Summary of Mask Testing Data: ASTM F2100-11

Intertek
3933 US Route 11
Cortland, New York 13045
February 12, 2021

Bacterial Filtration Efficacy:
%BFE, all results >= 99.37% barrier.
[PASS ALL LEVELS]

Breathability / Pressure Drop:
Average Delta P, 4.6 mm H2O/cm2
[PASS LEVEL 2]

Face Mask Fluid Barrier Testing:
160mmHg, 32 of 32 Pass
[PASS LEVEL 3 / ALL LEVELS]

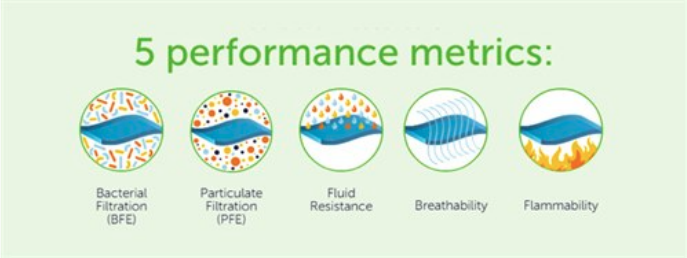
Flammability:
Class 1, Normal Flammability
[PASS ALL LEVELS]

Bioburden:
Could not detect any organisms
(aerobic, fungal, or total bioburden)
[PASS]

Nelson Laboratories, LLC
6280 S. Redwood Rd.
Salt Lake City, UT 84123 U.S.A.
March 25, 2021

Particle Filtration Efficiency
%PFE = 99.7%
[PASS ALL LEVELS]

Summary of Standard



ASTM F2100-11: Standard Specification for Performance of Materials Used in Medical Face Masks

TEST	LEVEL 1 BARRIER	LEVEL 2 BARRIER	LEVEL 3 BARRIER
ASTM F1862(Fluid Resistance)	80 mmHg	120 mmHg	160 mmHg
MIL-M-36954 C: ΔP (Breathability)	< 4 mm H2O	< 5 mm H2O	< 5 mm H2O
ASTM F2101: BFE (Filtration 3µm)	≥ 95%	≥ 98%	≥ 98%
ASTM F2299: PFE (Filtration 1µm)	≥ 95% @ 0.1 micron	≥ 98% @ 0.1 micron	≥ 98% @ 0.1 micron
16 CFR Part 1610: Flame Spread (Flammability)	Class 1	Class 1	Class 1

FOLIA WATER
TEST REPORT

SCOPE OF WORK
Performance Testing of Face Masks to
ASTM F2100 *Standard Specification for Performance of Materials Used in Medical Face Masks,* 2020 Edition

REPORT NUMBER
104488142CRT-001b

ISSUE DATE
February 9, 2021

REVISION DATE:
February 12, 2021

PAGES
14

DOCUMENT CONTROL NUMBER
GFT-OP-10i (28-Nov-2018)

3933 US Route 11
Cortland, New York 13045

Telephone: 1-607-753-6711
Facsimile: 1-607-756-9891
www.intertek.com

TEST REPORT

Issued February 12, 2021

Intertek Report No. 104488142CRT-001b
Intertek Project No. G104488142

CLIENT

FOLIA WATER
68 34th Street, C642
Brooklyn, NY 11232
USA

TEST STANDARD

ASTM F2100 *Standard Specification for Performance of Materials Used in Medical Face Masks,* 2020 Edition

AUTHORIZATION

Quote Number: Qu-01115268-1

SAMPLE IDENTIFIED BY THE CLIENT AS

Product Type: Face Masks, Disposable
Brand Name: Folia Water
Model Numbers: 1024220 A, B, C

SAMPLE INFORMATION

Date(s) Samples Received: November 17, 2020
Condition of Samples: Production Run
Date(s) of Testing: November 23. 2020 Through February 8, 2021

TEST INFORMATION	STATUS	TESTING LOCATION
ASTM F2101 *Bacterial Filtration Efficiency*	Test data attached	Intertek-Cortland, NY
EN 14683:2019 Annex C *Differential Pressure*	Testing in process	Intertek-Guatemala
ASTM F2299 *Sub-Micron Particulate Filtration*	Test data attached	Intertek-Guatemala
ASTM F1862 *Resistance to Penetration by Synthetic Blood*	Test data attached	Intertek-Cortland, NY
16 CFR 1610 *Flammability*	Test data attached	Intertek-Cortland, NY
EN 14683:2019 *Microbial Cleanliness (Bioburden)*	Test data attached	Nelson Labs
Non-Standard Viral Filtration Efficiency	Test data attached	Neslson Labs

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TEST REPORT

Issued February 12, 2021

Intertek Report No. 104488142CRT-001b
Intertek Project No. G104488142

SECTION 1
CONCLUSION

This test report represents the testing covered by proposal number Qu-01115268-1.

