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A Sotera Health company

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Yau Tong, Kowloon, 000000
HONG KONG

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

Test Article:	LHM-E1 Lot 001: 50 disposable surgical masks Lot 002: 50 disposable surgical masks Lot 003: 50 disposable surgical masks Lot 004: 50 disposable surgical masks Lot 005: 50 disposable surgical masks
Purchase Order:	M-03122021
Study Number:	1299037-S01.2 Amended
Study Received Date:	13 May 2020
Study Completion Date:	12 Jun 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.

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.

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:	~175 mm x ~156 mm
Positive Control Average:	2.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Alexa Sanders electronically approved — 20 Jul 2020 20:26 (+00:00)
Study Director Alexa Sanders — Amended Report Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9
2	99.9
3	99.8
4	99.8
5	99.7

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.5	33.9
2	3.7	35.9
3	3.8	37.1
4	3.7	36.0
5	3.7	36.2

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

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{A}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Amendment Justifications:

.2 Amended: At the request of the sponsor, the test article was updated from "LHM-E11" to "LHM-E1".

.1 Amended: At the request of the sponsor, "LHM-E11" was added to the test article ID.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	22 May 2020
Phase Inspected by Quality Assurance: BFE Challenge Procedure	27 May 2020
Audit Results Reported to Study Director	27 May 2020
Audit Results Reported to Management	27 May 2020

Scientists	Title
Denise Anderson	Supervisor
Alexa Sanders	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Robert De Vargas electronically approved
Quality Assurance

20 Jul 2020 20:24 (+00:00)
Date and Time

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HONG KONG

Synthetic Blood Penetration Resistance GLP Report

Test Article:	Fluid Resistant Procedure Mask, Model LHM-E1
Purchase Order:	M-071520201
Study Number:	1321627-S01
Study Received Date:	17 Jul 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: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	31
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.7°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1, 3-32	None Seen
2	Yes

Adam Brigham electronically approved — 03 Aug 2020 15:26 (+00:00)
Study Director — Adam Brigham — Study Completion Date and Time

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be ≤5% (±0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	23 Jul 2020
Phase Inspected by Quality Assurance: Sample Preparation and Conditioning	28 Jul 2020
Audit Results Reported to Study Director	29 Jul 2020
Audit Results Reported to Management	31 Jul 2020

Scientists	Title
Adrianne Sandall	Supervisor
Adam Brigham	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Camille Coffey electronically approved
Quality Assurance

31 Jul 2020 22:17 (+00:00)
Date and Time

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Hong Kong

Differential Pressure (Delta P) GLP Report

Test Article:	Fluid Resistant Procedure Mask MODEL: LHM-E1 LOT: 20100907245
Purchase Order:	012620208
Study Number:	1377149-S01
Study Received Date:	04 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: STP0004 Rev 18
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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met.

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

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sean Shepherd electronically approved — 21 Jan 2021 15:43 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)	Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.5	34.2	17	3.3	32.2
2	3.1	30.8	18	3.4	33.2
3	3.5	34.7	19	3.8	37.7
4	3.2	31.6	20	3.7	36.2
5	3.5	34.1	21	3.6	35.6
6	3.6	35.6	22	3.9	38.1
7	3.7	36.1	23	3.6	34.9
8	3.3	32.6	24	3.5	34.6
9	3.7	36.0	25	3.3	32.0
10	3.2	31.0	26	3.7	36.1
11	3.6	35.6	27	3.4	33.8
12	3.3	32.1	28	3.4	33.1
13	3.4	33.0	29	3.2	31.1
14	3.4	32.9	30	3.6	35.7
15	3.3	32.6	31	3.2	31.2
16	3.3	32.2	32	3.2	31.8

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to Delta P testing.

