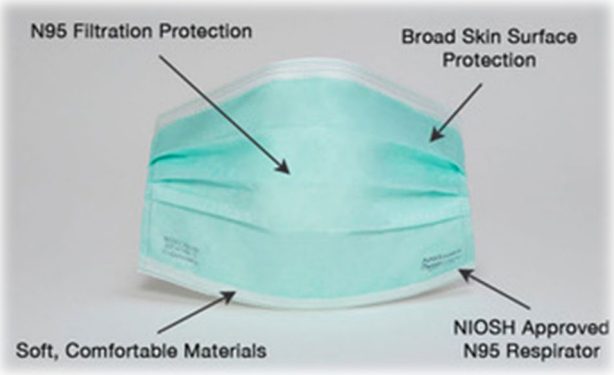
ViruDefense

Testing of the VDI-100 N95 Respirator

NIOSH Public Health Emergency FFR approval TC-84A-PH06

ViruDefense Inc in collaboration with Baril Corporation

June 25, 2020



National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Evaluation and Testing Branch

TEST REPORT

Task Number: TN-23984

Manufacturer: ViruDefense, Inc.

Prepared by: Nichole Suhon

Date: June 19, 2020

Tests Conducted by: Nichole Suhon

Respirator Tested: VID-100

Tests Completed

Test Description	STP Number
A. Inhalation Resistance Test	TEB-APR-STP-0007
B. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the above procedures.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-23984
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: ViruDefense, Inc.
Item Tested: VID-100

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	10.4	PASS
2	35	6.9	PASS
3	35	7.9	PASS

Overall Result: PASS

Signature: Nicholas L. Miller **Date:** 6/19/2020

Engineering Technician

Task Number: TN-23984
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: ViruDefense, Inc.
Item Tested: VID-100

Comments:
Samples were tested on manometer 000034.

Was all equipment verified to be in calibration throughout all testing?	◉ **Yes**	○ **No**

Signature: Linda L. Allen **Date:** 6/19/2020

Engineering Technician

National Institute for Occupational Safety and Health
Evaluation and Testing Branch
Test Data Sheet

Task Number: TN-23984
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: ViruDefense, Inc.
Item Tested: VID-100

Filter	Flow Rate lpm	Initial Filter Resistance mm water gauge	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	6.1	5.00	0.020	0.080	PASS
2	85	6.1	5.00	0.053	0.121	PASS
3	85	6.3	5.00	0.032	0.077	PASS
4	85	5.9	5.00	0.034	0.163	PASS
5	85	6.1	5.00	0.007	0.086	PASS
6	85	6.3	5.00	0.017	0.124	PASS
7	85	6.6	5.00	0.048	0.163	PASS
8	85	8.4	5.00	0.016	0.194	PASS
9	85	7.0	5.00	0.011	0.466	PASS
10	85	7.4	5.00	0.132	0.135	PASS
11	85	13.4	5.00	0.068	0.227	PASS
12	85	13.2	5.00	0.105	0.309	PASS
13	85	13.8	5.00	0.088	0.249	PASS
14	85	6.4	5.00	0.053	0.126	PASS
15	85	6.7	5.00	0.007	0.120	PASS
16	85	7.2	5.00	0.058	0.226	PASS
17	85	6.8	5.00	0.024	0.129	PASS
18	85	8.1	5.00	0.044	0.297	PASS
19	85	13.3	5.00	0.059	0.204	PASS
20	85	12.8	5.00	0.090	0.242	PASS

Overall Result: PASS

Signature: Nicole L. Milan **Date:** 6/19/2020

Engineering Technician

Task Number: TN-23984
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: ViruDefense, Inc.
Item Tested: VID-100

Comments:

Samples 1-6 were tested on the 000388 TSI machine, samples 7-13 were tested using the 000333 TSI machine, and samples 14-20 were tested using the 000333 TSI machine.

Was all equipment verified to be in calibration throughout all testing?	◉ **Yes**	◯ **No**

Signature: Nicole L. Miller **Date:** 6/19/2020

Engineering Technician

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A Sotera Health company

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Latex Particle Challenge GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292511-S01
Study Received Date:	24 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.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	24°C, 22% relative humidity (RH) at 1237; 25°C, 22% RH at 1359
Average Filtration Efficiency:	>99.9940%
Standard Deviation:	0.00525

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Sean Shepherd electronically approved — 02 Jun 2020 20:09 (+00:00)
Study Director Sean Shepherd — 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	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	<1[a]	13,219	>99.9975
2	<1[a]	14,053	>99.9976
3	<1[a]	13,996	>99.9976
4	2	14,288	99.986
5	1	11,316	99.9912

[a] There were no detected particles penetrating this filter during testing.

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 average 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

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Synthetic Blood Penetration Resistance GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292514-S01
Study Received Date:	24 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: 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:	20.4°C and 22% 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
1-24, 26-32	None Seen
25	Yes

Alexa Sanders electronically approved — 11 May 2020 19:38 (+00:00)
Study Director Alexa Sanders — 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.

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

Test Article:	ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292507-S01
Study Received Date:	24 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 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:	~202 mm x ~187 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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Sean Shepherd electronically approved — 09 Jul 2020 19:00 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.9	57.4
2	5.8	56.6
3	5.8	57.3
4	5.6	55.3
5	5.9	57.8

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:

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

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.