The observations and test results in this report are relevant only to the sample tested. Intertek makes no representations or warranties, express or implied, regarding units that were not tested including, but not limited to, units that may be part of the same lot.

If there are any questions regarding the results contained in this report, or any other services offered by Intertek, please do not hesitate to contact the undersigned.

Please note this Test Report does not represent authorization for the use of any Intertek certification marks.

Project Owner:	Steven Morey	**Project Reviewer:**	Jason Allen
Title:	Techincian	**Title:**	Technical Advisor
Signature:		**Signature:**	
Date:	February 12, 2021	**Date:**	February 12, 2021

REPORT REVISIONS

Date / Project #	Project Handler/ Reviewer	Description of Change
2/12/2021	Steven Morey / Jason Allen	Replaced PFE Test Report with Revised Test Report

Total Quality. Assured.

TEST REPORT

SECTION 2

ASTM F2100-20 TEST DATA

BACTERIAL FILTRATION EFFICIENCY (BFE), ASTM F2101-19

Specimens conditioned for 4-hours at 20.4-22.1°C and 83-86%RH

Test Set-up Information	
Area of Test Specimen (cm^2)	48.3
Specimen Side Facing Challenge	Inside of Mask
Flow Rate (LPM)	28.3
Averaged + Control Plate Count	2542
Mean Particle Size (µm)	3

Medical Face Mask Barrier Testing					
Plate Count	**Mask Specimen**				
Stage	**1**	**2**	**3**	**4**	**5**
Stage 1	0	0	0	0	0
Stage 2	0	0	0	0	0
Stage 3	0	0	0	0	0
Stage 4	0	2	1	8	0
Stage 5	3	6	3	7	0
Stage 6	1	2	1	1	0
Plate Count Total	4	10	5	16	0
% BFE	99.84	99.61	99.80	99.37	>99.9

TEST EQUIPMENT INFORMATION

Description	Control Number	Calibration Date	Calibration Due
Conditioning Chamber	308-H252	2/26/2020	2/26/2021
Timer	308-H358	1/13/2020	1/13/2021
Pipette	308-H294	2/26/2020	2/26/2021
Analytical Balance	308-S268	12/2/2019	12/2/2020

Date of Testing	11/23/2020

TEST REPORT

SECTION 4

ASTM F2100-20 TEST DATA

PARTICULATE FILTRATION EFFICIENCY (PFE), ASTM F2299-17

NUMBER :GUAT20026849-REV1

Original Sample

Outside Mask

Inside Mask

Intertek de Guatemala, S.A.
46 calle 21-53 zona 12, Expobodegas Petapa 46,
Ofibodega #10, Guatemala City 01012, Guatemala, PBX: +502 2303 5800

TEST REPORT

intertek
Total Quality. Assured.

protek

TEST REPORT

NUMBER : GUAT20026849-REV1
DATE : 29-Jan-2021

APPLICANT : **Intertek Testing Services NA Inc.**
3993 US Route 11, Cortland, NY, 13045, U.S.A.
ATTN : **Colin King, Matthew Stevens**

THIS IS TO SUPERSEDE REPORT NO. GUAT20026849 DATED 02-Dec-2020

Sample Description	: G104488142_Folia Water_ Brown
Buyer	: Not Provided
Vendor	: Not Provided
Agent	: Not Provided
Manufacturer / Factory	: Not Provided
Color	: Brown
Style Number	: Not Provided
PO Number	: Not Provided
Material /Fiber Content	: Not Provided
Standard	: Not Provided
Product end use	: Non-medical face mask
Date Sample Received / Date Test Started	: 01 Dec 2020

TEST CONDUCTED : AS PER THE REQUEST OF THE APPLICANT. FOR FURTHER DETAILS PLEASE REFER TO ENCLOSED PAGE(S)

CONCLUSION :

¤ Determination of the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres	D

NOTE: P = Meet Buyer's Requirement
* = See Remark
N/A = Not Applicable
F = Below Buyer's Requirement
C = Conform Label
D = Data

This report was issued in order to correct the pictures.

