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Sponsor:
Jessica Mao
Premium Plus (Dongguan) Ltd.
No. 1 Industrial Area
Tutang, Changping
Dongguan, Guangdong, 523581
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Product name: Disposable Face Mask Model #2288 LOT #95000330
Study Number:	1294277-S01
Study Received Date:	30 Apr 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: 202002490 Rev 01
Deviation(s):	None

Summary: The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in accordance with ANSI/AAMI/ISO 11737-1:2018. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results: When bioburden results are calculated using a validated 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.

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.3	3	<3	6.1	1.9
2	3.3	6	<3	8.9	2.7
3	3.3	3	<3	5.9	1.8
4	3.3	6	6	11.9	3.6
5	3.2	6	3	8.9	2.8
Recovery Efficiency	40.4%				

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.

Robert Putnam electronically approved
Study Director Robert Putnam

14 May 2020 18:00 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	100%

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 or more to meet an acceptable quality level of 4%. 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 for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Potato Dextrose Agar Tryptic Soy 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.

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Flammability of Clothing Textiles Final Report

Test Article:	Product name: Disposable Face Mask Model #2288 LOT #95000330
Study Number:	1294272-S01
Study Received Date:	29 Apr 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: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Brent Shelley electronically approved for Curtis Gerow
Study Director

08 May 2020 17:19 (+00:00)
Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished

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Premium Plus (Dongguan) Ltd.
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Tutang, Changping
Dongguan, Guangdong, 523581
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Product name: Disposable Face Mask Model #2288 LOT #95000330
Study Number:	1294276-S01
Study Received Date:	29 Apr 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 3.1 - 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; with the exception of the higher challenge level which may represent a more severe test.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~176 mm x ~158 mm
Positive Control Average:	3.1 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

During incubation, the incubator was noted to be out of range (OOR) for 1 hour 19 minutes. The incubation time was extended to meet the required parameters of 44 hours @ 33-37°C.

Study Director — James W. Luskin — 04 Jun 2020 — Study Completion Date

1294276-S01

The positive control average was out of specification per STP0004 Rev 18 section 6.1 which states, "The BFE positive control average shall be maintained at 1.7-3.0 x 10^3 CFU." Testing with a more severe challenge to the test articles represents a worse case. The sponsor accepted the use of the higher challenge; therefore, the results are considered valid at the testing conditions that occurred.

Results:

Test Article Number	Percent BFE (%)
1	99.3
2	99.8
3	99.5
4	99.4
5	99.4

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.1	40.4
2	4.4	43.1
3	4.0	39.0
4	4.0	39.4
5	4.2	40.9

The filtration efficiency percentages were calculated using the following equation:

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

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

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Premium Plus (Dongguan) Ltd.
No. 1 Industrial Area
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CHINA

Latex Particle Challenge Final Report

Test Article:	Product name: Disposable Face Mask Model #2288 Lot #95000330
Study Number:	1294273-S01
Study Received Date:	29 Apr 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: STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s): QE22125

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 and the counts were averaged. 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.

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:	21°C, 24% relative humidity (RH) at 1848; 21°C, 24% RH at 2000
Average Filtration Efficiency:	99.52%
Standard Deviation:	0.105

Christopher Acker electronically approved for Curtis Gerow
Study Director

31 May 2020 00:57 (+00:00)
Study Completion Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	54	11,049	99.51
2	38	10,783	99.65
3	71	11,190	99.37
4	55	11,382	99.52
5	47	11,206	99.58