

Test Report

SL52115270966401TX

Date: August 11, 2021

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WUJIANG TUTAIKE TEXTILES & FINISHING CO.,LTD
NO.1599, SOUTH 3RD RING ROAD, SHENGZE, WUJIANG, SUZHOU, JIANGSU

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A)Surgical Gown (EO sterilization)

Sample Color : (A)Blue

Composition : (A)SMS Non Woven Fabric

Style No. : TTK-C02

Lot No. : TTK-20200416

Manufacturer : Wujiang Tutaike Textiles & Finishing Co.,Ltd

Country of Origin : China

Other Info. : Country of Destination: Europe and America

Proposed Care Instruction : -

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 10, 2021

Testing Period : Jun 11, 2021 - Aug 11, 2021

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Test Result

Personal Protective Equipment - Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities

ANSI/AAMI PB70-2012

Section 4.2.1 Resistance to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage

Test Method :	ASTM F1671/F1671M-13
Product standard	ANSI AAMI PB70:2012
Number of test specimens :	64
Test specimens side tested :	outside
Dimension of the test specimens :	7.5 cm x 7.5cm
Test specimens sealed :	Yes
Test specimens conditioning :	21 ± 5°C and 30~80% RH for a minimum of 24 hours
Test procedure used :	B (Use retaining screen)
Compatibility ratio :	1.3 (Material) 1.7 (Seam)
Environmental plate results (PFU/ plate) :	0 PFU on each settle plate
Acceptance criteria :	Per Lot, an acceptable quality limit of 4.0 % is met for a single sampling plan when 29 or more of the 32 tested specimens show "pass" results.



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Test specimen: Material

Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
1	No penetration	2.3×10 ⁸	1.1×10 ⁸	< 1	Pass
2	No penetration	2.3×10 ⁸	1.1×10 ⁸	< 1	Pass
3	No penetration	2.3×10 ⁸	1.1×10 ⁸	< 1	Pass
4	No penetration	1.8×10 ⁸	1.4×10 ⁸	< 1	Pass
5	No penetration	1.8×10 ⁸	1.4×10 ⁸	< 1	Pass
6	No penetration	1.8×10 ⁸	1.4×10 ⁸	< 1	Pass
7	No penetration	3.4×10 ⁸	1.3×10 ⁸	< 1	Pass
8	No penetration	3.4×10 ⁸	1.3×10 ⁸	< 1	Pass
9	No penetration	3.4×10 ⁸	1.3×10 ⁸	< 1	Pass
10	No penetration	1.8×10 ⁸	1.1×10 ⁸	< 1	Pass
11	No penetration	1.8×10 ⁸	1.1×10 ⁸	< 1	Pass
12	No penetration	1.8×10 ⁸	1.1×10 ⁸	< 1	Pass
13	No penetration	2.9×10 ⁸	1.9×10 ⁸	< 1	Pass
14	No penetration	2.9×10 ⁸	1.9×10 ⁸	< 1	Pass
15	No penetration	2.9×10 ⁸	1.9×10 ⁸	< 1	Pass
16	No penetration	3.0×10 ⁸	2.4×10 ⁸	< 1	Pass
17	No penetration	3.0×10 ⁸	2.4×10 ⁸	< 1	Pass
18	No penetration	3.0×10 ⁸	2.4×10 ⁸	< 1	Pass
19	No penetration	3.0×10 ⁸	1.1×10 ⁸	< 1	Pass
20	No penetration	3.0×10 ⁸	1.1×10 ⁸	< 1	Pass
21	No penetration	3.0×10 ⁸	1.1×10 ⁸	< 1	Pass
22	No penetration	2.5×10 ⁸	1.1×10 ⁸	< 1	Pass
23	No penetration	2.5×10 ⁸	1.1×10 ⁸	< 1	Pass
24	No penetration	2.5×10 ⁸	1.1×10 ⁸	< 1	Pass
25	No penetration	1.7×10 ⁸	1.2×10 ⁸	< 1	Pass
26	No penetration	1.7×10 ⁸	1.2×10 ⁸	< 1	Pass
27	No penetration	1.7×10 ⁸	1.2×10 ⁸	< 1	Pass
28	No penetration	2.5×10 ⁸	1.8×10 ⁸	< 1	Pass
29	No penetration	2.5×10 ⁸	1.8×10 ⁸	< 1	Pass
30	No penetration	2.5×10 ⁸	1.8×10 ⁸	< 1	Pass