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Sodium Chloride (NaCl) Aerosol Test GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292512-S01
Study Received Date:	24 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: STP0014 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate the particle penetration and airflow resistance properties of filtration materials. A neutralized, poly-dispersed aerosol of sodium chloride (NaCl) was generated and passed through the test article. The performance of the test article was assessed by measuring the concentration of salt particles penetrating the test article compared to the challenge concentration entering the test article. The filtration performance and airflow resistance of each test article were calculated.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produced a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. All test method acceptance criteria were met.

Area Tested:	100 cm^2
Airflow Rate:	85 ± 4 liters per minute (L/min)
Test Side:	Outside
Test Type:	Load Testing (Load Amount: 200 mg/m^3) (Test Article #1-3) Initial Penetration (~1 min. LOAD Test) (Test Article #4-20)
Conditioning Parameters:	38 ± 2.5°C, 85 ± 5% relative humidity (RH) for 25 ± 1 hour

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Sean Shepherd electronically approved — 17 Jun 2020 18:16 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Results:

Test Article Number	Initial Airflow Resistance (mm H_2O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
1	15.0	0.918	99.082
2	15.4	0.816	99.184
3	15.4	0.922	99.078

Test Article Number	Airflow Resistance (mm H_2O)	Particle Penetration (%)	Filtration Efficiency (%)
4	14.4	0.249	99.751
5	14.7	0.257	99.743
6	15.3	0.265	99.735
7	14.7	0.247	99.753
8	15.4	0.266	99.734
9	15.0	0.270	99.730
10	15.1	0.263	99.737
11	15.0	0.256	99.744
12	14.8	0.257	99.743
13	15.2	0.269	99.731
14	15.2	0.279	99.721
15	13.7	0.232	99.768
16	15.5	0.265	99.735
17	15.2	0.279	99.721
18	15.1	0.258	99.742
19	15.3	0.274	99.726
20	15.0	0.170	99.830

Test Method Acceptance Criteria: The filter tester must pass the “Tester Set Up” procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Procedure:

Test Set-Up: The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 L/min.

With the filter holder empty, the transducer and photometer zeros, the aerosol concentration level and the photometer correlation factor (CF) were checked and determined to be acceptable. The CF is used to correlate upstream photometer measurements with those made downstream.

Filter Test: Prior to testing, test articles were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) at 38 ± 2.5°C for 25 ± 1 hours. Following conditioning, each test article was sealed in a container and tested within ten hours of removal from the chamber.

Each test article was placed into the filter holder and the NaCl aerosol passed through the test article at an airflow rate of approximately 85 ± 4 L/min. Instantaneous airflow resistance and particle penetration results for each test article were generated.

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Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292509-S01
Study Received Date:	24 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: STP0145 Rev 05
Deviation(s):	None

Summary: This procedure was performed to evaluate the differential pressure of the sponsor supplied product. The air exchange differential or breathability was measured for inhalation resistance using NIOSH procedure TEB-APR-STP-0007 and exhalation resistance with NIOSH procedure TEB-APR-STP-0003 (with the exception that the product was not a respirator). The differential pressure technique is a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate.

All test method acceptance criteria were met.

Results:

Test Article Number	Inhalation Resistance (mm H_2O)	Exhalation Resistance (mm H_2O)
1	13.3	6.6
2	16.1	6.9
3	15.4	6.4

Test Method Acceptance Criteria: The resistance measurement for the reference plate must be within ± 3 standard deviations of the mean established in the control chart.

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Sean Shepherd electronically approved — 30 May 2020 19:38 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Procedure: A product was mounted to a test fixture comprised of a metal plate with an approximate 3.5 inch diameter hole in the center to allow airflow to reach the mask. The sample holder was assembled by placing a Plexiglas collar around the test fixture and topping with another metal disc with a 3.5 inch opening in the center. The sample holder is held tightly together with clamps and connected to an air source. The manometer is attached to the sample holder by a connection port on the Plexiglas collar.

Before testing, the manometer was zeroed and the back pressure in the sample holder checked and verified to be acceptable. Resistance measurements were taken with a manometer capable of measuring at least 6 inches of water. For inhalation testing, a negative airflow (vacuum) was applied. For exhalation testing, a positive airflow (compressed air) was used. Airflow was passed through the sample holder at approximately 85 ± 2 liters per minute (L/min).

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Flammability of Clothing Textiles GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292508-S01
Study Received Date:	24 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.

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.

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Sean Shepherd electronically approved — 21 May 2020 13:56 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread (In Seconds)
1	7.9
2	8.2
3	8.0
4	7.6
5	8.2
Average	8.0

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.

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MEM Elution GLP Report

Test Article:	Device Name: ViruDefense, Model VDI-100 Surgical N95-F Respirator Mask
Purchase Order:	24364
Study Number:	1292513-S01
Study Received Date:	24 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: 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	3 cm^2/mL	684 cm^2 / 228 mL
1:2	**Pass**	0	0	0	0		
1:4	**Pass**	0	0	0	0		
1:8	**Pass**	0	0	0	0		
1:16	**Pass**	0	0	0	0		

Note: An additional 5 mL of media was added to account for absorbency.

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

Danielle Short electronically approved — 08 May 2020 15:26 (+00:00)
Study Director Danielle Short — Study Completion Date and Time

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