Test Method Acceptance Criteria: The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

Procedure:

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{A}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	07 Jan 2021
Phase Inspected by Quality Assurance: Delta P Measurements	08 Jan 2021
Audit Results Reported to Study Director	11 Jan 2021
Audit Results Reported to Management	11 Jan 2021

Scientists	Title
Adrianne Sandall	Supervisor
Sean Shepherd	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Erika Shewell electronically approved
Quality Assurance

20 Jan 2021 23:05 (+00:00)
Date and Time

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Flammability of Clothing Textiles GLP Report

Test Article:	Model #LHM-E1 Lot 001: 50 disposable surgical masks
Purchase Order:	M-03122021
Study Number:	1299036-S01
Study Received Date:	13 May 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.

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.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sean Shepherd electronically approved — 10 Jul 2020 17:09 (+00:00)
Study Director Sean Shepherd — 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

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~⅝ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	22 May 2020
Phase Inspected by Quality Assurance: Sample Preparation / Conditioning	27 May 2020
Audit Results Reported to Study Director	23 Jun 2020
Audit Results Reported to Management	23 Jun 2020

Scientists	Title
Alexa Sanders	Supervisor
Sean Shepherd	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Loxane Konesavanh electronically approved
Quality Assurance

10 Jul 2020 17:01 (+00:00)
Date and Time

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A Sotera Health company

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Yau Tong, Kowloon, 000000
HONG KONG

Intracutaneous Injection Test - ISO (GLP)

Test Article:	Lot 001: 50 disposable surgical masks (Blue) LHM-E1
Purchase Order:	M-03122021
Study Number:	1299032-S01.1 Amended
Study Received Date:	13 May 2020
Testing Facility:	Toxikon USA
Deviations:	None

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

Amendment Justification: The test article was updated throughout the final report.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 801-290-7500 or subcontracting@nelsonlabs.com. Thank you for testing with Nelson Laboratories, LLC.

Toxicologist — Trevor Fish, M.S.

07 July 2020
Amended Date

1299032-S01

TOXIKON
RIGHT. FROM THE START.SM

FINAL GLP REPORT: 20-01800-G2
SECOND AMENDED

Nelson Report Number: NL# 1299032

INTRACUTANEOUS INJECTION TEST – ISO

Test Article
Lot 001: 50 disposable surgical masks (Blue) LHM-E1

21 CFR Part 58 Compliance
Good Laboratory Practice for Nonclinical Laboratory Studies

Final Report Date
6/3/2020

Amended Final Report Date
6/30/2020

Second Amended Final Report Date
7/7/2020

Study Director
Sarah Goulet, M.S.

Sponsor
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A Sotera Health Company
6280 South Redwood Road
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STUDY SUMMARY

The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, Lot 001: 50 disposable surgical masks (Blue) LHM-E1, were evaluated for their potential to produce irritation after intracutaneous injection in New Zealand White rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.

Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993–10 guidelines.

QUALITY ASSURANCE STATEMENT

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to Toxikon's Management.

The final report was reviewed to assure that the report accurately describes the methods and standard operating procedures. The reported results accurately reflect the raw data of the nonclinical study conducted per the protocol.

Phase	Inspection Date	Date Reported to Study Director	Date Reported to Management
SCORING	5/28/2020	5/28/2020	5/28/2020
DATA	6/1/2020	6/1/2020	6/1/2020
FINAL REPORT	6/3/2020	6/3/2020	6/3/2020
AMENDED REPORT	6/30/2020	6/30/2020	6/30/2020
SECOND AMENDED REPORT	7/7/2020	7/7/2020	7/7/2020

Stephanie McHugh

Stephanie McHugh, B.S.
Quality Assurance

7-7-20
Date

GLP COMPLIANCE STATEMENT

This study meets the technical requirements of the protocol.

This study was conducted in compliance with the current U.S. Food and Drug Administration 21 CFR, Part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

The sections of the regulations not performed by or under the direction of Toxikon Corporation, exempt from this Good Laboratory Practice Statement, included characterization and stability of the test article, 21 CFR, Part 58.105, and its mixture with carriers, 21 CFR, Part 58.113.

SIGNATURES

Signature Information	
Protocol Number	p19-1787-00d
Study Director	Sarah Goulet, M.S.
Study Supervisor	Allan Sleger, A.S., LAT
Company	Toxikon Corporation

VERIFICATION DATES

The study initiation day is the date the protocol is signed by the Study Director.

