Disposable Face Mask
Product Datasheet

Revision 5 – July 19th, 2020

Gnomedica LLC
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Product Name	Disposable Face Masks, Carton of 50		
Product Image			
Description	Our disposable face masks are made from a 3-ply construction, consisting of a melt-blown polypropylene filtration media sandwiched between two layers of polypropylene spunbond fabric. We use best-in-class materials that offer industry-leading particle and bacterial filtration efficiencies in excess of 99%. All masks come with an adjustable nose piece as well.		
Short Description	3-Ply Disposable Face Masks with Earloops, Carton of 50		
Mask Dimensions	6.825” X 3.625”		
Standards Met	>99% PFE with 0.1 µm particles per ASTM F2299. >99% BFE per ASTM F2101-19 and EN 14683:2013. Class 1 Flammability Rating per 16 CFR Part 1610 GB/T 32610-2016: Technical Specification of Daily Protective Mask		
Materials of Construction	Polypropylene Non-Woven Fabric, Polypropylene Melt-Blown Filter Fabric, Elastic Earloops, Adjustable Nose Piece		
Shelf Life	2 Years		
Package SKU	FM-50	Package Contents	50 Face Masks
Package Dimensions	7.5” X 4.25” X 3.75”	Package Weight	8.75 oz
Case SKU	FM-2000	Case Contents	40 Packages (2000 Face Masks)
Case Dimensions	21” X 15.5” X 14.75”	Case Weight	20 lbs
Manufacturer	Zhongshan Haochen Work Safety Supplies & Equipment LTD		
Manufacturer Model No.	HC001		
GTIN	6973337440006		
Country of Origin	China		

Nelson Labs
A Sotera Health company

Sponsor:
Zhanpeng Li
Zhongshan Haochen Work Safety Supplies and Equipment Ltd.
3rd and 4th floor, Building D- No. 5
Nanyuan Road South District
Zhongshan, Guangdong, 528471
CHINA

Latex Particle Challenge GLP Report

Test Article:	April-2020
Purchase Order:	PO-00005
Study Number:	1298679-S01
Study Received Date:	12 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: 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:	21°C, 31% relative humidity (RH) at 11:43 a.m.; 21°C, 31% RH at 2:25 p.m.
Average Filtration Efficiency:	99.58%
Standard Deviation:	0.062

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Christopher Acker electronically approved — 07 Jul 2020 22:47 (+00:00)
Study Director Christopher Acker — 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	59	11,682	99.49
2	54	12,039	99.55
3	43	12,209	99.65
4	48	11,660	99.59
5	44	11,997	99.63

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

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	29 May 2020
Audit Results Reported to Study Director	29 May 2020
Audit Results Reported to Management	29 May 2020

Scientists	Title
Denise Anderson	Supervisor
Christopher Acker	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

07 Jul 2020 16:55 (+00:00)
Date and Time

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Sponsor:
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Nanyuan Road South District
Zhongshan, Guangdong, 528471
CHINA

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

Test Article:	April-2020
Purchase Order:	PO-00005
Study Number:	1298682-S01
Study Received Date:	12 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: 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 ~165 mm
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

Alexa Sanders electronically approved — 07 Jul 2020 18:19 (+00:00)
Study Director Alexa Sanders — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.5
3	99.2
4	99.7
5	99.8

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	6.8	66.9
2	7.3	71.4
3	6.9	68.1
4	7.0	68.3
5	6.4	62.8

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.

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: Counting Procedure	03 Jun 2020
Audit Results Reported to Study Director	03 Jun 2020
Audit Results Reported to Management	03 Jun 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

07 Jul 2020 18:01 (+00:00)
Date and Time

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CHINA

Flammability of Clothing Textiles GLP Report

Test Article:	April-2020
Purchase Order:	PO-00005
Study Number:	1298677-S01
Study Received Date:	12 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.

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Sean Shepherd electronically approved — 25 Jun 2020 21:54 (+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: Preliminary Test	27 May 2020
Audit Results Reported to Study Director	29 May 2020
Audit Results Reported to Management	29 May 2020

Scientists	Title
Denise Anderson	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

25 Jun 2020 21:39 (+00:00)
Date and Time

黄埔海关技术中心
HUANGPU CUSTOMS DISTRICT TECHNOLOGY CENTER
检 验 报 告
TEST REPORT

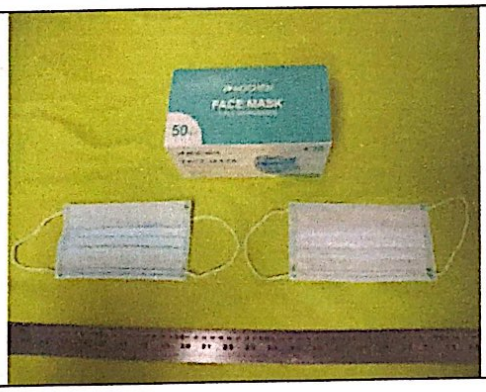
地址：东莞市南城三元路66号
邮编：523372
电话：0769-22005790
传真：0769-22005792

（副本）

委托编号：24202000198
(Commission No.)

