | | | | | | | *Average* | ***2.80E+08*** | ***4.48E+06*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 3x | 14 | 19 | 17 | 17 | 167 | 1.67E+05 | 3.33E+06 | 5.3E+04 | 1.2% | |
| | 4x | 1 | 1 | 1 | 1 | 100 | 1.00E+05 | 2.00E+06 | 3.2E+04 | 0.7% | |
| | 5x | - | - | - | - | - | - | - | - | - | |
| | | | | | | | *Average* | ***2.67E+06*** | ***4.27E+04*** | **0.952%** | **-2.02** |
| 1 | Neat | 13 | 14 | 11 | 13 | 127 | 1.27E+02 | 2.53E+03 | 4.1E+01 | 0.0% | |
| | 1x | 1 | 2 | 2 | 2 | 167 | 1.67E+04 | 3.33E+05 | 5.3E+03 | 0.1% | |
| | 2x | 0 | 0 | 0 | 0 | 0 | | | | | |
| | | | | | | | *Average* | ***1.68E+05*** | ***2.69E+03*** | **0.060%** | **-3.22** |
| 1.5 | Neat | 7 | 11 | 6 | 8 | 80 | 8.00E+01 | 1.60E+03 | 2.6E+01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | | | | | |
| | 2x | - | - | - | - | - | - | - | - | - | |
| | | | | | | | *Average* | ***1.60E+03*** | ***2.56E+01*** | **0.001%** | **-5.24** |
| 2 | Neat | 1 | 0 | 0 | 0 | 3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | - | |
| | | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.000%** | **-6.92** |

# MS2 MDU/Rx Trial #3 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 4x | TNTC | TNTC | TNTC | - | - | - | - | - |
| | 5x | 14 | 16 | 14 | 15 | 1.47E+07 | 2.93E+08 | 4.7E+06 | |
| | 6x | 1 | 0 | 1 | 1 | 6.67E+06 | 1.33E+08 | | |
| | | | | | | *Average* | ***2.13E+08*** | ***4.69E+06*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 1x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 2x | 22 | 24 | 27 | 24.3 | 2.43E+04 | 4.87E+05 | 7.8E+03 | 0.2% | |
| | 3x | 1 | 4 | 3 | 2.7 | 2.67E+03 | 5.33E+04 | 8.5E+02 | 0.0% | |
| | | | | | | *Average* | ***2.70E+05*** | ***4.32E+03*** | **0.092%** | **-3.04** |
| 1 | Neat | 47 | 37 | 34 | 39.3 | 3.93E+02 | 7.87E+03 | 1.3E+02 | 0.0% | |
| | 1x | 6 | 4 | 7 | 5.7 | 5.67E+02 | 1.13E+04 | 1.8E+02 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***9.60E+03*** | ***1.54E+02*** | **0.003%** | **-4.49** |
| 1.5 | Neat | 3 | 4 | 6 | 4.3 | 4.33E+01 | 8.67E+02 | 1.4E+01 | 0.0% | |
| | 1x | 0 | 1 | 2 | 1.0 | 1.00E+02 | 2.00E+03 | 3.2E+01 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***1.43E+03*** | ***2.29E+01*** | **0.0005%** | **-5.31** |
| 2 | Neat | 3 | 4 | 6 | 4.3 | 4.33E+01 | 8.67E+02 | 1.4E+01 | 0.0% | |
| | 1x | 0 | 1 | 0 | 0.3 | 3.33E+01 | 6.67E+02 | 1.1E+01 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***7.67E+02*** | ***1.23E+01*** | **0.0003%** | **-5.58** |
| 3 | Neat | 0 | 0 | 1 | 0.3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | - | - | - | - | - | - | - | - | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***6.67E+01*** | ***1.07E+00*** | **0.0000%** | **-6.64** |

