

Lumin Bullet Disinfection Validation Study Design

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Date: February 13, 2019

Overview

This study aims to determine the minimum exposure time to the Lumin Bullet UVC-emitting lamp required to achieve a log 2 reduction in microbial load of a highly radiation-resistant biological indicator organism on the interior of a CPAP hose. Tests will be conducted at 3 separate cycle time durations to allow for comparisons of outcomes.

Materials

Biological Indicator

To test the disinfection success of the Lumin Bullet UV-C lamp, a biological indicator will be required. Biological indicators (BI) are characterized preparations of a specific microorganism that provides a defined and stable resistance to a specific disinfection process. Suitable biological indicators are spore-forming bacteria because they are significantly more resistant than normal microflora.

The selection of the biological indicator requires a knowledge of the resistance of the BI system to the specific sterilization or disinfection process. It must be established that the BI system provides a challenge to the disinfection process that exceeds the challenge of the natural microbial burden in or on the product.

Bacillus pumilus is highly resistant to ionizing and UV radiation processes. *B. pumilus* is a mesophilic organism with an optimal growth temperature of 30 - 35°C.

Commercially available BIs using spores of *B. pumilus*:

1. crosstex.com <https://www.crosstex.com/industry-industriallife-sciences/cat-sterilization-monitoring-products-596/cat-gamma-e-beam-705>

2. Mesa Labs
<https://biologicalindicators.mesalabs.com/industrial-use-biological-indicators/>

Carrier Type

My recommendation is a disc (paper or stainless steel). Standard discs are 6mm in diameter, which is considerably smaller than the other main option of a strip (up to 38mm in length).

Preliminary Method:

1. 6mm discs inoculated with 10^5 *B. pumilus* will be placed along the interior of a CPAP hose. 3 Lumin Bullets will be configured to cycle times of 0.75 s, 1.0 s and 1.25 s to determine appropriate dosing necessary to reach target disinfection goal of 99%. A backup timer may also be used to confirm exposure time.
2. Insert two discs into each hose. Insert the Lumin Bullet in the hose carefully following the directions for us. Slowly pull the CPAP hose to allow the Lumin Bullet to traverse the total length of the hose. The hose can be pulled through and back several times for the total of the exposure time indicated (i.e. 0.75s, 1.0s and 1.25s). Two discs will be inserted in the CPAP hose to provide for duplicate measurements.
3. Reserve 2 inoculated discs as negative controls that will not be exposed to a disinfection procedure.
4. The BI samples will then need to be transferred to Trypticase Soy Agar plates after diluting at 10^{-1} , 10^{-2} , 10^{-3} and 10^{-4} (depending on inoculation population) - aim to achieve 3-30 CFU for one dilution.
5. Incubate all samples at 35°C for 48 hours and count colonies.

Lumin Bullet Lab Study-Population Assay

Date: 7/14/19	Time: 0900
Carrier: Bacillus pumilus spore	Technician: A.Giudice

Description:

Following the Lumin Bullet Disinfection Validation Study Design provided, 3mm stainless steel disc carriers inoculated with the challenge strain, *Bacillus pumilus*, were adhered to CPAP tubing. The test articles were labeled A1 & A2 for .75s exposure, B1 & B2 for 1.0s, C1 & C2 for 1.25s exposure. A control disc was not subjected to the Lumin Bullet cleaning cycle and labeled CN1. At conclusion, carrier discs were packed in dry ice and overnighted to Mesa Laboratory.

Sample ID	Description	Lumin Bullet Duration
A1	CPAP hose	.75s
A2	"	.75
B1	"	1.0s
B2	"	1.0
C1	"	1.25s
C2	"	1.25
CN1	"	0

Performed by: _____

Date: _____



7/14/19



Population Analysis Report #593-193

Study #1

Report date: 19 July 2019

Prepared For:

3B Medical
799 Overlook Dr
Winter Haven FL 33884-1671

Sample Identification #: Mesa Labs *Bacillus pumilus* Spore Disc Biological Indicators, DPSSC/3

Test Article: Lumin Bullet

Date Testing Performed: 16-Jul-2019

Date Testing Completed: 18-Jul-2019

Test Procedure: Per Mesa Labs' population assay procedures

Procedure: A population assay was performed on the Mesa Labs Spore Discs following Mesa Labs' procedures. Plates were incubated at 30-35°C and results were recorded after 48 hours. Pictures were taken of the BIs upon receipt at Mesa Labs (Attachment 1) and of the plates after incubation (Attachment 2).

Population Results:

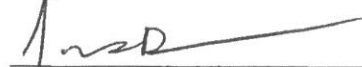
Table I: Exposed Sample Results

Sample ID	Distance	Duration	Verified Population
A1	3mm	0.75s	1.5000×10^1 *
A2	3mm	0.75s	2.5000×10^0 *
B1	3mm	1.0s	0
B2	3mm	1.0	3.5000×10^1
C1	3mm	1.25s	7.5000×10^0 *
C2	3mm	1.25s	2.5000×10^0 *

*Estimated population only due to less than 6 CFUs.

