

Test Report No. : 721624368-1
Report Date: 22 March 2016



ORIGINAL

SUBJECT Microbiological Analysis

TEST LOCATION TÜV SÜD China
TÜV SÜD Products Testing (Shanghai) Co., Ltd.
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CLIENT NAME Blue Sail Medical Co., Ltd

CLIENT ADDRESS NO.21 QingTian Road, Qilu Chemical Industrial Park, ZiBo City, ShanDong
Province, China, 255414

TEST PERIOD 25-Feb-2016~18-Mar-2016

TEST REQUEST Penetration of Phi-X174 Bacteriophage Test - with reference to ASTM F
1671-2013

Prepared By


(Zhu Yichen)
Customer Service

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.

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RECEIPT DATE / TEST DATE

25-Feb-2016/ 25-Feb-2016

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Disposable Vinyl Glove
Sample Type: L
Sample Batch: /
Manufactory: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721624368	Translucent gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test
- with reference to ASTM F 1671-2013 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

REQUIREMENT

- Exposure Procedure: B
Sampling Size: 70mm×70mm
Negative control: Polyethylene material
Positive control: 0.04 μm microporous membrane
Prior to testing, condition all test -s and controls for a minimum of 24 hours at (21 ± 5)°C and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

上海同硕检测技术有限公司



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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 laboratory bench, insert the - in the test cell with the normal outside surface 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 -.
 - 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 -.
 - 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 . ($(2 \pm 1) \times 10^8$ 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 laboratory bench, insert the - in the test cell with the normal outside surface 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 - at anytime during the test, terminate the test.
 - (1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-X174 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.- 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 -.
 - (2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
 - 2.7. Remove the - 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.

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TEST RESULT(S)

Test Items	Initial titer PFU/ml	Final titer PFU/ml	Test Results					
			Step1	Step2	Step3	Assay titer (PFU)	Pass/Fail	
Penetration of Phi-X174 Bacteriophage	Control(+)	2.3x10 ⁸	2.3x10 ⁸	None Seen	Seen	-	-	Acceptable
	Control(-)	2.3x10 ⁸	2.3x10 ⁸	None Seen	None Seen	None Seen	<1	Acceptable
	-1	2.3x10 ⁸	2.3x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-2	2.3x10 ⁸	2.3x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-3	2.3x10 ⁸	2.3x10 ⁸	None Seen	None Seen	None Seen	<1	Pass

Note:
PFU: Plaques Forming Unit.

-END OF THE TEST REPORT-

Chem Co., Ltd