



Population Analysis Report #593-193

Study #3

Report date: 19 July 2019

Prepared For:

3B Medical
799 Overlook Dr
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Sample Identification #: Mesa Labs *Bacillus pumilus* Spore Disc Biological Indicators, DPSSC/3

Test Article: CPAP Accessories – Lumin CPAP Cleaner

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

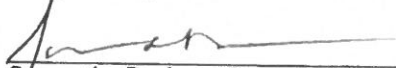
| Sample ID | Description | Duration | Verified Population |
|-----------|--------------------|----------|----------------------------|
| G1 | CPAP Mask | 5 Min | 0 |
| G2 | CPAP Mask | 5 Min | 0 |
| H1 | CPAP Hose | 5 Min | 0 |
| H2 | CPAP Hose | 5 Min | 0 |
| I1 | CPAP Water Chamber | 5 Min | 2.5000 x 10 ⁰ * |
| I2 | CPAP Water Chamber | 5 Min | 0 |

*Estimated population only due to less than 6 CFUs.

Table II: Unexposed (Positive Control) Results


| Sample ID | Verified Population |
|-----------|--------------------------|
| CN3 | 2.1300 x 10 ³ |

Prepared by:


Samantha Bodnar, Contract Studies Lab Analyst
Mesa Labs, Bozeman Manufacturing Facility

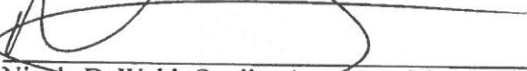
Date: 25 Jul 2019

Approved by:


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

Date: 25 JUL 2019

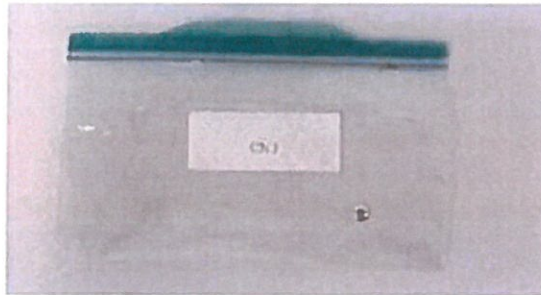
Approved by:


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

Date: 25 JUL 2019

Attachment 1

Sample Receipt Pictures



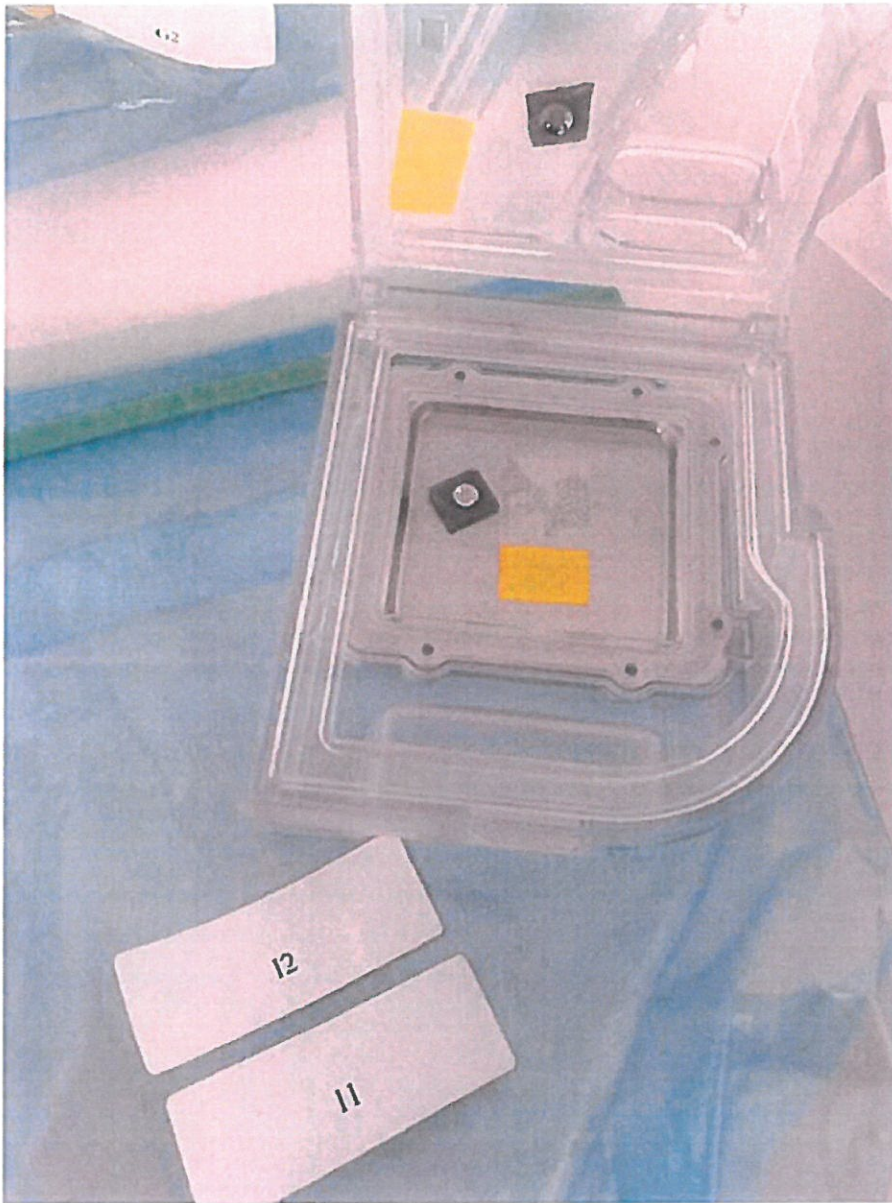
Attachment 1 (cont.)