Verification Dates	
Test Article Receipt	5/21/2020
Project Log	5/21/2020
Study Initiation	5/21/2020
Study Completion	6/3/2020

Sarah Goulet
Sarah Goulet, M.S.
Study Director

7/7/2020
Date

1.0 PURPOSE

The purpose of the study was to determine the potential irritation effects of the test article extract as a result of an intracutaneous injection in New Zealand White rabbits.

2.0 REFERENCES

The study was based upon the following references:

- ISO 10993–10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993–12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials.
- ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

3.0 COMPLIANCE

The study conformed to the current FDA 21 CFR, Part 58 – Good Laboratory Practice for Nonclinical Laboratory Studies.

4.0 IDENTIFICATION OF TEST AND CONTROL ARTICLES

The Sponsor supplied the following information on a Test Requisition Form or other correspondence, wherever applicable (excluding confidential or trade secret information). The Sponsor was responsible for all test article characterization data as specified in the GLP regulations.

4.1 Test Article:

Name: Lot 001: 50 disposable surgical masks (Blue) LHM-E1

CAS/Code Number: Not Supplied by Sponsor (N/S)

Lot/Batch Number: Lot 001

Physical State: Solid

Color: Blue

Expiration Date: N/S

Density: Unknown

Stability: Unknown

Sterility: Not Sterile

Sterilization Conditions: N/S

Storage Conditions: Room Temperature

Safety Precautions: Unknown

Intended Use: N/S

4.2 Negative Control Articles (Toxikon Supplied):

4.2.1 Negative Control Article 1:

Name: USP 0.9% Sodium Chloride for Injection (NaCl)

Toxikon QC Number: CSC-20-02-00174

4.2.2 Negative Control Article 2:

Name: Cottonseed Oil (CSO)

Toxikon QC Number: CSC-20-03-00033

5.0 IDENTIFICATION OF TEST SYSTEM

5.1 Animals Used in the Study:

Number and Species: 3 New Zealand White rabbits (*Oryctolagus cuniculus*)

Sex: female (females were non–pregnant and nulliparous)

Weight/Age Range: 2.86 – 3.10 kilograms / at least 10 weeks old (adult) weighed to the nearest 10 g

Health Status: healthy, previously used in other experimental procedures

Animal Purchase: Envigo Global Services, Denver, PA

Animal Identification: ear tattoo

Acclimation: minimum 5 days, under same conditions as for the actual test

Animal Selection: selected from larger pool and examined to ensure lack of adverse clinical signs

5.2 Animal Care and Maintenance:

Animal Room Target Temperature: 68 ± 5 °F

Animal Room Target Relative Humidity: 30–70%

Air Exchanges per Hour: a minimum of 10 changes per hour

Lights: 12–hour light/dark cycle, full spectrum fluorescent lights

Housing: individually housed

Cages: suspended stainless steel

Bedding: Alfa Cobs, ScottPharma Solutions, Marlborough, MA (non-contact)

Animal Rations: Teklad Global High Fiber Rabbit Diet 2031, Envigo, Madison, WI, *ad libitum*

Water: tap water, *ad libitum*

There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

The laboratory and animal rooms were maintained as limited–access facilities.

6.0 JUSTIFICATION OF TEST SYSTEM AND ROUTE OF ADMINISTRATION

6.1 Justification of Test System:

Historically, New Zealand White rabbits have been used in intracutaneous safety evaluation studies because the guidelines have no alternative (non–animal) methods. The animal species, number, and route of test article administration are recommended by the ISO 10993–10 guidelines.

6.2 Route of Administration:

Animals were treated by intracutaneous injections. The test article was extracted and administered *in vivo* through a medium compatible with the test system, as indicated on the Test Requisition Form.