委托人(Client)：	中国检验认证集团广东有限公司 China Certification&Inspection Group Guangdong Co.,Ltd		
地址(Address)：	广州市天河区珠江新城花城大道66号C塔1602室 Rm 1602,16/F,West Tower,No.66 Hua Cheng Da Dao,Zhu Jiang New Town,Guangzhou		
样品名称(Sample Name)：	一次性防护口罩 Disposable respirato mask		
型号规格(Type)：	HC001		
样品标记(Sample Mark)：	——		
制造商(Manufacturer)：	中山市浩宸劳保医疗用品有限公司 Zhongshan Haochen Work Safety Supplies & Equipments LTD		
地址(Address)：	中山市南区南源路5号D幢3、4层 3rd and 4th Floor,Building D,No.5, Nanyuand Road,South District,Zhongshan City,Guangdong Province,China		
样品数量(Sample Quantity)：	50个 50pcs		
检验项目(Test Item)：	详见检验结果 See Test Results		
检验方法(Test Method)：	详见检验结果 See Test Results		
委托日期(Date of Commission)：	2020-04-26	检验日期 (Date of Test)：	2020-04-27 至 2020-04-30

样品照片
Photo



（检验报告专用章）
(Official Seal)

拟稿人：_____ 审核人：_____ 授权签字人：_____

签发日期：2020-04-30

检验结果(Test Results)

检测项目 Test Item	结果数据 Result	限量规格 Limit	单位 Unit	检测方法 Test Method	检测结果评价 Assessment
5.1 基本要求 Basic Requirements	符合要求 Meet the requirement	a. 口罩应能安全牢固地护住口、鼻； b. 口罩原材料不应使用再生材料，含高毒性、致癌性或潜在致癌性物质以及已知的可导致皮肤刺激或其他不良反应的材料，其他限制使用物质的残留量应符合相关要求，无异味。 c. 口罩不应存在可触及的锐利角和锐利边缘，不应对佩戴者构成伤害。 d. 口罩应便于佩戴和摘除，在佩戴过程中无明显的压迫感或压痛现象，对头部活动影响小。 a. The mask must protect the month and the nose safety. b. The raw material of the mask must not use of regrown material, highly toxic, carcinogenicity, or potential carcinogenicity, or something is leaded to skin irritation or other untoward effect material, the other restricted remaining material shall be meeted with relevant requirement, none of odor. c. There must not be sharp point or sharp edge of the mask, it is not hurt to the wearer. d. It is convenient for wearing and removing, there is no constriction when wearing, this may has less effect on the movement of the head.	—	GB/T 32610-2016	合格 Pass
5.2 外观 Appearance	符合要求 Meet the requirement	口罩表面不应有破损、油污斑渍、变形级其他明显的缺陷。 There is not damaged, oil contamination, blotch, transmutative or other defect of the surface of the mask.	—	GB/T 32610-2016	合格 Pass
5.3 内在质量5.3 Quality					
甲醛含量 Formaldehyde	ND	≤20	mg/kg	GB/T 2912.1-2009	合格 Pass
pH值 pH	6.4	4.0-8.5	—	GB/T 7573-2009	合格 Pass
可分解致癌芳香胺染料 Banned Azo Colourants	ND	禁用 Forbidden	mg/kg	GB/T 17592-2011	合格 Pass
连接处断裂强力 The breaking strength of the connection	21.7	≥20	N	GB/T 32610-2016	合格 Pass

备注：1. 禁用偶氮染料的报告限为5mg/kg；甲醛含量的报告限为20mg/kg。“ND”=未检出（少于报告限）。

2. 本报告有中英文两种文本，如有歧义请以中文文本为准，英文版本则为参考。

Remark: 1. AZO reporting limit: 5mg/kg; Formaldehyde reporting limit: 20mg/kg. “ND”=Not Detected(less than Reporting Limit).

2. This report is made out in both Chinese and English versions. We hereby take Chinese version as standard and English version as a reference.

*** 报告结束 ***

The End