

Products Name.....:	Surgical Mask
Manufacturer.....:	Guangdong Taibao Medical Science Technology Co., Ltd.
Address.....:	Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City, Guangdong Province, P.R. China.

<b>Test Information:</b>	
Test Location.....:	TÜV SÜD Products Testing (Shanghai) Co., Ltd.
Test Address.....:	B-3/4, No. 1999 Du Hui Road, Minhang District Shanghai 201108, P. R. China.
Standard.....:	ASTM F2100 Standard Specification for Performance of Materials Used in Medical Face Masks
Test procedure.....:	FDA

The classification of medical face masks according to the ASTM F2100

**TABLE 1 Medical Face Mask Material Requirements by Performance Level**

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥95	≥98	≥98
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	<5.0	<6.0	<6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	80	120	160
Flame spread	Class 1	Class 1	Class 1

Classification.....:	<input type="checkbox"/> Level 1
	<input type="checkbox"/> Level 2
	<input checked="" type="checkbox"/> Level 3

After testing, the surgical masks meet the requirements of **Level 3** in ASTM F2100 standard. Refer to the following specific reports for detailed.

Performance	Test report No.
Bacterial Filtration Efficiency (BFE)	721653065-7
Differential pressure	721653065-2
Sub-micron particulate filtration efficiency at 0.1 micron, %	721653065-3
Synthetic Blood Penetration	721653065-8



**SUBJECT** Microbiological Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Guangdong Taibao Medical Science And Technology CO.,LTD.

**CLIENT ADDRESS** Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City,  
Guangdong Province.

**TEST PERIOD** 13-Mar-2020~31-Mar-2020

Prepared By

*Bella Xu*

(Bella Xu)  
Report Drafter

Authorized By



Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.



## Bacterial Filtration Efficiency (BFE) Test

### 1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

### 2. Sample description was given by the client

Surgical Mask  
Size: 17.5\*9.5cm  
Model: non-sterile  
Lot/Batch#: 20200202

### 3. References

ASTM F2101-2019

### 4. Apparatus and materials

- 4.1 *Staphylococcus aureus* ATCC 6538
- 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±5)°C and (85±5)% relative humidity.

### 6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately  $5 \times 10^5$  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 in contact with the challenge.
- 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.
- 6.9 Incubate agar plates at (35±2)°C for (48±4) 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 manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:

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

Where:

C= average plate count total for positive controls

T= plate count total for sample

## 8. Test results

Test Items*		Test Results	Test Methods
Bacterial Filtration Efficiency(BFE)(%) <i>Staphylococcus aureus</i> ATCC 6538	1	>99.9	ASTM F2101-2019
	2	>99.9	
	3	>99.9	
	4	>99.9	
	5	>99.9	

Note:

- Control average: 1842 CFU.
- Mean particle size: 3.0 μm.
- Testing side: outside of specimen
- Testing area: 39.5cm<sup>2</sup>.
- The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.
- \* denotes this test was carried out by external laboratory assessed as competent.
- This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-





**SUBJECT** Physical Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Guangdong Taibao Medical Science And Technology CO.,LTD.

**CLIENT ADDRESS** Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City,  
Guangdong Province.

**TEST PERIOD** 13-Mar-2020~31-Mar-2020

Prepared By

*Bella Xu*

(Bella Xu)  
Report Drafter

Authorized By



(Leo Liu)  
Authorized Signatory



**Note:** (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:  
TÜV SÜD Products Testing (Shanghai) Co.,  
Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai  
201108  
P.R. China

Phone : +86 (21) 6037 6375  
Fax : +86 (21) 6037 6345  
Email: food.chem@tuv-sud.cn  
Webpage: www.tuv-sud.cn

Regional Head Office:  
TÜV SÜD Certification and Testing  
(China) Co., Ltd.  
No.151 Heng Tong Road Shanghai  
200 070 P.R.China





## Differential pressure of a medical face mask

### 1. Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

### 2. Sample description was given by the client

Surgical Mask  
Size: 17.5\*9.5cm  
Model: non-sterile  
Lot/Batch#: 20200202

### 3. References

MIL-M-36954C

### 4. Apparatus

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 Each test specimen shall be conditioned at (21±5)°C and (85±5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

### 6. Procedure

- 6.1 The test specimen is placed across the 2.5 cm diameter orifice (total area 4.9 cm<sup>2</sup>) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.
- 6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.
- 6.3 The manometers M1 and M2 are read and recorded.
- 6.4 The procedure described in steps 6.1~6.3 is carried out on 5 different areas of the mask and readings averaged.

### 7. Calculation

For each test specimen calculate the different pressure  $\Delta P$  as follows:

$$\Delta P = \frac{(X_{m1} - X_{m2})}{4.9}$$

$X_{m1}$ : is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;  
 $X_{m2}$ : is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;  
4.9 is the cm<sup>2</sup> area of the test material;  
 $\Delta P$  is the different pressure per cm<sup>2</sup> of the test material expressed in Pa.





**8. Test results**

Test Items*		Test Results	Test Methods
Different Pressure Test (mmH <sub>2</sub> O/cm <sup>2</sup> )	1	5.1	MIL-M-36954C
	2	5.8	
	3	5.2	
	4	5.7	
	5	6.2	

Note:

- 1.\*denotes this test was carried out by external laboratory assessed as competent.
- 2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-





**SUBJECT** Physical Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Guangdong Taibao Medical Science And Technology CO.,LTD.

