Test Report

Report No.: TL1008-OASIS3009202201

Report Issue Date: 30 Sept 2022

Applicant	:	Oasis Medical Technology Company Limited
Address	:	Flat/Rm 13-24, Sino Industrial Plaza, 9 Kai Cheung Road, Kowloon Bay, Kowloon, Hong Kong
Sample Received	:	22 Sept 2022
Sample Description	:	Oasis Medicare 3D Face Mask
Model /Lot No.	:	SPORT
Test Period	:	22 – 29 Sept 2022
Test Standard	:	ASTM F2100-19

Summary of Test Results

Standard: ASTM F2100-19	**Conclusion for Level 3**
Particle Filtration Efficiency (PFE%)	**Pass**
Bacterial Filtration Efficiency (BFE%)	**Pass**
Synthetic Blood Penetration Resistance (160 mmHg)	**Pass**
Different Pressure (H_2O/cm^2)	**Pass**
Flammability	**Pass**

– FOR TEST REPORT DETAILS. PLEASE REFER TO THE ATTACHED PAGE(S) –

Tested By:

Eric Wong, Technical Engineer

Approved By:

Chen Zheng, Lab Manager

LONG JING TECHNOLOGY LTD ISO/IEC 17025:2017

Test Completion Date: 29 Sept 2022

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Latex Particle Challenge (PFE) Test Report

Test method

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 count was performed. 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 upstream and downstream.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions.

Laboratory Conditionings : 22°C and relative humidity (RH) of 63%

Test Side:	Inside
PFE Flow Rate:	28.3 Liters per minute (L/min)
Area Tested:	100 cm^2
Particle size:	0.1 µm ± 0.003 µm

Results

Test Sample #	Test Article Counts Upstream	Test Article Counts Downstream	Filtration Efficiency (%)
1	135171	360	99.734
2	131551	261	99.802
3	130025	345	99.735
4	129414	444	99.657
5	129463	440	99.660

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Bacterial Filtration Efficiency (BFE) Test Report

Test method

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 (ATCC#6538) 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.

Conditioning Period (At temperature of 21 ± 5 °C and relative humidity of 85 ± 5 %): 4 hours

Test Side:	Inside
BFE Flow Rate:	28.3 Liters per minute (L/min)
Area Tested:	~ 47 cm^2
Mean Positive Control Counts :	2918 CFU
Negative Control Count:	<01 CFU
MPS:	3.0 µm ± 0.3 µm

Results

Test Sample #	Filtration Efficiency (BFE) (%)
1	99.9*
2	99.9
3	99.9*
4	99.9*
5	99.9

* No CFU visible on any Anderson Sampler stage plates.

The filtration efficiency percentages were calculated using the following equation:

$$\%\text{BFE} = \frac{\text{C} - \text{T}}{\text{C}} \; x \; 100$$

C = Positive control average

T= Plate count total recovered downstream of the test article

Remark:

1. The plate count total is available upon request.

2. The sample is tested as received.

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Synthetic Blood Penetration Resistance Test Report

Test method

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 (as referenced in EN 14683:2019)

Conditioning Period (At temperature of 21 ± 5 °C and relative humidity of 85 ± 5 %): 4 hours

Test Side:	Outside
Number of Test Articles Tested:	32
Number of Test Articles Passed:	30
Laboratory Conditionings :	22°C and relative humidity (RH) of 62 %

Results (Test Pressure: 160 mmHg (21.3 kPa)

Test Sample #	Synthetic Blood Penetration
1, 3 – 13, 19 – 32	None Seen
2, 18	Seen

Remark

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.

Differential Pressure (Delta P) Test Report

Test method

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.

Conditioning Period (At temperature of 21 ± 5 °C and relative humidity of 85 ± 5 %): 4 hours

Test Side: Inside

Delta P Flow Rate: 8 Liters per minute (L/min)

Results

Differential Pressure (Delta P)						
Test Sample	Test Location					Average
	Centre Left	Top Centre	Centre Right	Bottom Centre	Centre	(mmH_2O/cm^2)
1	1.9	2.0	2.2	2.0	2.0	**2.01**
2	2.1	1.9	1.9	1.9	2.0	**1.97**
3	1.9	1.9	2.1	2.1	2.1	**2.01**
4	2.0	2.0	2.0	2.1	2.0	**2.00**
5	1.8	2.1	2.0	2.0	2.1	**2.00**

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Flammability of Clothing Textiles Test Report

Test method

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.

Article Side Tested: Outside Surface
Orientation: Machine

Results

Test Sample #	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Did Not Ignite

Remark

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.

Appendix:

Photo(s) of Submitted Samples

ASTM F2100-19 and EN 14683:2019 Requirements Reference:

	Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Requirements	**ASTM F2100-19**			**EN 14683:2019**		
Particle Filtration Efficiency (PFE%)	≥ 95%	≥ 98%	≥ 98%	Not Required		
Bacterial Filtration Efficiency (BFE%)	≥ 95%	≥ 98%	≥ 98%	≥ 95%	≥ 98%	≥ 98%
Synthetic Blood Penetration Resistance (mmHg)	80	120	160	Not Required		120
Different Pressure	< 5.0 H_2O/cm^2	< 6.0 H_2O/cm^2		< 40 Pa/ cm^2		< 60 Pa/ cm^2
Flammability	Class I			Not Required		
Microbial Cleanliness (Cfu/g)	Not Required			≤ 30		

---- End of Report ---