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 Horigen Mother & Baby Products Co., Ltd.**
CLIENT ADDRESS	No. 18, Pingnan Industrial Zone, Mianbei Street, Chaoyang District, 515100 Shantou, Guangdong, PEOPLE'S REPUBLIC OF CHINA
TEST PERIOD	23-Mar-2020~22-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo Liu
(Bella Xu) Report Drafter	(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:
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Cleanliness of Microbial (Bioburden) Test for Masks

1. Purpose

For determination of a population of microorganisms (Facultative, non-fastidious, aerobic bacteria; Yeasts and moulds).

2. Sample description was given by the client

Single-use Medical Face Mask

Type: KZ-170A

Lot: 2002292701

Manufacture: Guangdong Horigen Mother & Baby Products Co., Ltd.

3. References

EN 14683:2019
EN ISO 11737-1:2018

4. Apparatus and materials

4.1 Orbital shaker
4.2 Sterile 500 mL bottle
4.3 Extraction liquid (1 g/L Peptone, 5 g/L NaCl and 2 g/L Tween 20)
4.4 Tryptone soya agar (TSA)
4.5 Sabouraud dextrose agar (SDA) with chloramphenicol
4.6 Filtration equipment
4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 As requested by client, take a total of 5 masks.

6. Procedure

6.1 Weight each mask prior testing
6.2 The full mask is aseptically removed from the packaging and placed in a stomacher bag.
6.3 Pour into 100 mL extraction liquid and process 5 min in a stomacher individually by highest speed.
6.4 After this extraction step, 100 mL of the extraction liquid is filtered through a 0.45μm 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 with chloramphenicol for fungi enumeration. Additionally, plate 10 mL, 1 mL and 0.1 mL of the extraction liquid both for TSA and SDA with chloramphenicol.
6.5 The plates are incubated for 3 d at 30℃ and 7 d at 25℃ for TSA and SDA plates respectively.
6.6 The colonies formed on incubation are counted.

7. Calculation

The total bioburden is expressed by addition of the TSA and SDA counts. Microbial cleanliness is based on the mask weigh, which is the total bioburden per gram tested.

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8. Test results

Test Items*		Test results	Test Methods
Microbial cleanliness (CFU/g)	1	3.0	EN 14683:2019 EN ISO 11737-1:2018
	2	2.0	
	3	<2.0	
	4	2.0	
	5	2.0	

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-