Nelson Labs
A Sotera Health company

Sponsor:
Natachnon Mongkolchotyada
Med-Con (Thailand) Co., Ltd.
20 Soi Ruammit, Rama 6 Rd.
Samsennai, Phayathai
Bangkok, 10400
THAILAND

Latex Particle Challenge Final Report

Test Article:	MCBJJ-1095-PFE
Study Number:	1196117-S01
Study Received Date:	25 Jun 2019
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 06
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, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average 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, 32% relative humidity (RH) at 0906; 20°C, 32% RH at 1018
Average Filtration Efficiency:	99.73%
Standard Deviation:	0.026

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Curtis Gerow For 05 Jul 2019

Study Director — Janelle R. Bentz, M.S. — Study Completion Date

1196117-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	28	11,534	99.76
2	35	11,302	99.69
3	29	11,018	99.74
4	28	11,144	99.75
5	31	11,135	99.72

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

Test Article:	MCBJJ-1095-BFE
Study Number:	1196118-S01
Study Received Date:	25 Jun 2019
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 16
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 - 2.7 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 F2101-14, Annex B, and AS4381:2015.

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 was designed to comply with MIL-M-36954C, Section 4.4.1.2, and complies with AS4381:2015.

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:	~177 mm x ~164 mm
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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Curtis Dixon For — Study Director — Janelle R. Bentz, M.S.

15 Jul 2019 — Study Completion Date

1196118-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9	2.2	21.7
2	99.5	2.5	24.2
3	99.6	2.5	24.5
4	99.4	2.3	22.9
5	99.8	2.2	21.1

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

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Flammability of Clothing Textiles Final Report

Test Article: MCBJJ-1095-FTS
Study Number: 1196119-S01
Study Received Date: 25 Jun 2019
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.

Results:

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

IBE = Test Article ignited, but extinguished

Curtis Gerow For Janelle R. Bentz, M.S. — Study Director

05 Jul 2019 — Study Completion Date

1196119-S01

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Differential Pressure (Delta P) Final Report

Test Article:	MCBJJ-1095-DPT
Study Number:	1196120-S01
Study Received Date:	25 Jun 2019
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 16
Deviation(s):	None

Summary: 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 was designed to comply with EN 14683:2019, Annex C.

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
Delta P Flow Rate:	8 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:	~179 mm x ~166 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.7	35.9
2	4.1	40.0
3	4.1	40.5
4	4.1	40.3
5	4.2	41.2

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Curtis Gerow — Study Director

For Janelle R. Bentz, M.S.

05 Jul 2019 — Study Completion Date

1196120-S01

Test Report

Date : 2020-10-30
No. : HC20100291

Applicant(Code:01325844) : Med-Con (Thailand) Company Limited
20 Soi Ruammit, Rama 6 Road, Phayathai, Phayathai, Bangkok, Thailand 10400

Description of Sample(s) : One submitted sample said to be 3 Ply Disposable Medical Facemask.
Country of Origin : Thailand

Sample(s) Received Condition(s): In plastic bag under ambient temperature

Date Sample(s) Received : 2020-10-12

Date Tested : 2020-10-16 to 2020-10-28

Investigation Requested : Bacterial Filtration Efficiency 細菌過濾效率 (BFE) %
– *Staphylococcus aureus*金黃色葡萄球菌 (ATCC 6538)

Method(s) Used : ASTM F2100-2019 9.1 &ASTM F2101-2019

LAU Yuk Kuen, Joey
Authorized Signatory
Chemical and Food Department
For and on behalf of
The Hong Kong Standards and Testing Centre Ltd

In the event of any discrepancy between the English and Chinese versions of the text mentioned before, the English version shall prevail to the extent of such discrepancy only.

The Hong Kong Standards and Testing Centre Limited 香港標準及檢定中心有限公司
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Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

Test Report

Date : 2020-10-30
No. : HC20100291

Test Result(s):

Bacterial Filtration Efficiency細菌過濾效率 (BFE) %
– *Staphylococcus aureus*金黃色葡萄球菌 (ATCC 6538)

Specimen(s)	**3 Ply Disposable Medical Facemask**
1	>99.9%
2	>99.9%
3	>99.9%
4	>99.9%
5	>99.9%

Notes : - Control average 對照組的平均菌落數 : 1730 CFU
- Mean particle size 平均粒徑 : 3.1μm
- Testing side 測試面 : Outside of specimen外側
- Testing area 測試面積 : 47 cm^2

******* End of Test Report *******

The Hong Kong Standards and Testing Centre Limited 香港標準及檢定中心有限公司
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