AUTHORIZED BY
FOR Intertek de Guatemala, S.A. [Guatemala]

RUDY SEMRAU
GENERAL MANAGER

REPORTES GUATEMALA

Nelson Labs
A Sotera Health company

Sponsor:
Shubhangi Maheshwari
Folia Materials
390 W Cumming Park
Woburn, MA 01801

Latex Particle Challenge Final Report

Test Article:	102420A - 7 samples 102420B - 7 samples 102420E - 7 samples
Study Number:	1397030-S01
Study Received Date:	10 Mar 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: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	16 Mar 2021: 21.2°C, 22% relative humidity (RH) at 2204; 21.1°C, 22% RH at 2252; 20.9°C, 22% RH at 2308 21 Mar 2021: 21.2°C, 22% RH at 1401; 21.0°C, 22% RH at 1446

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Cameron Brierley electronically approved — 25 Mar 2021 16:48 (+00:00)
Study Director Cameron Brierley — Study Completion Date and Time

Results:

Test Article: 102420A

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	43	13,392	99.68
2	34	13,340	99.75
3	38	13,131	99.71
4	38	12,764	99.70
5	38	12,922	99.71
6	32	12,504	99.74
7	34	11,547	99.71

Average Filtration Efficiency: 99.71%
Standard Deviation: 0.024

Test Article: 102420B

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	37	11,995	99.69
2	30	12,466	99.76
3	41	12,135	99.66
4	45	11,434	99.61
5	28	11,785	99.76
6	45	11,365	99.60
7	44	11,019	99.60

Average Filtration Efficiency: 99.67%
Standard Deviation: 0.071

Test Article: 102420E

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	52	12,331	99.58
2	37	13,258	99.72
3	40	13,731	99.71
4	62	14,017	99.56
5	44	14,341	99.69
6	64	14,715	99.57
7	22	12,463	99.82

Average Filtration Efficiency: 99.66%
Standard Deviation: 0.100

Total Quality. Assured.

TEST REPORT

SECTION 5

ASTM F2100-20 TEST DATA

RESISTANCE TO PENETRATION BY SYNTHETIC BLOOD, ASTM F1862-17

Specimens conditioned for 4-hours at 21-22°C and 83-86%RH

Specimens tested at 21-23°C and 55-62% RH

Medical Face Mask Barrier Testing				
Specimen	**Pressure**	**Test Volume (mL)**	**Visible Penetration of Blood or Wetness**	**Pass/Fail**
1	160 mmHg	2	None	Pass
2	160 mmHg	2	None	Pass
3	160 mmHg	2	None	Pass
4	160 mmHg	2	None	Pass
5	160 mmHg	2	None	Pass
6	160 mmHg	2	None	Pass
7	160 mmHg	2	None	Pass
8	160 mmHg	2	None	Pass
9	160 mmHg	2	None	Pass
10	160 mmHg	2	None	Pass
11	160 mmHg	2	None	Pass
12	160 mmHg	2	None	Pass
13	160 mmHg	2	None	Pass
14	160 mmHg	2	None	Pass
15	160 mmHg	2	None	Pass
16	160 mmHg	2	None	Pass
17	160 mmHg	2	None	Pass
18	160 mmHg	2	None	Pass
19	160 mmHg	2	None	Pass
20	160 mmHg	2	None	Pass
21	160 mmHg	2	None	Pass
22	160 mmHg	2	None	Pass
23	160 mmHg	2	None	Pass
24	160 mmHg	2	None	Pass
25	160 mmHg	2	None	Pass
26	160 mmHg	2	None	Pass
27	160 mmHg	2	None	Pass
28	160 mmHg	2	None	Pass
29	160 mmHg	2	None	Pass
30	160 mmHg	2	None	Pass
31	160 mmHg	2	None	Pass
32	160 mmHg	2	None	Pass

Total Quality. Assured.