7.0 EXPERIMENTAL DESIGN AND DOSAGE

7.1 Preparation of Test and Control Articles:

7.1.1 Preparation, Extraction Medium, and Extraction Conditions:

The test article (585 cm^2 as per Sponsor) was combined with 195.0 mL of vehicle following an ISO 10993–12 ratio of 3 cm^2 per 1 mL. The test article was separately extracted in NaCl and CSO at 50 ± 2 °C for 72 ± 2 hours under dynamic conditions. A total of 2 units were used for testing.

7.1.2 Addition of Extraction Medium:

Properly prepared test articles were placed in separate extraction vessels, and to each vessel the appropriate medium was added. The extraction medium completely covered the test article.

7.1.3 Control Conditions:

An untreated control (blank) was prepared for parallel treatment and comparison. The untreated control was the extraction medium that was subjected to the same temperature and for the same duration as the test article.

7.1.4 Extract Agitation:

Each extract was agitated vigorously prior to administration.

7.1.5 Extract Examination:

The test article appeared unchanged by the extraction procedure. The extracts were clear and free of particulates and the color of the vehicle unchanged.

7.1.6 Extract Manipulation:

The extracts were not filtered, centrifuged, or pH adjusted.

7.1.7 Extract Storage:

Following extraction, the vessel containing each test or control article was cooled to room temperature.

After the completion of the extraction, the extracts were kept at room temperature and were used the same day the extraction was completed. No storage of the extracts occurred.

7.1.8 Other Test Article Preparation:

All other test article preparation was as specified by the Sponsor.

7.2 Pre–Dose Procedure:

7.2.1 Pre–Treatment Screening Procedure:

Animals selected for the study were examined to ensure that their skin was free from irritation, trauma, and disease.

7.2.2 Body Weights:

Each animal was weighed on the day of the study prior to injection.

7.2.3 Fur Clipping:

Each animal was clipped free of fur on the dorsal side within 4 to 18 hours prior to injection.

7.3 Dose Administration:

A volume of 0.2 mL per site of one extract was injected intracutaneously at one side of each of three rabbits, five sites for the test article extract and five posterior sites for the control.

Similarly, at the other side of each rabbit, the other extract was injected.

The maximum injections per rabbit was limited to 2 test articles and 2 corresponding control articles.

Extracts prepared with NaCl and CSO were tested at 100% (neat) concentration.

7.4 Post–Dose Procedure:

The injection sites on each animal were observed for signs of erythema and edema immediately following injection and at 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours after injection of the test article. Observations were scored according to the Classification System for Scoring Skin Reactions (see Appendix I).

7.4.1 Clinical Observations:

Observations conducted also included all clinical and toxicologic signs.

7.4.2 Body Weights:

At the end of the observation period, the animals were weighed.

7.4.3 Euthanasia:

At the end of the study, the animals were returned to the general colony.

8.0 EVALUATION CRITERIA

8.1 Evaluation of Data:

After the 72 ± 2 hours grading, all erythema grades plus edema grades from 24 ± 2 hours, 48 ± 2 hours, and 72 ± 2 hours were totaled separately for each test article or vehicle control for each individual animal. To calculate the score of a test article or vehicle control on each individual animal, divide each of the totals by 15 (3 scoring time points × 5 test or vehicle control injection sites). To determine the overall mean score for each test article and each corresponding vehicle control, add the scores for the three animals and divide by three. The final test article score was obtained by subtracting the score of the vehicle control from the test article score. The requirements of the test will be met if the difference between the test article mean score and the vehicle control mean score is 1.0 or less. If at any observation period the average reaction to the test article is questionably greater than the average reaction to the vehicle control, the test will be repeated using three additional rabbits.

8.2 Control of Bias Statement:

The study as designed employed methodology to minimize uncertainty of measurement and to control bias for data collection and analysis, which included but was not limited to: concurrent control data, system suitability assessment, randomization, and method controls such as blanks and replicates.

9.0 RESULTS

9.1 Animal Weights:

All of the test animals maintained or increased in weight (Table 1).

9.2 Clinical Observations:

None of the animals exhibited overt signs of toxicity at any of the observation points (Table 1).