# Phi-X174 Control Run Plating Results

| PhiX174 Large chamber control | | | | | | | Total Chamber Volume Liters | 100% eff Chamber Theoretical Concentration (t=0) \ | Averaged Chamber Measured Concentration (t=0) pfu/L | Chamber Dissemination Effeciency (t=0) |
|---|---|---|---|---|---|---|---|---|---|---|
| Sample hour AGI | Plate dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average pfu/100ul | Actual concentration pfu/mL | | | | |
| | | | | | | | | | | |
| Generation Stock | 5x | TNTC | TNTC | TNTC | - | - | 15936 | 8.20E+04 | 9.92E+03 | 12.10% |
| | 6x | 5 | 6 | 7 | 6 | 6.00E+07 | | | | |
| | 7x | 0 | 0 | 0 | | | | | | |
| | | | | | Average | 6.00E+07 | | | | |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average pfu/100ul | Enumerated Concentration pfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 2x | 41 | 34 | 31 | 35 | 3.53E+04 | 7.07E+05 | 1.1E+04 | |
| | 3x | 3 | 3 | 2 | 3 | 2.67E+04 | 5.33E+05 | 8.5E+03 | |
| | 4x | 0 | 3 | 1 | 1 | 1.33E+05 | | | |
| | | | | | | Average | **6.20E+05** | **9.92E+03** | **100.0%** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul on Plate 1 | 2 | 3 | Average Plate Count | Enumerated Concentration pfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 2x | 14 | 17 | 22 | 18 | 1.77E+04 | 3.53E+05 | 5.7E+03 | 57.0% | |
| | 3x | 1 | 2 | 2 | 2 | 1.67E+04 | 3.33E+05 | 5.3E+03 | 53.8% | |
| | 4x | 1 | 0 | 0 | 0 | 3.33E+04 | 6.67E+05 | 1.1E+04 | 107.5% | |
| | | | | | | Average | **4.51E+05** | **7.22E+03** | **72.8%** | **-0.14** |
| 1 | 1x | 43 | 51 | 63 | 52 | 5.23E+03 | 1.05E+05 | 1.7E+03 | 16.9% | |
| | 2x | 4 | 7 | 3 | 5 | 4.67E+03 | 9.33E+04 | 1.5E+03 | 15.1% | |
| | 3x | | | | | | | | | |
| | | | | | | Average | **9.90E+04** | **1.58E+03** | **16.0%** | **-0.80** |
| 2 | 1x | 19 | 22 | 20 | 20 | 2.03E+03 | 4.07E+04 | 6.5E+02 | 6.6% | |
| | 2x | 1 | 3 | 2 | 2 | 2.00E+03 | 4.00E+04 | 6.4E+02 | 6.5% | |
| | 3x | 0 | 0 | 1 | 0 | 3.33E+03 | 6.67E+04 | 1.1E+03 | 10.8% | |
| | | | | | | Average | **4.91E+04** | **7.86E+02** | **7.9%** | **-1.10** |
| 3 | 1x | 17 | 13 | 18 | 16 | 1.60E+03 | 3.20E+04 | 5.1E+02 | 5.2% | |
| | 2x | 1 | 0 | 0 | 0 | 3.33E+02 | 6.67E+03 | 1.1E+02 | 1.1% | |
| | 3x | | | | | - | - | - | - | |
| | | | | | | Average | **1.93E+04** | **3.09E+02** | **3.1%** | **-1.51** |
| 4 | 1x | 11 | 9 | 7 | 9 | 9.00E+02 | 1.80E+04 | 2.9E+02 | 2.9% | |
| | 2x | 1 | 0 | 0 | 0 | 3.33E+02 | 6.67E+03 | 1.1E+02 | 1.1% | |
| | 3x | | | | | | | | | |
| | | | | | | Average | **1.23E+04** | **1.97E+02** | **2.0%** | **-1.70** |

# Phi-X174 MDU/Rx Trial #1 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 2x | TNTC | TNTC | TNTC | | | | | |
| | 3x | 13 | 18 | 26 | 19 | 1.90E+05 | 3.80E+06 | 6.1E+04 | |
| | 4x | 1 | 2 | 4 | 2 | 2.33E+05 | 4.67E+06 | 7.5E+04 | |
| | | | | | | *Average* | ***4.23E+06*** | ***6.77E+04*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 31 | 23 | 15 | 23 | 2.30E+02 | 4.60E+03 | 7.4E+01 | 0.1% | |
| | 1x | 1 | 2 | 3 | 2 | 2.00E+02 | 4.00E+03 | 6.4E+01 | 0.1% | |
| | 2x | | | | | | | | | |
| | | | | | | *Average* | ***4.30E+03*** | ***6.88E+01*** | **0.102%** | **-2.99** |
| 1 | Neat | 2 | 0 | 1 | 1 | 1.00E+01 | 2.00E+02 | 3.2E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | - | - | - | - | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***2.00E+02*** | ***3.20E+00*** | **0.005%** | **-4.33** |
| 1.5 | Neat | 1 | 0 | 1 | 1 | 6.67E+00 | 1.33E+02 | 2.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***6.67E+01*** | ***1.07E+00*** | **0.002%** | **-4.80** |
| 2 | Neat | 0 | 0 | 1 | 0 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.001%** | **-5.10** |