Table II: Unexposed (Positive Control) Results


Sample ID	Verified Population
CN1	1.1600×10^3

Prepared by:

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Date: 25 Jul 2019**Approved by:**

Jared Turner, Contract Studies Lab Coordinator
Mesa Labs, Bozeman Manufacturing Facility

Date: 25 JUL 2019**Approved by:**

Nicole DeWald, Quality Assurance Manager
Mesa Labs, Bozeman Manufacturing Facility

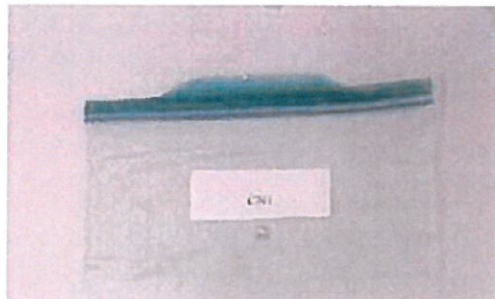
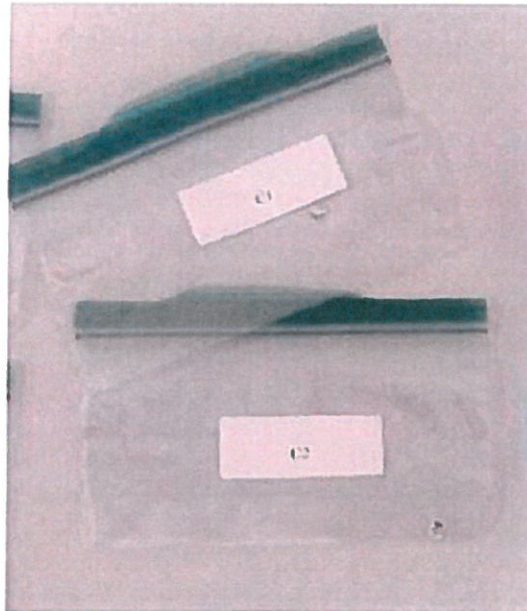
Date: 25 Jul 2019

Attachment 1

Sample Receipt Pictures

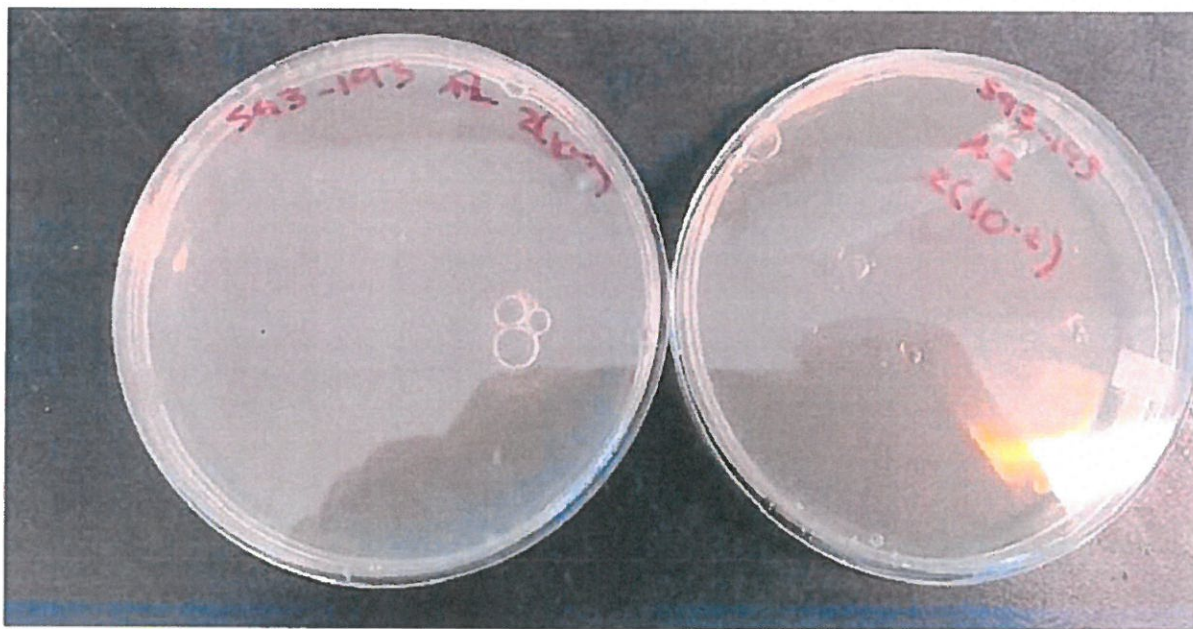
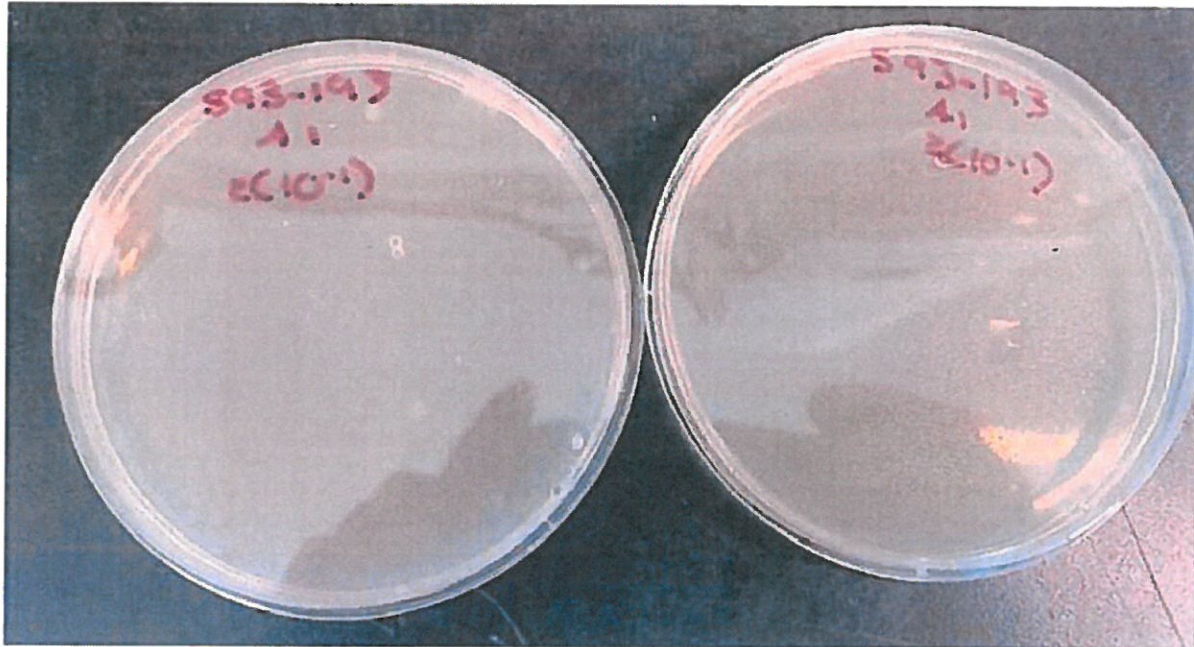


