

# REVi

## GUOYU GLOBAL, INC



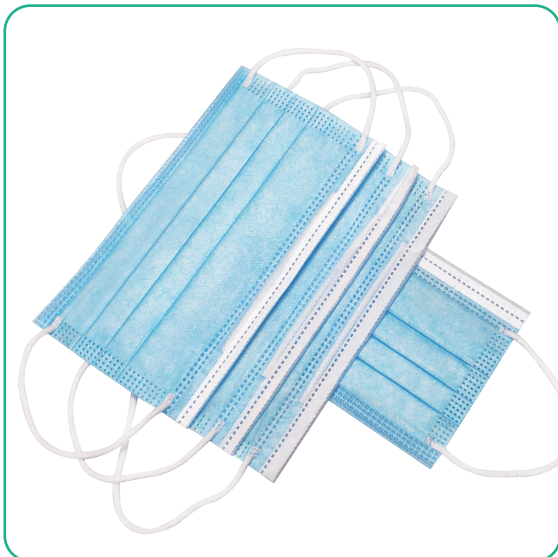
# Disposable Face Mask

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

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



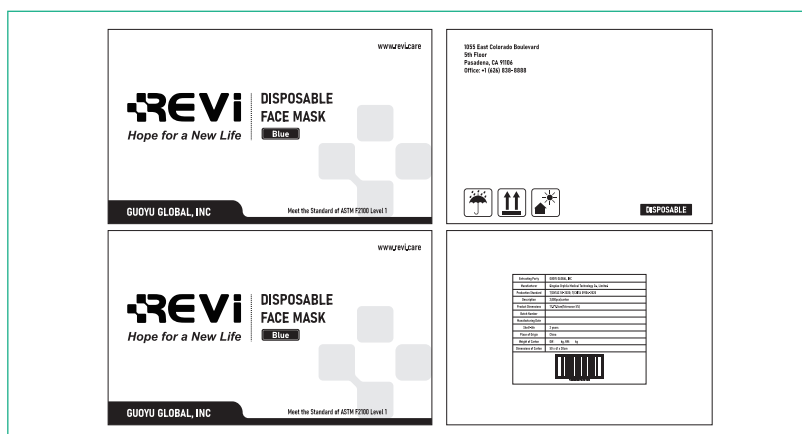
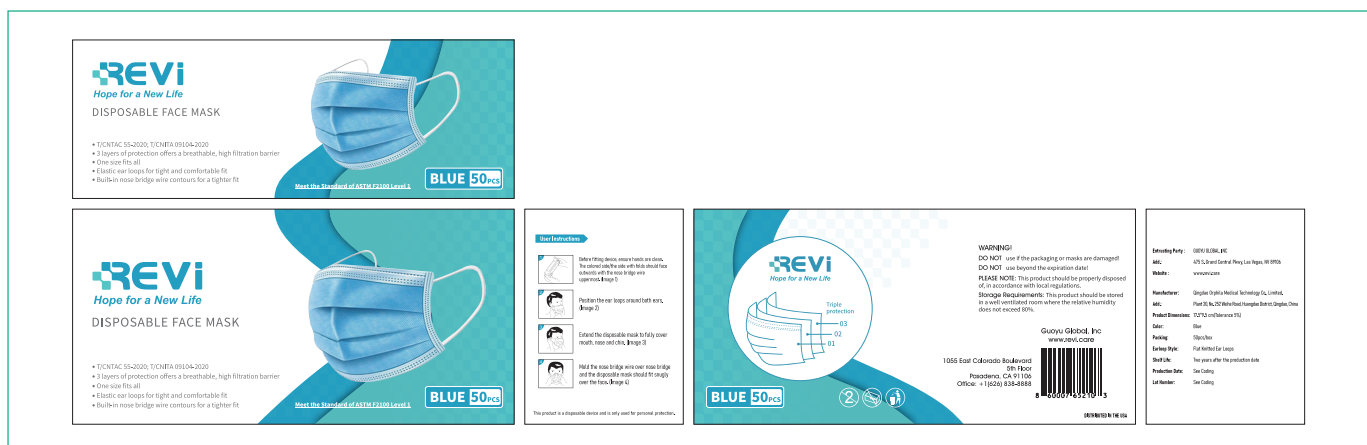
- T/CNTAC 55-2020; T/CNITA 09104-2020
- 3 layers of protection offers a breathable, high filtration barrier
- One size fits all
- Elastic ear loops for tight and comfortable fit
- Built-in nose bridge wire contours for a tighter fit



# Packing of Disposable Face Mask



Description	Carton Size	Carton Weight	Masks/Box	Boxes/Carton	Masks/Carton
Disposable Face Mask	50*41*30cm	8.13kg	50	40	2,000



## 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  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . 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:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 L/min  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Test Article Dimensions:  $\sim 170 \text{ mm} \times \sim 90 \text{ mm}$   
Positive Control Average:  $3.0 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $2.8 \mu\text{m}$



Reid Jones electronically approved for  
Study Director

Janelle Bentz

20 May 2020 15:55 (+00:00)  
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 <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
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:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

## 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 $\geq 3.5$ 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.



*Shang Huang for*  
Study Director

Janelle R. Bentz, M.S.

*04 May 2020*  
Study Completion Date



1289184-S01

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tjl

FRT0073-0001 Rev 9

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**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

## 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<sup>2</sup>  
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  
Study Director

Janelle Bentz

20 May 2020 23:07 (+00:00)  
Study Completion Date and Time

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

**Results:**

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	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



## 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  $21 \pm 5^{\circ}\text{C}$  and a relative humidity of  $85 \pm 10\%$ . 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  $21 \pm 5^{\circ}\text{C}$  and  $85 \pm 5\%$  relative humidity (RH)  
Test Conditions:  $23.7^{\circ}\text{C}$  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  $\geq 29$  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

## 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  $\Phi$ X174 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  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) of  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . 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:  $\sim 40 \text{ cm}^2$   
VFE Flow Rate: 28.3 Liters per minute (L/min)  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Positive Control Average:  $2.6 \times 10^3$  PFU  
Negative Monitor Count:  $<1$  PFU  
MPS:  $3.0 \mu\text{m}$



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:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

# *Hope for a New Life*

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



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