The sites injected with the test article did not show a significantly greater biological reaction than the sites treated with the control article (Table 2). The difference of the overall mean score between the test article and the control article was 0.0.

10.0 CONCLUSION

The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article, Lot 001: 50 disposable surgical masks (Blue) LHM-E1, were evaluated for their potential to produce irritation after intracutaneous injection in New Zealand White rabbits. The test article sites did not show a significantly greater biological reaction than the sites injected with the control article.

Based on the criteria of the protocol, the test article meets the requirements of the ISO 10993–10 guidelines.

11.0 RECORDS

- Original raw data will be archived by Toxikon Corporation.
- The original final report and any report amendments will be archived by Toxikon Corporation.

- A copy of the final report and a copy of any protocol amendments or deviations will be forwarded to the Sponsor.
- The test article will be disposed by Toxikon.
- Test article retention upon study completion is the responsibility of the Sponsor.

12.0 CONFIDENTIALITY AGREEMENT

Per corporate policy, confidentiality shall be maintained in general, and in specific accordance with any relevant agreement specifically executed between Toxikon and the Sponsor.

13.0 ANIMAL WELFARE STATEMENT

The Sponsor assured that, to the best of their knowledge, this study did not unnecessarily duplicate previous testing and that there were no non–animal alternatives acceptable for the evaluation of this test article as defined by the protocol.

No evidence of pain and distress was reported to the Veterinarian and/or Study Director during the course of this study.

Toxikon strictly adheres to the following standards in maintaining the animal care and use program:

United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, 9 CFR Ch. 1, Subchapter A–Animal Welfare.

"Guide for the Care and Use of Laboratory Animals," National Research Council, 2011.

Office for Laboratory Animal Welfare (OLAW), "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Health Research Extension Act of 1985 (Public Law 99–158 November 20, 1985), revised 2015.

ISO 10993–2, 2006, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements.

AAALAC International accreditation.

14.0 UNFORESEEN CIRCUMSTANCES

Any unforeseen circumstances were documented in the raw data. However, no unforeseen circumstances that affected the integrity of the study were noted.

15.0 PROTOCOL AMENDMENTS/DEVIATIONS

There were no protocol amendments or deviations. No changes to the protocol were required.

TABLE 1:
Animal Weights and Clinical Observations

Group	Animal #	Sex	Body Weight (kg)			Signs of Toxicity*
			Day 0 5/27/2020	Day 3 5/30/2020	Weight Change	
NaCl & CSO	00596	Female	2.99	3.01	0.02	None
	00604	Female	2.86	2.86	0.00	None
	00608	Female	3.10	3.16	0.06	None

* Summary of Clinical Observations at 24, 48, and 72 hours excluding skin reactions.

TABLE 2:
Intracutaneous Test Skin Reaction Scores

NaCl Extract

Animal #	Vehicle	Time	Site Numbers Scoring (ER/ED)									
			T–1	T–2	T–3	T–4	T–5	C–1	C–2	C–3	C–4	C–5
00596	NaCl	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
00604	NaCl	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
00608	NaCl	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

† = Immediately after injection, not used for the evaluation criteria.

Animal #	Vehicle	Total Scores (ER + ED)		*Individual Score	
		Test	Control	Test	Control
00596	NaCl	0	0	0.0	0.0
00604	NaCl	0	0	0.0	0.0
00608	NaCl	0	0	0.0	0.0
			**Overall Mean Score	0.0	0.0

*Individual Score = Total (ER + ED) divided by 15 (3 grading periods × 5 test or control sites)

** Overall Mean Score = Total Individual Scores divided by 3 animals
Overall Mean Score for Test Article = 0.0
Overall Mean Score for Control Article = 0.0
Difference between Test Article and Control Article Overall Mean Score = 0.0 – 0.0 = 0.0

ER = Erythema T = Test Site
ED = Edema C = Control Site

TABLE 2:
Intracutaneous Test Skin Reaction Scores (Cont.)