Attachment 1 (cont.)



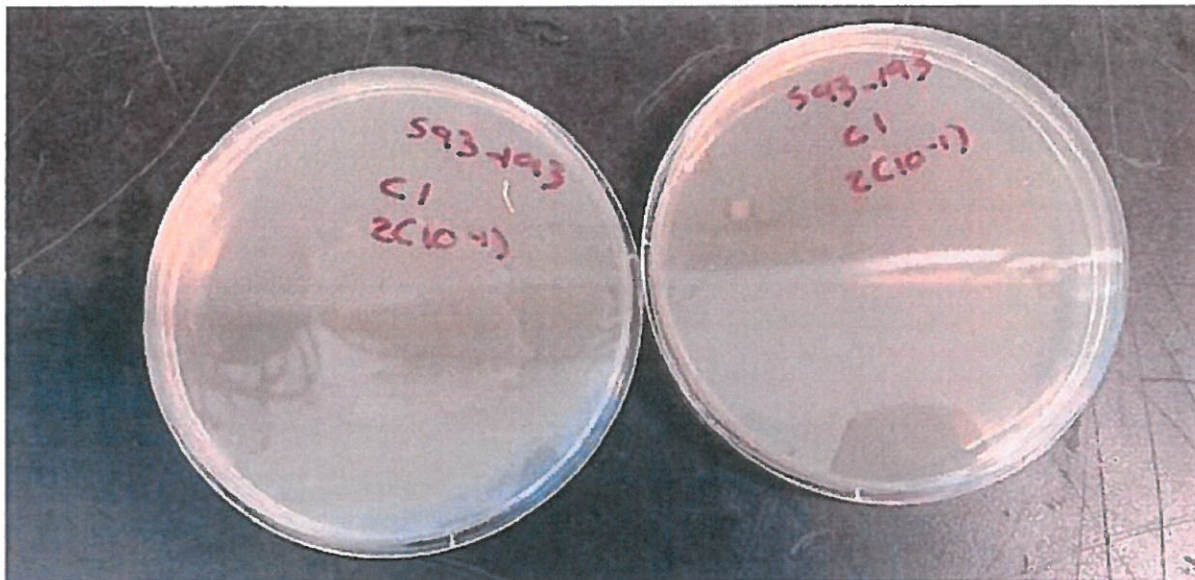
Attachment 2

Post-Incubation Pictures



Attachment 2 (cont.)

Attachment 2 (cont.)



Attachment 2 (cont.)

