REVi

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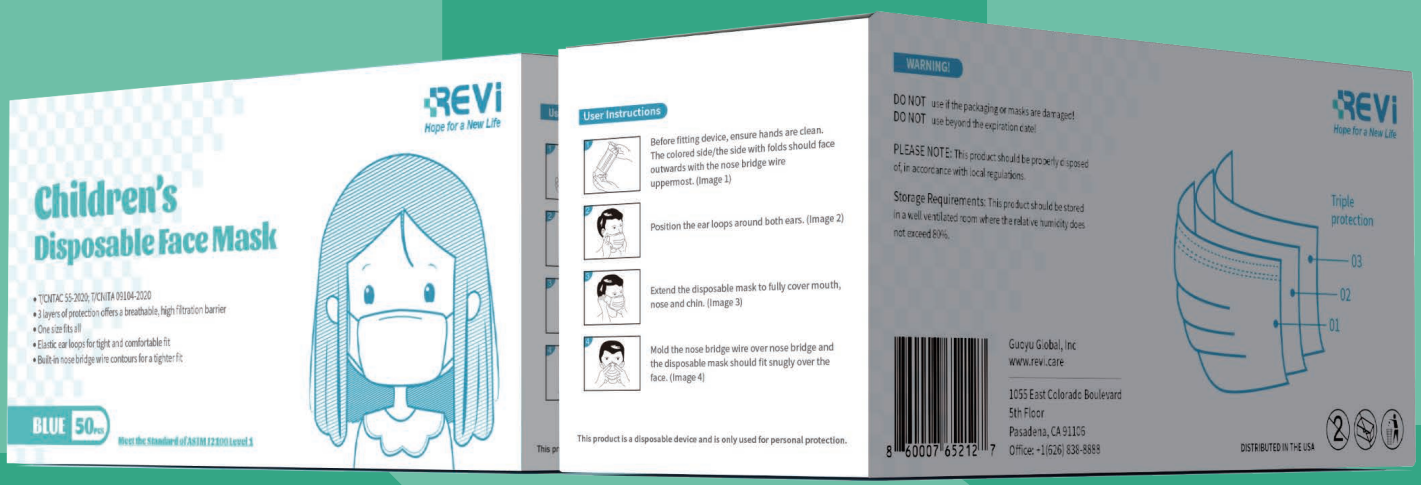

IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung

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REVi
Hope for a New Life

Children's Disposable Face Mask

FDA

Nelson Labs
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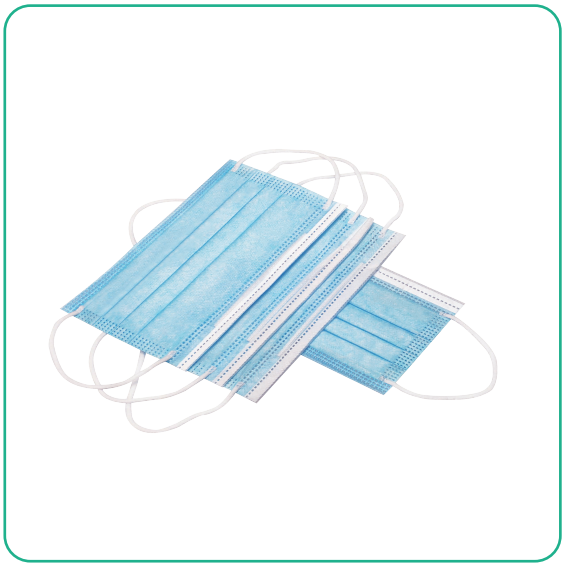
T/CNTAC 55-2020; T/CNITA 09104-2020

Meet the Standard of ASTM F2100 Level 1
Nelson Labs No.1310035-01

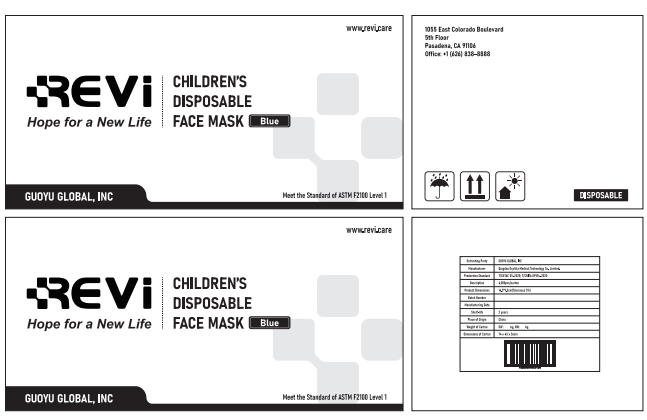
- T/CNTAC 55-2020; T/CNITA 09104-2020
- 3 layers of protection offers a breathable, high filtration barrier
- One size fits all
- Elastic ear loops for tight and comfortable fit
- Built-in nose bridge wire contours for a tighter fit