CSO Extract

Animal #	Vehicle	Time	Site Numbers Scoring (ER/ED)									
			T–6	T–7	T–8	T–9	T–10	C–6	C–7	C–8	C–9	C–10
00596	CSO	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
00604	CSO	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
00608	CSO	0 hours†	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		24 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		48 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
		72 hours	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

† = Immediately after injection, not used for the evaluation criteria.

Animal #	Vehicle	Total Scores (ER + ED)		*Individual Score	
		Test	Control	Test	Control
00596	CSO	0	0	0.0	0.0
00604	CSO	0	0	0.0	0.0
00608	CSO	0	0	0.0	0.0
			**Overall Mean Score	0.0	0.0

*Individual Score = Total (ER + ED) divided by 15 (3 grading periods × 5 test or control sites)

** Overall Mean Score = Total Individual Scores divided by 3 animals
Overall Mean Score for Test Article = 0.0
Overall Mean Score for Control Article = 0.0
Difference between Test Article and Control Article Overall Mean Score = 0.0 – 0.0 = 0.0

ER = Erythema T = Test Site
ED = Edema C = Control Site

REPORT AMENDMENT PAGE

SPONSOR:
Nelson Laboratories, LLC
A Sotera Health Company
6280 South Redwood Road
Salt Lake City, UT 84123
USA

TESTING LABORATORY:
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730

Test Article Name:	Lot 001: 50 disposable surgical masks (Blue) LHM-E1
CAS/Code #:	Not Supplied by Sponsor (N/S)
Lot/Batch Number:	Lot 001

FIRST AMENDMENT:

Per Sponsor request, we have changes the Test Article Name from:

Lot 001: 50 disposable surgical masks (Blue)

To:

Lot 001: 50 disposable surgical masks (Blue) LHM-E11

SECOND AMENDMENT:

Per Sponsor request, we have changes the Test Article Name from:

Lot 001: 50 disposable surgical masks (Blue) LHM-E11

To:

Lot 001: 50 disposable surgical masks (Blue) LHM-E1

These amendments do not affect the integrity of the study.

AUTHORIZED PERSONNEL:

Sarah Goulet, M.S.
Study Director

7/7/2020
Date

APPENDIX I:
Classification System for Scoring Skin Reactions

Erythema and Eschar Formation	Value
No erythema	0
Very slight erythema (barely perceptible)	1
Well–defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation (preventing grading of erythema)	4

Total possible erythema score = 4

Edema Formation	Value
No edema	0
Very slight edema (barely perceptible)	1
Well–defined edema (edges are well–defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible score for irritation = 8

APPENDIX II:
Software Systems

Software	Use	21 CFR Part 11 Status	Publisher/ Vendor	Location
Adobe Acrobat 8, 9, and 10 Professional	Document preparation	Not Applicable	Adobe Systems, Inc.	San José, CA
Matrix Gemini 5.3.19	Laboratory Information Management System	Compliant	Autoscribe Limited	Reading, UK
MS Office 2010 Small Business Suite and MS Office 2013 Professional Suite and higher	Business software (suite includes Word, Excel, PowerPoint, Outlook, Publisher, Office tools)	Not Applicable	Microsoft Corporation	Redmond, WA
Rees Scientific Centron Presidio 3.0	Automated Environmental Monitoring	Compliant	Rees Scientific	Trenton, NJ
TMS Web 7	Document management for SOPs and training records management software system	Compliant	Quality Systems Integrators	Eagle, PA
Toxikon Protocol Manager 1.0	Protocol requisition application	Not Applicable	Toxikon Corporation	Bedford, MA

Lloyd's Register

Current issue date: 1 August 2020
Expiry date: 31 July 2023
Certificate identity number: 10285324

Original approval(s):
ISO 13485 - 1 August 2020

Certificate of Approval

This is to certify that the Management System of:

LHM Medical Technology (Hong Kong) Limited

Unit No. 2, 3/F, Block A, Ko Fai Industrial Building, No. 7 Ko Fai Road, Yau Tong, Kowloon, Hong Kong

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 00026428

The scope of this approval is applicable to:

Manufacture of face mask.

