**Test Report No.: 721656704**
**Report Date:31 July 2020**

| | |
|---|---|
| **SUBJECT** | **Microbiological Analysis** |
| **TEST LOCATION** | **TÜV SÜD China**<br>TÜV SÜD Products Testing (Shanghai) Co., Ltd.<br>B-3/4, No.1999 Du Hui Road, Minhang District<br>Shanghai 201108, P.R. China |
| **CLIENT NAME** | **Shandong Intco Medical Products Co., Ltd** |
| **CLIENT ADDRESS** | No.9888 Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China |
| **TEST PERIOD** | 20-Jul-2020~31-Jul-2020 |
| **TEST REQUEST** | Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016 |

**Prepared By**

Bella Xu

(Bella Xu)
Report Drafter

**Authorized By**

Leo Liu

(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

## RECEIPT DATE / TEST DATE

20-Jul-2020/ 20-Jul-2020

## THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

## BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: SYNMAX VINYL GLOVES

Sample Specification: M

Batch No./Date: /

Manufacturer: Shandong Intco Medical Products Co., Ltd

| SAMPLE NO. | DESCRIPTION | PHOTOGRAPH |
|---|---|---|
| 721656704 | Gloves |  |



## TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks, 5.3 Protection against viruses. Test method with reference to ISO 16604-2004 Clothing for protection against contact with blood and body fluids -Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

## REQUIREMENT

- Exposure Procedure: B

Sampling Size: 75mm×75mm
Negative control: Polyethylene material
Positive control: 0.04 μm microporous membrane
Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21±5)℃ and 30%~80% relative humidity.

## TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

## PROCEDURE

1. Compatibility testing
   1.1. Test three specimens representing each material type to be tested.
   1.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
   1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
   1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 μL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.

1.5. Prepare a control by adding a 2.0 µL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:

$$\text{ratio}=\frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}}=1.1$$

1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ( (2 ±1)x$10^8$ PFU/mL times the ratio calculated.)

2. Test procedure
2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
2.2. With the sterile cell placed horizontally on the laboratry bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
(1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-XI74 bacteriophage challenge suspension
(2) Step1: Observe for 5 min at 0 psi.
Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
(3) At the end of the time period, open the drain valve and drain the test cell of the bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration.
2.6. Specimen surface assay procedure
(1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
(2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.
3. Test controls
3.1. The negative control was negative for bacteriophage penetration.
3.2. The positive control was positive for bacteriophage penetration.
3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.

**TEST RESULT(S)**

| Test Items | | Initial titer PFU/ml | Final titer PFU/ml | Test Results | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Step1 | Step2 | Step3 | Assay titer (PFU/ml) | Pass/Fail |
| Penetration of Phi-X174 Bacteriophage | Control(+) | 1.9x$10^8$ | 1.9x$10^8$ | None Seen | Seen | - | - | Acceptable |
| | Control(-) | 1.9x$10^8$ | 1.9x$10^8$ | None Seen | None Seen | None Seen | <1 | Acceptable |
| | -1 | 1.9x$10^8$ | 1.9x$10^8$ | None Seen | None Seen | None Seen | <1 | Pass |
| | -2 | 1.9x$10^8$ | 1.9x$10^8$ | None Seen | None Seen | None Seen | <1 | Pass |
| | -3 | 1.9x$10^8$ | 1.9x$10^8$ | None Seen | None Seen | None Seen | <1 | Pass |

**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

Note:
1.PFU: Plaque Forming Unit.
2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

**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