Hope for a New Life

Packing of Children's Disposable Face Mask

Description	Carton Size	Carton Weight	Masks/Box	Boxes/Carton	Masks/Carton
Children's Disposable Face Mask	74*43*36cm	13.13kg	50	80	4,000



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Qingdao Orphila Medical Technology Co., Ltd.
Rm 0501, Futai Square No. 18, Hong Kong Middle Road
Qingdao Shandong,
CHINA

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

Test Article:	Surgical Mask
Purchase Order:	20-233A
Study Number:	1289187-S01
Study Received Date:	15 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. 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:	~170 mm x ~90 mm
Positive Control Average:	3.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

Reid Jones electronically approved for — 20 May 2020 15:55 (+00:00)
Study Director — Janelle Bentz — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.2
2	99.1
3	99.0
4	99.4
5	99.0

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.7	26.4
2	2.8	27.1
3	2.5	24.9
4	2.8	27.8
5	2.8	27.1

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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Rocky Ma
Qingdao Orphila Medical Technology Co., Ltd.
Rm 0501, Futai Square No. 18, Hong Kong Middle Road
Qingdao, Shandong,
CHINA

Flammability of Clothing Textiles Final Report

Test Article:	Surgical Mask
Purchase Order:	20-233A
Study Number:	1289184-S01
Study Received Date:	16 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.

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Study Director: Thang Thuong for Janelle R. Bentz, M.S.

Study Completion Date: 04 May 2020

1289184-S01

Results:

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

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

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Rocky Ma
Qingdao Orphila Medical Technology Co., Limited
Rm 0501, Futai Square No. 18, Hong Kong Middle Road
Qingdao, Shandong
CHINA

Latex Particle Challenge Final Report

Test Article:	Surgical Mask	
Purchase Order:	20-233A	
Study Number:	1289188-S01	
Study Received Date:	16 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, 23% relative humidity (RH) at 1030; 21°C, 23% RH at 1059; 22°C, 23% RH at 1108; 22°C, 23% RH at 1112
Average Filtration Efficiency:	98.8%
Standard Deviation:	0.27

Thomas Luo electronically approved for — 20 May 2020 23:07 (+00:00)
Study Director — Janelle Bentz — 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	130	12,006	98.9
2	137	12,537	98.9
3	125	12,127	99.0
4	134	12,141	98.9
5	208	12,405	98.3

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Qingdao Orphila Medical Technology Co., Limited
Rm 0501, Futai Square No. 18 Hongkong middle road
Qingdao Shandong
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Surgical Mask
Purchase Order:	20-594A
Study Number:	1310044-S01
Study Received Date:	15 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: 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. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	32
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 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: 80 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Brent Shelley electronically approved for
Study Director James Luskin

26 Jun 2020 18:15 (+00:00)
Study Completion Date and Time

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Rocky Ma
Qingdao Orphila Medical Technology Co., Ltd.
Rm 0501, Futai Square No. 18, Hong Kong Middle Road
Qingdao, Shandong,
CHINA

Viral Filtration Efficiency (VFE) Final Report

Test Article:	Surgical Mask
Purchase Order:	20-233A
Study Number:	1289183-S01
Study Received Date:	16 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: STP0007 Rev 16
Deviation(s):	None

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

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Test Area:	~40 cm^2
VFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Control Average:	2.6 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	3.0 µm

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(RWJ) for
Study Director — Janelle R. Bentz, M.S.

06 May 2020
Study Completion Date

1289183-S01

Results:

Test Article Number	Percent VFE (%)
1	99.5
2	98.8
3	99.0
4	98.8
5	99.1

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

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

Hope for a New Life

WE ARE ONE!
Zusammen sind wir stark!
Unis Nous Vaincrons!
Sii forte. Non sei solo.

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GUOYU GLOBAL, INC

1055 EAST COLORADO BOULEVARD
5TH FLOOR
PASADENA, CA 91106
OFFICE: +1 (626) 838-8888
WWW.REVI.CARE