TEST REPORT

TEST EQUIPMENT INFORMATION

Description	Control Number	Calibration Date	Calibration Due
Conditioning Chamber	308-H252	2/26/2020	2/26/2021
Automated Dispenser	308-H386	VBU	VBU
Ambient Conditions Monitor	308-G183	4/21/2020	4/21/2021
Timer for Dispenser Verification	308-N1257	3/12/2020	3/12/2021

Date of Testing	12/7/2020

Total Quality. Assured.

TEST REPORT

SECTION 6

16 CFR 1610 TEST DATA
FLAMMABILITY OF CLOTHING TEXTILES

Surface type: Plain, Single Layer
Tested side: Face

Prelminary Test - Original State	
Length Direction	**Burn Time (s)**
Up	IBE
Down	9.85
Width Direction	**Burn Time (s)**
Up	9.86
Down	10.23

Final Test - Original State Width Up Direction	
Specimen	**Burn Time (s)**
1	8.68
2	11.12
3	12.68
4	8.98
5	9.86

Classification:	Class 1, Normal Flammability

Note: Sample is one-time use item, flammability testing performed in original state only

Test Result Codes: Plain Surface Fabrics	
DNI	Did not ignite (no time)
IBE	Ignited, but extinguished (no time

TEST EQUIPMENT INFORMATION

Description	Control Number	Calibration Date	Calibration Due
Circulating Oven	308-H223	2/26/2020	2/26/2021
Flame Chamber	US20041501	VBU	VBU

Date of Testing	12/4/2020

Total Quality. Assured.

TEST REPORT

SECTION 6

EN 14683:2019 TEST DATA

MICROBIAL CLEANLINESS (BIOBURDEN)

Nelson Labs.
A Sotera Health company

Sponsor:
Colin King
Intertek Etl Semko Division
3933 Us Rte. 11
Cortland, NY 13045

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	G104488142_FW_ Brown_MASK
Purchase Order:	USA20-0000246160
Study Number:	1370695-S01
Study Received Date:	09 Dec 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: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202002096 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019 and ANSI/AAMI/ISO 11737-1:2018. When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.7	<3	<3	<6.1	<1.7
2	3.6	<3	<3	<6.0	<1.7
3	3.8	<3	<3	<6.2	<1.6
4	3.6	<3	<3	<6.0	<1.7
5	3.6	<3	<3	<6.0	<1.7
Recovery Efficiency	UTD*				

< = No Organisms Detected
UTD = Unable to Determine
Note: The results are reported as colony forming units (CFU) per mask.
* UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended.

ilac-MRA ANAB ACCREDITED

Gabrielle Waldron electronically approved
Study Director Gabrielle Waldron

18 Dec 2020 16:54 (+00:00)
Study Completion Date and Time

801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com hcb FRT0036-0010 Rev 12
Page 1 of 2

These results apply to the samples as received and relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NLS terms and conditions at www.nelsonlabs.com.

TEST REPORT

Nelson Labs
A Sotera Health company

Study Number 1370695-S01
Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	0%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5.The bioburden of the medical mask shall be ≤ 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar
	Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3-7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5-7 days at 20-25°C, then enumerated.

Total Quality. Assured.

TEST REPORT

SECTION 7

NON-STANDARD VIRAL FILTRATION EFFICIENCY

Nelson Labs
A Sotera Health company

Sponsor:
Krissie Brown
Intertek Etl Semko Division
3933 US Route 11
Cortland, NY 13045

Viral Filtration Efficiency (VFE) Final Report

Test Article:	Folia Water G104488142 VFE
Purchase Order:	USA20-0000246336
Study Number:	1377843-S01
Study Received Date:	06 Jan 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: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 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 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

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
Test Area:	~40 cm^2
VFE 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
Positive Control Average:	1.1 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Janelle Bentz electronically approved for
Study Director Mikell Goldsberry

08 Feb 2021 19:50 (+00:00)
Study Completion Date and Time

Total Quality. Assured.

TEST REPORT

Nelson Labs
A Sotera Health company

Study Number 1377843-S01
Viral Filtration Efficiency (VFE) Final Report

Results:

Test Article Number	Percent VFE (%)
1	99.6
2	99.3
3	99.3
4	99.5
5	99.7

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request