# Phi-X174 MDU/Rx Trial #2 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 2x | TNTC | TNTC | TNTC | - | - | - | - | |
| | 3x | 14 | 11 | 18 | 14 | 1.43E+05 | 2.87E+06 | 4.6E+04 | |
| | 4x | 2 | 1 | 2 | 2 | 1.67E+05 | 3.33E+06 | 5.3E+04 | |
| | | | | | | *Average* | ***3.10E+06*** | ***4.96E+04*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 2 | 1 | 1 | 1 | 1.33E+01 | 2.67E+02 | 4.3E+00 | 0.0% | |
| | 1x | 0 | 0 | 1 | 0 | 3.33E+01 | 6.67E+02 | 1.1E+01 | 0.0% | |
| | 2x | | | | | - | - | - | - | |
| | | | | | | *Average* | ***4.67E+02*** | ***7.47E+00*** | **0.0151%** | **-3.82** |
| 1 | Neat | 1 | 0 | 0 | 0 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | | | | | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.0011%** | **-4.97** |
| 1.5 | Neat | 1 | 0 | 0 | 0 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | - | - | - | - | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.001%** | **-4.97** |
| 2 | Neat | 0 | 0 | 1 | 0 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.001%** | **-4.97** |

# Phi-X174 MDU/Rx Trial #3 Plating Results

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|
| 0 | 2x | TNTC | TNTC | TNTC | - | - | - | - | - |
| | 3x | 15 | 9 | 13 | 12 | 1.23E+05 | 2.47E+06 | 3.9E+04 | |
| | 4x | 1 | 0 | 2 | 1 | 1.00E+05 | 2.00E+06 | 3.2E+04 | |
| | | | | | | *Average* | ***2.23E+06*** | ***3.57E+04*** | ***100.0%*** |

| Sample Time (h) | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Enumerated Concentration cfu/mL | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | Neat | 17 | 15 | 21 | 17.7 | 1.77E+02 | 3.53E+03 | 5.7E+01 | 0.2% | |
| | 1x | 2 | 1 | 1 | 1.3 | 1.33E+02 | 2.67E+03 | 4.3E+01 | 0.1% | |
| | 2x | 0 | 0 | 0 | 0.0 | | | | | |
| | | | | | | *Average* | ***3.10E+03*** | ***4.96E+01*** | **0.139%** | **-2.86** |
| 1 | Neat | 2 | 1 | 1 | 1.3 | 1.33E+01 | 2.67E+02 | 4.3E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***1.33E+02*** | ***2.13E+00*** | **0.006%** | **-4.22** |
| 1.5 | Neat | 0 | 0 | 1 | 0.3 | 3.33E+00 | 6.67E+01 | 1.1E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***3.33E+01*** | ***5.33E-01*** | **0.0015%** | **-4.83** |
| 2 | Neat | 0 | 0 | 0.5 | 0.2 | 1.67E+00 | 3.33E+01 | 5.3E-01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***1.67E+01*** | ***2.67E-01*** | **0.0007%** | **-5.13** |