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31	No penetration	2.5×10 ⁸	1.2×10 ⁸	< 1	Pass
32	No penetration	2.5×10 ⁸	1.2×10 ⁸	< 1	Pass
Number of Test Specimen Passed:			32		
Overall result:			Acceptable		
Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
Negative Control for specimen 1-3	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 1-3	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 4-9	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 4-9	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 10-12	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 10-12	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 13-15	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 13-15	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 16-21	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 16-21	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 22-24	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 22-24	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 25-27	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 25-27	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 28-30	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 28-30	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 31-32	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 31-32	Penetration	N/A	N/A	TNTC	Acceptable

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Test specimen: seam

Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
1	No penetration	2.9×10 ⁸	1.1×10 ⁸	< 1	Pass
2	No penetration	2.9×10 ⁸	1.1×10 ⁸	< 1	Pass
3	No penetration	2.9×10 ⁸	1.1×10 ⁸	< 1	Pass
4	No penetration	3.7×10 ⁸	1.5×10 ⁸	< 1	Pass
5	No penetration	3.7×10 ⁸	1.5×10 ⁸	< 1	Pass
6	No penetration	3.7×10 ⁸	1.5×10 ⁸	< 1	Pass
7	No penetration	2.1×10 ⁸	1.1×10 ⁸	< 1	Pass
8	No penetration	2.1×10 ⁸	1.1×10 ⁸	< 1	Pass
9	No penetration	2.1×10 ⁸	1.1×10 ⁸	< 1	Pass
10	No penetration	2.6×10 ⁸	1.5×10 ⁸	< 1	Pass
11	No penetration	2.6×10 ⁸	1.5×10 ⁸	< 1	Pass
12	No penetration	2.6×10 ⁸	1.5×10 ⁸	< 1	Pass
13	No penetration	2.5×10 ⁸	2.0×10 ⁸	< 1	Pass
14	No penetration	2.5×10 ⁸	2.0×10 ⁸	< 1	Pass
15	No penetration	2.5×10 ⁸	2.0×10 ⁸	< 1	Pass
16	No penetration	3.1×10 ⁸	1.5×10 ⁸	< 1	Pass
17	No penetration	3.1×10 ⁸	1.5×10 ⁸	< 1	Pass
18	No penetration	3.1×10 ⁸	1.5×10 ⁸	< 1	Pass
19	No penetration	3.0×10 ⁸	2.6×10 ⁸	< 1	Pass
20	No penetration	3.0×10 ⁸	2.6×10 ⁸	< 1	Pass
21	No penetration	3.0×10 ⁸	2.6×10 ⁸	< 1	Pass
22	No penetration	2.0×10 ⁸	1.2×10 ⁸	< 1	Pass
23	No penetration	2.0×10 ⁸	1.2×10 ⁸	< 1	Pass
24	No penetration	2.0×10 ⁸	1.2×10 ⁸	< 1	Pass
25	No penetration	2.5×10 ⁸	1.3×10 ⁸	< 1	Pass
26	No penetration	2.5×10 ⁸	1.3×10 ⁸	< 1	Pass
27	No penetration	2.5×10 ⁸	1.3×10 ⁸	< 1	Pass
28	No penetration	2.4×10 ⁸	1.7×10 ⁸	< 1	Pass
29	No penetration	2.4×10 ⁸	1.7×10 ⁸	< 1	Pass
30	No penetration	2.4×10 ⁸	1.7×10 ⁸	< 1	Pass
31	No penetration	2.5×10 ⁸	1.9×10 ⁸	< 1	Pass

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32	No penetration	2.5×10 ⁸	1.9×10 ⁸	< 1	Pass
Number of Test Specimen Passed:			32		
Overall result:			Acceptable		
Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
Negative Control for specimen 1-3	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 1-3	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 4-9	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 4-9	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 10-12	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 10-12	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 13-15	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 13-15	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 16-21	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 16-21	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 22-24	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 22-24	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 25-27	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 25-27	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 28-30	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 28-30	Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 31-32	No penetration	N/A	N/A	< 1	Acceptable
Positive Control for specimen 31-32	Penetration	N/A	N/A	TNTC	Acceptable

*A value of <1 PFU/ ml is reported for assay plates showing no plaques.
TNTC= PFUs were too numerous to count.

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Sample Photo



Face

Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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