



中国认可
国际互认
检测
TESTING
CNAS L1842



佛山中纺联检验技术服务有限公司
CNTAC Testing Service Co., Ltd. (Foshan)

Report No: ZFLJ2641040

Report security check web: www.fcl-sz.org.cn

Date:2020-08-17

Security code: 2237436007



TEST REPORT

Applicant : Chongqing COE Display Technology Co.,Ltd.
Applicant Address : No.3,Tonggui Avenue, Yufengshan Town, Yubei District, Chongqing
Manufacturer : Chongqing COE Display Technology Co.,Ltd.
Manufacturer Address : No.3,Tonggui Avenue, Yufengshan Town, Yubei District, Chongqing

Sample Description : Disposable medical mask

Sample Quantity : 40 pieces

Lot Number/Batch Code : M200801CN01

Specification : /

Size : 17.5*9.5(cm)

Brand Name : COE

Colour : Black

Model : CCMM-NA

Remark: The above information was provided by applicant.

Date Received : 2020-08-05

Date Test Start : 2020-08-05

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Summary of Test Results

No.	Test Item	Test Method	Test Standard Type I	Judgement
1	Bacterial Filtration Efficiency Test (BFE), %	EN 14683:2019+AC:2019(E) Annex B	≥ 95	Pass
2	Differential Pressure Test (Pa/cm ²)	EN 14683:2019+AC:2019(E) Annex C	< 40	Pass
3	Microbial Cleanliness Test (CFU/g)	EN 14683:2019+AC:2019(E) Annex D	≤ 30	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
= No comment;
N.D. = Not detected.



Photo of Samples





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Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.9% Specimen 2#: 99.9% Specimen 3#: 99.9% Specimen 4#: 99.9% Specimen 5#: 99.9%
2	Differential Pressure Test	38.9 Pa/cm ²
3	Microbial Cleanliness Test	Specimen 1#: <1 CFU/g Specimen 2#: <1 CFU/g Specimen 3#: <1 CFU/g Specimen 4#: <1 CFU/g Specimen 5#: <1 CFU/g

Signed for and on behalf of

CNTAC Testing Service Co., Ltd. (Foshan)

Approver:

(Technical Director for Textile Project)

MS HE HUI YAN

(Technical Director for Microorganism)

MS LUO GUI LIAN





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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of masks.

2. Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : M200801CN01
Sample Receiving Date : 2020-08-05

3. Test Method

EN 14683:2019+AC:2019(E) Annex B

4. Apparatus and materials

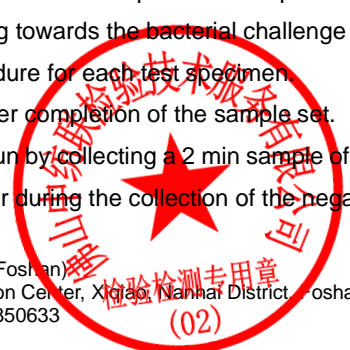
- 4.1 *Staphylococcus aureus* ATCC 6538 (Particle Diameter $3.0 \pm 0.3 \mu\text{m}$).
- 4.2 Peptone water.
- 4.3 Tryptic Soy Broth (TSB).
- 4.4 Tryptic Soy Agar (TSA).
- 4.5 Bacterial filtration efficiency test apparatus.
- 4.6 Six-stage viable particle Anderson sampler.
- 4.7 Flow meters.

5. Test specimen

- 5.1 As requested by client, take a total of 5 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at $(21 \pm 5)^\circ\text{C}$ and $(85 \pm 5)\%$ relative humidity.

6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
- 6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
- 6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
- 6.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
 - 6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the Anderson sampler.
 - 6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
 - 6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
 - 6.4.4 At the conclusion of the positive control run, remove plates from the Anderson sampler.
- 6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm^2).
- 6.6 Repeat the challenge procedure for each test specimen.
- 6.7 Repeat a positive control after completion of the sample set.
- 6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.





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- 6.9 Incubate agar plates at $(37\pm 2)^{\circ}\text{C}$ for (20 to 52) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$\text{BFE} = (C - T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

RESULTS:

P Value Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	26	19	0	0	0	0	0	0
2	73	108	0	0	0	0	0	0
3	102	126	0	0	0	0	0	0
4	179	223	0	0	0	0	0	0
5	1023	1142	0	2	0	0	0	0
6	440	472	0	0	0	0	1	0
Total (T), CFU	1843	2090	<1	2	<1	<1	1	<1
Average (C), CFU	$2.0 \times 10^3 = (P_A + P_B) / 2$							
BFE, %				99.9	99.9	99.9	99.9	99.9
Requirements	≥ 95							
Remarks	P is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. T is the total of P value for the test specimen. C is the mean of the total of P value of the two positive controls.							





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Differential Pressure Test

1. Purpose

The purpose of the test was to measure the differential pressure of masks.

2. Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : M200801CN01
Sample Receiving Date : 2020-08-05

3. Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument.

5. Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.

5.2 Prior to testing, condition all test specimens for a minimum of 4 h at $(21 \pm 5)^\circ\text{C}$ and $(85 \pm 5)\%$ relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.

6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2 , test area diameter 25mm, airflow direction from the inside of the mask to the outside of the mask) and clamped into place so as to minimize air leaks.

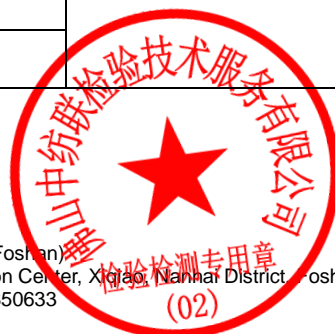
6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.

6.4 The differential pressure is read directly.

6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

RESULTS:

Specimen	Test Result (Pa/cm ²)	Average (Pa/cm ²)	Requirements	Judgement
1#	38.8	38.9	< 40	Pass
2#	38.8			
3#	38.5			
4#	39.0			
5#	39.3			





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Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description : Disposable medical mask
Specification : /
Lot Number : M200801CN01
Sample Receiving Date : 2020-08-05

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D.

4. Apparatus and materials

- 4.1 Orbital shaker.
- 4.2 0.45 um filter.
- 4.3 Tryptic Soy Agar (TSA).
- 4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
- 4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
- 4.6 Extraction apparatus.

5. Test specimen

- 5.1 As requested by client, take a total of 5 mask samples.
- 5.2 Mask samples for testing are provided in the original primary packaging.
- 5.3 Condition at (18 to 26)°C and (45 to 65)% relative humidity during testing.

6. Procedure

- 6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
- 6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
- 6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
- 6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA for fungi enumeration.
- 6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
- 6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by:

$$N_i = 3 n_i / M$$

$$\text{Microbial Cleanliness} = N_1 + N_2$$

$i = 1, 2.$

n = Colonies of the TSA plate or the SDA Plate.

M = Weight of the mask.





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RESULTS:

Specimen	1#	2#	3#	4#	5#
Weight of the Mask (M , g)	4.03	4.01	4.08	4.05	4.02
Colonies of the TSA Plate (n_1)	0	0	0	0	0
Colonies of the SDA Plate (n_2)	0	0	0	0	0
Aerobic Microbial Number (N_1 , CFU/g)	0	0	0	0	0
Fungi Number (N_2 , CFU/g)	0	0	0	0	0
Microbial Cleanliness, (CFU/g)	<1	<1	<1	<1	<1
Requirements	≤ 30				

==== End of Report =====