# A. *niger* Spores - Control Run and MDU/Rx Trial Plating Results (TCID50 Technique)

**A. niger Large Chamber MDU Testing**
**47mm Filter Sample Plate Enumeration Results - Plated using TCID50 Small Drop Analysis**

| MDU Control | 0 Neat | 1x 10x | 2x 100x | 3x 1000x | 4x 10000x | 5x 100000x | cfu 5ul | cfu 1000ul | 20 ml Dilution Sample | Sample Flow Rate L/min | Sample Time Minutes | Sampling volume L | Conc. cfu/L | Conc. cfu/Ft3 | *Normalized Concentration (t=0, basis)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **0** | NA | TNTC | TNTC | 6 of 6 | 3 of 6 | 0 of 6 | 5.00E+04 | 1.00E+07 | 2.00E+08 | 12.5 | 10 | 125 | 1.60E+06 | 4.53E+07 | 100.00% |
| **0.5** | NA | TNTC | TNTC | 6 of 7 | 1 of 7 | 1 of 7 | 1.50E+04 | 3.00E+06 | 6.00E+07 | 12.5 | 10 | 125 | 4.80E+05 | 1.36E+07 | 30.00% |
| **1** | NA | TNTC | 7 of 7 | 5 of 7 | 2 of 7 | 0 | 7.10E+03 | 1.42E+06 | 2.84E+07 | 12.5 | 10 | 125 | 2.27E+05 | 6.43E+06 | 14.20% |
| **2** | NA | TNTC | 7 of 7 | 2 of 7 | 0 | 0 | 1.70E+03 | 3.40E+05 | 6.80E+06 | 12.5 | 10 | 125 | 5.44E+04 | 1.54E+06 | 3.40% |
| **3** | NA | 12 of 12 | 3 of 12 | 0 | 0 | 0 | 2.50E+01 | 5.00E+03 | 1.00E+05 | 12.5 | 10 | 125 | 8.00E+02 | 2.26E+04 | 0.05% |
| **4** | NA | 6 of 6 | 1 of 5 | 0 | 0 | 0 | 6.00E+00 | 1.20E+03 | 2.40E+04 | 12.5 | 10 | 125 | 1.92E+02 | 5.43E+03 | 0.01% |

| MDU Trial #1 Test 1 | 0 Neat | 1x 10x | 2x 100x | 3x 1000x | 4x 10000x | 5x 100000x | cfu 5ul | cfu 1000ul | 20 ml Dilution Sample | Sample Flow Rate L/min | Sample Time Minutes | Sampling volume L | Conc. cfu/L | Conc. cfu/Ft3 | *Normalized Concentration (t=0, basis)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **0** | TNTC | 12of 12 | 12of 12 | 12of 12 | 12of 12 | 12of 12 | 1.00E+05 | 2.00E+07 | 4.00E+08 | 12.5 | 10 | 125 | 3.20E+06 | 9.06E+07 | 100.0000% |
| **0.5** | TNTC | 10of10 | 2 of 10 | 2of10 | 1 of 10 | NA | 4.00E+01 | 8.00E+03 | 1.60E+05 | 12.5 | 10 | 125 | 1.28E+03 | 3.62E+04 | 0.0800% |
| **1** | 6of10 | 2of10 | 0 | 0 | 0 | 0 | 6.00E+00 | 1.20E+03 | 2.40E+04 | 12.5 | 10 | 125 | 1.92E+02 | 5.43E+03 | 0.0120% |
| **1.5** | 1of11 | 0 | 0 | 0 | 0 | 0 | 9.00E-02 | 1.80E+01 | 3.60E+02 | 12.5 | 10 | 125 | 2.88E+00 | 8.15E+01 | 0.0002% |
| **2** | 0 | 0 | 0 | 0 | | | | | | | | | | | 0.0000% |

| MDU Trial #2 Test 2 | 0 Neat | 1x 10x | 2x 100x | 3x 1000x | 4x 10000x | 5x 100000x | cfu 5ul | cfu 1000ul | 20 ml Dilution Sample | Sample Flow Rate L/min | Sample Time Minutes | Sampling volume L | Conc. cfu/L | Conc. cfu/Ft3 | *Normalized Concentration (t=0, basis)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **0** | TNTC | TNTC | TNTC | 12 of12 | 6of12 | 3of12 | 5.00E+03 | 1.00E+06 | 2.00E+07 | 12.5 | 10 | 125 | 1.60E+05 | 4.53E+06 | 100.00% |
| **0.5** | 12of12 | 8of12 | 0 | 0 | 0 | 0 | 6.60E+01 | 1.32E+04 | 2.64E+05 | 12.5 | 10 | 125 | 2.11E+03 | 5.98E+04 | 0.1320% |
| **1** | 1of12 | 0 | 0 | 0 | 0 | 0 | 8.00E-02 | 1.60E+01 | 3.20E+02 | 12.5 | 10 | 125 | 2.56E+00 | 7.24E+01 | 0.0002% |
| **1.5** | 0 | 0 | 0 | 0 | | | | | | | | | | | 0.0000% |
| **2** | 0 | 0 | 0 | 0 | | | | | | | | | | | 0.0000% |