Rhett Wang

Area Operations Manager, North Asia

Issued by: Lloyd's Register Quality Assurance (Shanghai) Co., Ltd.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

Nelson Labs
A Sotera Health company

Sponsor:
Martin Chui
LHM Medical Technology (Hong Kong) Ltd.
Unit No.2, 3/F, Block A, Ko Fai
Industrial Building, No.7 Fai Road
Yau Tong, Kowloon, 000000
HONG KONG

Latex Particle Challenge GLP Report

Test Article:	Lot 001: 50 disposable surgical masks LHM-E1 Lot 002: 50 disposable surgical masks LHM-E1 Lot 003: 50 disposable surgical masks LHM-E1 Lot 004: 50 disposable surgical masks LHM-E1 Lot 005: 50 disposable surgical masks LHM-E1
Purchase Order:	M-03122021
Study Number:	1299035-S01.1 Amended
Study Received Date:	13 May 2020
Study Completion Date:	04 Jun 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.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20°C, 32% relative humidity (RH) at 1106; 21°C, 32% RH at 1253
Average Filtration Efficiency:	99.80%
Standard Deviation:	0.044

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sarah Guzman electronically approved — 08 Jul 2020 15:51 (+00:00)
Study Director — Sarah Guzman — Amended Report 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	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
Lot 001	28	10,726	99.74
Lot 002	18	12,295	99.85
Lot 003	24	12,675	99.81
Lot 004	23	12,368	99.81
Lot 005	28	12,224	99.77

Test Method Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:
Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <100 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL was aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The number of particles being delivered to the test article was determined (no medium in air stream) as one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. One-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

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

Where: C = Combined average of the control counts
T = Average test article counts

Amendment Justification: At the request of the sponsor, the test article was updated to include "LHM-E1".

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	22 May 2020
Phase Inspected by Quality Assurance: Latex Test	28 May 2020
Audit Results Reported to Study Director	29 May 2020
Audit Results Reported to Management	29 May 2020

Scientists	Title
Denise Anderson	Supervisor
Sarah Guzman	Study Director
Sean Shepherd	Scientist

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nicole Widmer electronically approved
Quality Assurance

08 Jul 2020 15:03 (+00:00)
Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Martin Chui
LHM Medical Technology (Hong Kong) Ltd.
Unit No.2, 3/F, Block A, Ko Fai
Industrial Building, No.7 Fai Road
Yau Tong, Kowloon, 000000
HONG KONG

MEM Elution GLP Report

Test Article:	Lot 001: 50 disposable surgical masks (Blue) LHM-E1
Purchase Order:	M-03122021
Study Number:	1299031-S01.1 Amended
Study Received Date:	13 May 2020
Study Completion Date:	28 May 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: STP0032 Rev 10
Deviation(s):	None

Summary: The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. All test method acceptance criteria were met.

Results:
Test Article:

Dilution	Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
		#1	#2	#3	Average		
Neat	**Pass**	0	0	0	0		
1:2	**Pass**	0	0	0	0		
1:4	**Pass**	0	0	0	0	3 cm^2/mL	585 cm^2 / 195 mL
1:8	**Pass**	0	0	0	0		
1:16	**Pass**	0	0	0	0		

Note: An additional 10 mL of media was added to account for absorbency.

Danielle Short
Study Director — Danielle M. Short, B.S., SM(NRCM)

30 Jun 2020
Amended Report Date

1299031-S01

Controls:

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average		
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL
Media Control	0	0	0	0	N/A	20 mL
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL

Test Method Acceptance Criteria: The United States Pharmacopeia & National Formulary (USP <87>) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