Attachment 1 (cont.)

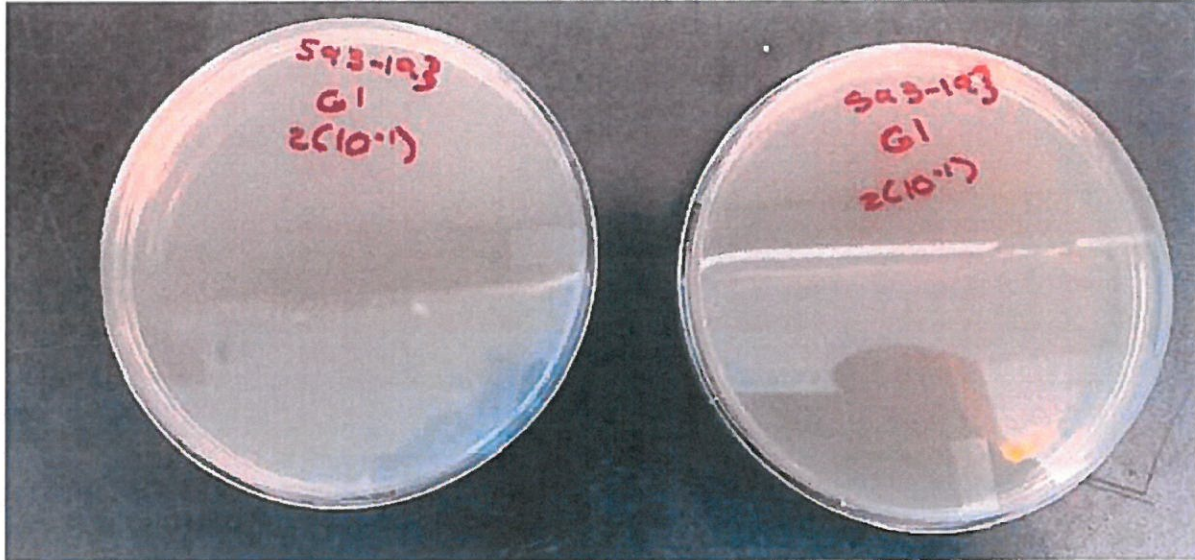


Attachment 1 (cont.)



Attachment 2

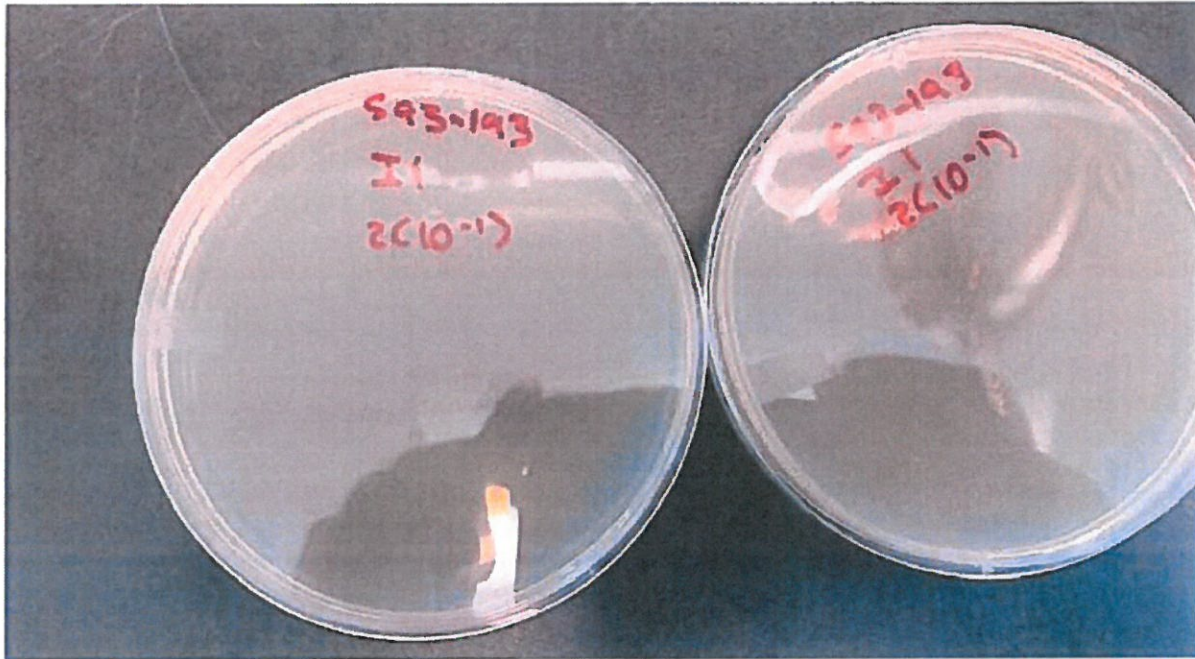
Post-Incubation Pictures



Attachment 2 (cont.)



Attachment 2 (cont.)



Attachment 2 (cont.)

