AgDESMO Mask Case Certifications by International Reputable Test Labs

1. VFE Test AgDesmo SB3P92086 1414376-S01
2. 11807 Wandz WNE80006 100x wash - - 99.8 reduction
3. 11808 Wandz WTT92001 Ionic+ Finished 100x wash - SA JIS 1902
4. Nelson Labs_Bacterial Filtration Efficiency

Nelson Labs
A Sotera Health company

Sponsor:
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Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article:	SAMPLE 2 - MODEL NO.: AgDESMO SB3P92086 IN PEWTER / GREENERY COLOR
Study Number:	1415988-S01
Study Received Date:	10 May 2021
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0010 Rev 16
Deviation(s):	None

Summary: This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than 10^6 plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 12 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. NL has not performed a validation using the flow rate performed in this testing; however, adequate controls are included to verify the reliability of this study. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Challenge Flow Rate:	12 LPM
Area Tested:	~40 cm^2
Side Tested:	Pewter Colour Side (Front/Face Size)
Challenge Level:	4.4 x 10^6 PFU
MPS:	~2.9 µm
Test Monitor Results:	Acceptable

Lisa Bonner electronically approved for James Luskin
Study Director

02 Jun 2021 18:40 (+00:00)
Study Completion Date and Time

Results:

Total PFU Recovered	Filtration Efficiency (%)
<1[a]	>99.999977

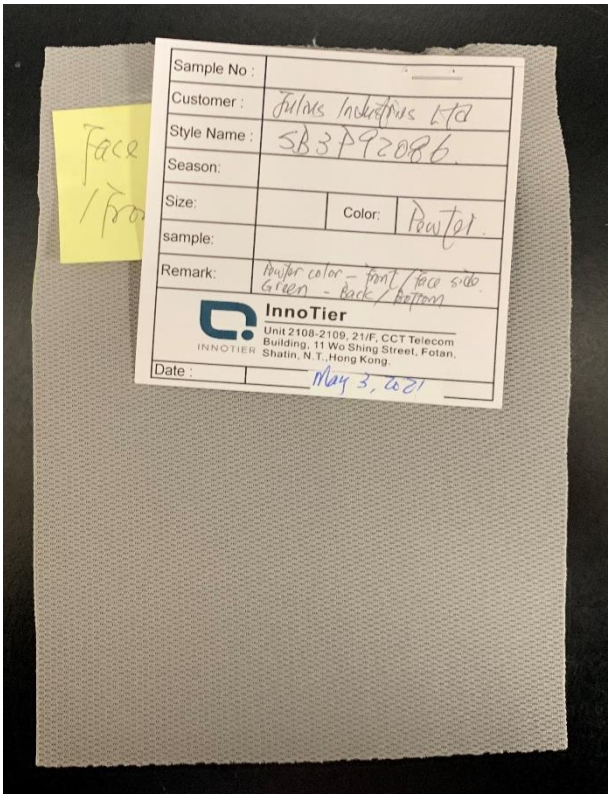
[a] There were no detected plaques on any of the assay plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

$$\% VFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total PFU recovered downstream of the test article

Test Article Photos:



Client: Noble Biomaterials
300 Palm Street
Scranton, PA 18505

MSL Report ID: R2020-424-1
Testing Completed: 8/3/2020
Testing Reported: 8/4/2020
A2LA Testing Cert: #2832.01

JIS L 1902:2015 Test Report

11807 Wandz WNE80006 100x wash*

	Control - log C_o	Control - log C_t	Growth Value of Control (F)
Fabric Control	5.7	8.0	2.3

Sample - log T_o	Sample - log T_t	Growth Value of Sample(G)	Antibacterial Activity Value (A)	Log Reduction	Percent Reduction
5.6	5.3	-0.3	2.6	2.7	99.8

Test Variables

Test Org and Starting Concentration:	S. aureus ATCC 6538 at 2.9 x 10^5
Sample Size:	0.75 gram ± 0.05
Method of Sterilization/Pre-Cleaning:	None
Control:	Untreated Fabric Control - ISO 105-F02 Adjacent Cotton
Inoculum Dilution Medium Used:	Nutrient Broth diluted 20x with sterile water with 0.05% Triton X-100
Amount of Inoculum:	1.0mL
Neutralizing Broth:	20 mL D/E neutralizing broth
Shaking Method:	Vortex mixer and Shaking by hand
Contact Time	24 hours
Incubation:	35 ± 2°C
Quantitative Measurement Method:	Plate Count Method
Deviations from Standard Test Method:	Sample size: 0.75 gram; Inoculum Amount: 1.0mL; Addition to Inoculum Dilution Medium: 0.05% Triton X-100

*Results given relate only to items tested.

Approved By: Debbie Koester
Title: Quality Manager

Client: Noble Biomaterials
300 Palm Street
Scranton, PA 18505

MSL Report ID: R2020-399-1
Testing Completed: 7/20/2020
Testing Reported: 7/20/2020
A2LA Testing Cert: #2832.01

JIS L 1902:2015 Test Report

11808 Wandz WTT92001 XT2 Finished 100x*

	Control - log C_o	Control - log C_t	Growth Value of Control (F)
Fabric Control	5.7	7.8	2.1

Sample - log T_o	Sample - log T_t	Growth Value of Sample(G)	Antibacterial Activity Value (A)	Log Reduction	Percent Reduction
5.7	6.0	0.3	1.8	1.8	98

Test Variables

Test Org and Starting Concentration:	S. aureus ATCC 6538 at 3.3 x 10^5
Sample Size:	0.75 gram ± 0.05
Method of Sterilization/Pre-Cleaning:	None
Control:	Untreated Fabric Control - ISO 105-F02 Adjacent Cotton
Inoculum Dilution Medium Used:	Nutrient Broth diluted 20x with sterile water with 0.05% Triton X-100
Amount of Inoculum:	1.0 mL
Neutralizing Broth:	20 mL D/E neutralizing broth
Shaking Method:	Vortex mixer and Shaking by hand
Contact Time	24 hours
Incubation:	35 ± 2°C
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Deviations from Standard Test Method:	Sample size: 0.75 gram; Inoculum Amount: 1.0mL; Addition to Inoculum Dilution Medium: 0.05% Triton X-100

*Results given relate only to items tested.

Approved By: Debbie Koester
Title: Quality Manager

Nelson Labs
A Sotera Health company

Sponsor:
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Fo Tan, New Territories 11214
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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	ISM3
Study Number:	1354480-S01
Study Received Date:	21 Oct 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~7.8 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~212 mm x ~220 mm
Positive Control Average:	2.4 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

David Brown electronically approved for — 02 Dec 2020 23:27 (+00:00)
Study Director — James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.7
2	99.0
3	99.9
4	99.0
5	99.1

The filtration efficiency percentages were calculated using the following equation:

$$\% \, BFE = \frac{C - T}{C} \, x \, 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request