| MDU Trial #3 Test 3 | 0 Neat | 1x 10x | 2x 100x | 3x 1000x | 4x 10000x | 5x 100000x | cfu 5ul | cfu 1000ul | 20 ml Dilution Sample | Sample Flow Rate L/min | Sample Time Minutes | Sampling volume L | Conc. cfu/L | Conc. cfu/Ft3 | *Normalized Concentration (t=0, basis)* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **0** | TNTC | TNTC | TNTC | 10of10 | 7of10 | 2of10 | 7.00E+03 | 1.40E+06 | 2.80E+07 | 12.5 | 10 | 125 | 2.24E+05 | 6.34E+06 | 100.00% |
| **0.5** | TNTC | 10of10 | 4of10 | 1of10 | 0 | 0 | 4.00E+01 | 8.00E+03 | 1.60E+05 | 12.5 | 10 | 125 | 1.28E+03 | 3.62E+04 | 0.0800% |
| **1** | 4 of 12 | 0 | 0 | 0 | 0 | 0 | 2.50E-01 | 5.00E+01 | 1.00E+03 | 12.5 | 10 | 125 | 8.00E+00 | 2.26E+02 | 0.0005% |
| **1.5** | 0 | 0 | 0 | 0 | | | | | | | | | | | 0.0000% |
| **2** | 0 | 0 | 0 | 0 | | | | | | | | | | | 0.0000% |

# *B. Subtilis* Endospores - Control Run Plating Results

**B. Subtilis Control Enumeration Data**

| Sample Time | Plate Dilution Factor | Plate counts 100ul 1 | 2 | 3 | Average cfu/100ul | Average cfu/1mL | Enumerated Concentration cfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) | Log Reduction (t=0, basis) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | 2x | | | | | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | | |
| | 3x | 45 | 47 | 46 | 46 | 460 | 4.60E+05 | 9.20E+06 | 7.4E+04 | | |
| | 4x | 4 | 3 | 4 | 4 | 35 | 3.50E+05 | 7.00E+06 | 5.6E+04 | | |
| | | | | | | | *Average* | ***8.10E+06*** | ***6.48E+04*** | ***100.0%*** | ***0.00*** |

| Sample Time | Plate Dilution Factor | Plate counts 100ul on Plate 1 | 2 | 3 | Average Plate Count | Average pfu/1mL | Enumerated Concentration pfu/mL | Total pfu Collected (pfu) (per AGI) | Average Chamber Concentration (pfu/l) | Normalized Concentration (t=0, basis) | Log Reduction |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 0.5 | 2x | | | | | - | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 3x | 38 | 36 | 37 | 37 | 370 | 3.70E+05 | 7.40E+06 | 5.9E+04 | 91.4% | |
| | 4x | 4 | 3 | 4 | 4 | 35 | 3.50E+05 | 7.00E+06 | 5.6E+04 | 86.4% | |
| | | | | | | | *Average* | ***7.20E+06*** | ***5.76E+04*** | **88.9%** | **-0.05** |
| 1 | 1x | | | | | | | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | | | | | | | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 3x | 28 | 24 | 26 | 26 | 260 | 2.60E+05 | 5.20E+06 | 4.2E+04 | | |
| | | | | | | | *Average* | ***1.73E+06*** | 4.8E+04 | **74.1%** | **-0.13** |
| 2 | 1x | | | | | | | | | | |
| | 2x | 58 | 73 | 66 | 66 | 655 | 6.55E+04 | 1.31E+06 | 1.0E+04 | 16.2% | |
| | 3x | 11 | 12 | | 12 | 115 | 1.15E+05 | 2.30E+06 | 1.8E+04 | 28.4% | |
| | | | | | | | *Average* | ***1.81E+06*** | ***1.44E+04*** | **22.3%** | **-0.65** |
| 3 | 1x | | | | | | | | | | |
| | 2x | 44 | 48 | 46 | 46 | 460 | 4.60E+04 | 9.20E+05 | 7.4E+03 | 11.4% | |
| | 3x | 4 | 5 | 5 | 5 | 45 | 4.50E+04 | 9.00E+05 | 7.2E+03 | - | |
| | | | | | | | *Average* | ***9.10E+05*** | ***7.28E+03*** | **11.2%** | **-0.95** |
| 4 | 1x | | | | | | | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | 23 | 34 | 28 | 29 | 285 | 2.85E+04 | 5.70E+05 | 4.6E+03 | 7.0% | |
| | 3x | 5 | 5 | 5 | 5 | 50 | 5.00E+04 | 1.00E+06 | 8.0E+03 | 12.3% | |
| | | | | | | | *Average* | ***5.23E+05*** | ***4.19E+03*** | **6.5%** | **-1.19** |