**CLIENT ADDRESS** Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City,  
Guangdong Province.

**TEST PERIOD** 13-Mar-2020~31-Mar-2020

Prepared By

*Bella Xu*

(Bella Xu)  
Report Drafter

Authorized By



(Leo Liu)  
Authorized Signatory



**Note:** (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:  
TÜV SÜD Products Testing (Shanghai) Co.,  
Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai  
201108  
P.R. China

Phone : +86 (21) 6037 6375  
Fax : +86 (21) 6037 6345  
Email: food.chem@tuv-sud.cn  
Webpage: www.tuv-sud.cn

Regional Head Office:  
TÜV SÜD Certification and Testing  
(China) Co., Ltd.  
No.151 Heng Tong Road Shanghai  
200 070 P.R.China







**Initial Efficiency of materials used in medical  
face mask to Penetration by Particulates Using Latex Spheres**

**1.Purpose**

The purpose of the test was to measure the initial efficiency and pressure drop of a medical face mask.

**2.Sample description was given by the client**

Surgical Mask  
Size: 17.5\*9.5cm  
Model: non-sterile  
Lot/Batch#: 20200202

**3.References**

ASTM F2299-2017

**4.Apparatus**

Initial Efficiency of Materials testing instrument

**5.Test specimen**

5.1 Test specimens are complete masks or materials used in medical face masks.

**6.Procedure**

- 6.1 The test specimen is placed across the material specimen holder.
- 6.2 Open the pump and adjust the flow rate to 28 L/min.
- 6.3 Conduct the material testing in a relative humidity range of 30 to 50% and hold the relative humidity  $\pm 5\%$  during a given test.
- 6.4 Record the pressure drop at 28 L/min.
- 6.5 Record the upstream and downstream counts and calculate the initial efficiency.
- 6.6 The procedure described in steps 6.2~6.5 is carried out on 5 mask.

**7. Calculation**

For each test specimen calculate the initial efficiency as follows:

$$PFE = \left\{ 1 - \frac{\text{downsreamcounts}}{\text{upstreamcounts}} \right\} \times 100\%$$





**8. Test results**

Test Items*		Test Results	Test Methods
Filtration Efficiency (%)	1	99.73	ASTM F2299-2017 Flow rate: 28.1(Liter/min)
	2	99.68	
	3	99.80	
	4	99.83	
	5	99.78	
	Ave.	99.76	

Note:

- 1.\*denotes this test was carried out by external laboratory assessed as competent.
- 2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-





**SUBJECT** Physical Test

**TEST LOCATION** TÜV SÜD China  
TÜV SÜD Products Testing (Shanghai) Co., Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai 201108, P.R. China

**CLIENT NAME** Guangdong Taibao Medical Science And Technology CO.,LTD.

**CLIENT ADDRESS** Yingge Mountain Avenue North, Yingge Mountain Industrial Park, Puning City,  
Guangdong Province.

**TEST PERIOD** 13-Mar-2020~31-Mar-2020

Prepared By

*Bella Xu*

(Bella Xu)  
Report Drafter

Authorized By



(Leo Liu)  
Authorized Signatory

**Note:** (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:  
TÜV SÜD Products Testing (Shanghai) Co.,  
Ltd.  
B-3/4, No.1999 Du Hui Road, Minhang District  
Shanghai  
201108  
P.R. China

Phone : +86 (21) 6037 6375  
Fax : +86 (21) 6037 6345  
Email: food.chem@tuv-sud.cn  
Webpage: www.tuv-sud.cn

Regional Head Office:  
TÜV SÜD Certification and Testing  
(China) Co., Ltd.  
No.151 Heng Tong Road Shanghai  
200 070 P.R.China





## Synthetic Blood Penetration Test for Masks

### 1. Purpose

For evaluating the resistance of medical face masks to penetration by a fixed volume of synthetic blood at a high velocity.

### 2. Sample description was given by the client

Surgical Mask  
Size: 17.5\*9.5cm  
Model: non-sterile  
Lot/Batch#: 20200202

### 3. References

ASTM F1862-2017

### 4. Apparatus and materials

- 4.1 Synthetic blood
- 4.2 Tensiometer
- 4.3 Synthetic blood penetration test apparatus
- 4.4 Targeting plate
- 4.5 Air pressure source
- 4.6 Ruler
- 4.7 Balance
- 4.8 Controlled temperature and humidity chamber

### 5. Test specimen

- 5.1 As requested by client, take a total of 13 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4h at  $(21\pm 5)^{\circ}\text{C}$  and  $(85\pm 5)\%$  relative humidity.

### 6. Procedure

- 6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
- 6.2 Determine the density of the synthetic blood.
- 6.3 Fill the reservoir with new synthetic blood.
- 6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
- 6.5 Set the reservoir pressure to the approximate pressure.
- 6.6 Place the targeting plate approximately 1 cm away from the mask.
- 6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).





- 6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.005, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.
- 6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

Table 1 Target weight differences

Fluid Pressure (mmHg)	Weight difference for 1 s difference in spurt duration (g)		
	Min.	Target	Max.
80	2.456	2.506	2.556
120	3.002	3.063	3.124
160	3.466	3.537	3.607

- 6.11 Record the weight difference for the spurts exiting the nozzle.
- 6.12 Record the pressure in the reservoir.
- 6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 %, -5 % of the difference in weight from the nozzle.
- 6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.
- 6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).
- 6.18 For standard synthetic blood, the timer duration can be estimated using the formula:  
( $\rho$  is the density of the test fluid.)  $t = 0.5 + (2 \times \rho - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s})$ .
- 6.19 Record the timer setting to use as the starting point for subsequent testing.
- 6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.
- 6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.
- 6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.
- 6.23 Report the results (none / penetration) for each test specimen at the test pressure.





**7. Test results**

Test Items*		Test Results	Test Methods
Penetration of Synthetic Blood Pressure: 160 mmHg	1	None Seen	ASTM F1862-2017
	2	None Seen	
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	

**Note:**

1. The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.
2. \*denotes this test was carried out by external laboratory assessed as competent.
3. This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-