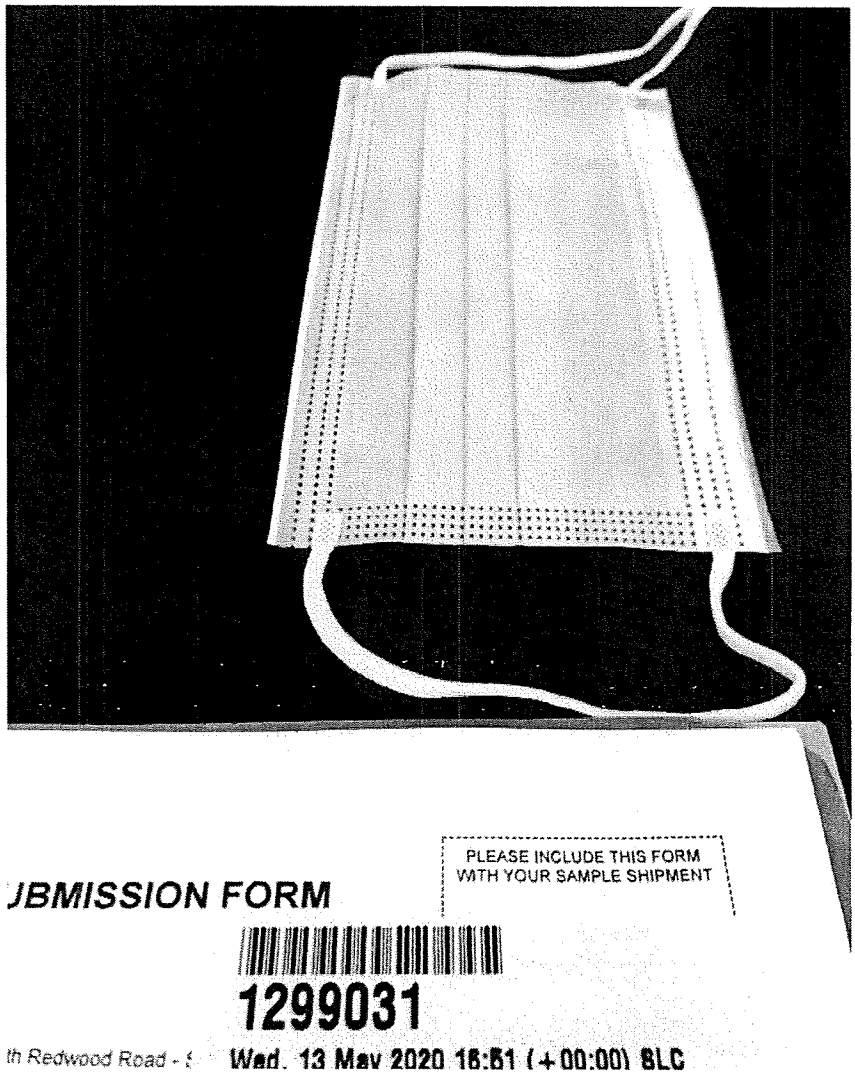
Conditions of All Cultures	Reactivity	Grade
No cell lysis, intracytoplasmic granules.	None	0
Less than or equal to 20% rounding, occasional lysed cells.	Slight	1
Greater than 20% to less than or equal to 50% rounding, no extensive cell lysis.	Mild	2
Greater than 50% to less than 70% rounding and lysed cells.	Moderate	3
Nearly complete destruction of the cell layers.	Severe	4

The results from the three wells were averaged to give a final cytotoxicity score.

Procedure: The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at 37 ± 1°C with agitation. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were held at room temperature for less than four hours before testing. The extract fluids were not filtered, centrifuged or manipulated in any way following the extraction process. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at 37 ± 1°C with 5 ± 1% CO_2 for 48 ± 3 hours.

Pre and Post Extract Appearance		
Test Article	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted
Controls	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted

Test Article Preparation:



Amendment Justification: At the request of the sponsor, the test article was changed from "Lot 001" to "Lot 001: 50 disposable surgical masks (Blue) LHM-E1".

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	20 May 2020
Phase Inspected by Quality Assurance: Cell Exposure	22 May 2020
Audit Results Reported to Study Director	26 May 2020
Audit Results Reported to Management	27 May 2020

Scientists	Title
Chad Summers	Supervisor
Danielle Short	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

30 Jun 2020
Date