# *B. Subtilis* Endospores - MDU/Rx Trial #1 Plating Results

| B. Subtilis Trial 1 Plate Enumeration data | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* *1* | *2* | *3* | *Average cfu/100ul* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction (t=0, basis)* |
| 0 | 2x | TNTC | TNTC | TNTC | | | | | | |
| | 3x | 34 | 29 | 32 | 32 | 3.15E+05 | 6.30E+06 | 1.0E+05 | | |
| | 4x | 8 | 4 | 6 | 6 | 6.00E+05 | 1.20E+07 | 1.9E+05 | | |
| | | | | | | *Average* | ***9.15E+06*** | ***1.46E+05*** | ***100.0%*** | ***0.0%*** |
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* *1* | *2* | *3* | *Average cfu/100ul* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction* |
| 0.5 | Neat | | | | | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 1x | 77 | 75 | 76 | 76 | 7.60E+03 | 1.52E+05 | 2.4E+03 | 1.7% | |
| | 2x | | | | | | | | | |
| | | | | | | *Average* | ***7.60E+04*** | ***1.22E+03*** | **0.831%** | **-2.08** |
| 1 | Neat | 94 | 85 | 90 | 90 | 8.95E+02 | 1.79E+04 | 2.9E+02 | 0.2% | |
| | 1x | 12 | 9 | 10 | 11 | 1.05E+03 | 2.10E+04 | 3.4E+02 | 0.2% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***1.95E+04*** | ***3.11E+02*** | **0.213%** | **-2.67** |
| 1.5 | Neat | 30 | 36 | 32 | 33 | 3.30E+02 | 6.60E+03 | 1.1E+02 | 0.1% | |
| | 1x | 6 | 5 | 6 | 6 | 5.50E+01 | 1.10E+03 | 1.8E+01 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***3.85E+03*** | ***6.16E+01*** | **0.042%** | **-3.38** |
| 2 | Neat | 4 | 8 | 6 | 6 | 6.00E+01 | 1.20E+03 | 1.9E+01 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | | | | | | | | | |
| | | | | | | *Average* | ***6.00E+02*** | ***9.60E+00*** | **0.007%** | **-4.18** |

# *B. Subtilis* Endospores - MDU/Rx Trial #2 Plating Results

| B. Subtilis Trial 2 Plate Enumeration Results | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* *1* | *2* | *3* | *Average cfu/100ul* | *Average cfu/1mL* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction (t=0, basis)* |
| 0 | 2x | TNTC | TNTC | TNTC | - | - | - | - | - | | |
| | 3x | 38 | 41 | 39 | 40 | 395 | 3.95E+05 | 7.90E+06 | 6.3E+04 | | |
| | 4x | 7 | 7 | 6 | 7 | 70 | 7.00E+05 | 1.40E+07 | 1.1E+05 | | |
| | | | | | | | *Average* | ***1.10E+07*** | ***8.76E+04*** | ***100.0%*** | ***0.0%*** |
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* *1* | *2* | *3* | *Average cfu/100ul* | *Average cfu/1mL* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction* |
| 0.5 | Neat | | | | | | | | | | |
| | 1x | 47 | 46 | 48 | 47 | 465 | 4.65E+03 | 9.30E+04 | 7.4E+02 | 0.8% | |
| | 2x | | | | | | - | - | - | - | |
| | | | | | | | *Average* | ***9.30E+04*** | ***7.44E+02*** | **0.8493%** | **-2.07** |
| 1 | Neat | 57 | 48 | 52 | 53 | 525 | 5.25E+02 | 1.05E+04 | 8.4E+01 | 0.1% | |
| | 1x | 7 | 5 | 6 | 6 | 60 | 6.00E+02 | 1.20E+04 | 9.6E+01 | 0.1% | |
| | 2x | | | | | | | | | | |
| | | | | | | | *Average* | ***1.13E+04*** | ***9.00E+01*** | **0.1027%** | **-2.99** |
| 1.5 | Neat | 25 | 19 | 21 | 22 | 220 | 2.20E+02 | 4.40E+03 | 3.5E+01 | 0.0% | |
| | 1x | 3 | 5 | 4 | 4 | 40 | 4.00E+02 | 8.00E+03 | 6.4E+01 | 0.1% | |
| | 2x | | | | | | - | - | - | - | |
| | | | | | | | *Average* | ***6.20E+03*** | ***4.96E+01*** | **0.057%** | **-3.25** |
| 2 | Neat | 3 | 5 | 4 | 4 | 40 | 4.00E+01 | 8.00E+02 | 6.4E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0 | 0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 2x | - | - | - | - | - | - | - | - | - | |
| | | | | | | | *Average* | ***4.00E+02*** | ***3.20E+00*** | **0.004%** | **-4.44** |

# *B. Subtilis* Endospores - MDU/Rx Trial #3 Plating Results

| B. Subtilis Trial 3 Plate Enumeration Results | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* 1 | 2 | 3 | *Average cfu/100ul* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction (t=0, basis)* |
| 0 | 2x | TNTC | TNTC | TNTC | - | - | - | - | - | |
| | 3x | 57 | 54 | 56 | 56 | 5.55E+05 | 1.11E+07 | 1.8E+05 | | |
| | 4x | 7 | 8 | 8 | 8 | 7.50E+05 | 1.50E+07 | 2.4E+05 | | |
| | | | | | | *Average* | ***1.31E+07*** | ***2.09E+05*** | ***100.0%*** | ***0.0%*** |
| *Sample Time* | *Plate Dilution Factor* | *Plate counts 100ul* 1 | 2 | 3 | *Average cfu/100ul* | *Enumerated Concentration cfu/mL* | Total cfu Collected (cfu) (per AGI) | Average Chamber Concentration (cfu/l) | *Normalized Concentration (t=0, basis)* | *Log Reduction* |
| 0.5 | Neat | | | | | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 1x | 27 | 24 | 1 | 17.3 | 1.73E+03 | 3.47E+04 | 5.5E+02 | 0.3% | |
| | 2x | 3 | 4 | 2 | 3.0 | 3.00E+03 | 6.00E+04 | 9.6E+02 | 0.5% | |
| | | | | | | *Average* | ***3.16E+04*** | ***5.05E+02*** | **0.242%** | **-2.62** |
| 1 | Neat | | | | | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | 1x | 14 | 12 | 13 | 13 | 1.30E+03 | 2.60E+04 | 4.2E+02 | 0.2% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***1.30E+04*** | ***2.08E+02*** | **0.100%** | **-3.00** |
| 1.5 | Neat | 16 | 15 | 15 | 15.5 | 1.55E+02 | 3.10E+03 | 5.0E+01 | 0.0% | |
| | 1x | 3 | 4 | 4 | 3.5 | 3.50E+02 | 7.00E+03 | 1.1E+02 | 0.1% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***5.05E+03*** | ***8.08E+01*** | **0.0387%** | **-3.41** |
| 2 | Neat | 4 | 2 | 3 | 3.0 | 3.00E+01 | 6.00E+02 | 9.6E+00 | 0.0% | |
| | 1x | 0 | 0 | 0 | 0.0 | 0.00E+00 | 0.00E+00 | 0.0E+00 | 0.0% | |
| | | - | - | - | - | - | - | - | - | |
| | | | | | | *Average* | ***3.00E+02*** | ***4.80E+00*** | **0.0023%** | **-4.64** |