



Date: August 11,202



中国认可 国际互认 检测 TESTING CNAS L0599

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Test Report

SL52115270966401TX

WUJIANG TUTAIKE TEXTILES & FIN SHING 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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Date: August 11,2021

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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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Date:August 11,2021

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Test specimen: Material

	*^				.1
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
714	No penetration	1.8×10 ⁸	1.4×10 ⁸	<1	Pass
5	No penetration	1.8×10 ⁸	1.4×10 ⁸	×**<	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		Pass
16	No penetration	3.0×10 ⁸	2.4×10 ⁸	_1/51	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	1.7×108	1.2×10 ⁸	< 1	Pass
26	No penetration	1.7×10 ⁸	1.2×10 ⁸	/517	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
1					



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	SGS	3	来流氓,			<i>X</i> 2,
. 1	Test Report	SL52115270966	401TX Da	te:August 11,202	Pa	ge 4 of 7
1	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 Pa	ssed:		32	,
		Overali 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	77-21	Acceptable
	Positive Control for specimen 4-9	Penetration	N/A	N/A	TNTC	Acceptable
1X	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
ļ	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	1/5/17	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
ļ	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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SL52115270966401TX

Date: August 11,2021

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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 _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
1+5	No penetration	3.7×10 ⁸	1.5×10 ⁸	<u> </u>	Pass
6	No penetration	3.7×10 ⁸	1.5×10 ⁸	X 1 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 x 1	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
1///16	No penetration	3.1×10 ⁸	1.5×10 ⁸	// <u>\$</u> 1)	Pass
17	No penetration	3.1×10 ⁸	1.5×10 ⁸	17×1	Pass
18	No penetration	3.1×10 ⁸	1.5×10 ⁸	⁽¹⁾ <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	<14.	Pass
27	No penetration	2.5×10 ⁸	1.3×10 ⁸	X<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
-	7(-1)		12		73



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	SGS		***************************************			
. 1	Test Report	SL52115270966	401TX Dat	te:August 11,202	1 Pa	ge 6 of 7
1	32	No penetration	2.5×10 ⁸	1.9×10 ⁸	<1	Pass
	Number	of Test Specimen Pas	ssed:	A\$\ \	32	
		Overall result:		X.0X.	Acceptable	-
7.	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
.X	Negative Control for specimen 10-12	No penetration	N/A	N/A	<1	Acceptable
XX	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	X <1	Acceptable
	Positive Control for specimen 25-27	Penetration	N/A	N/A	TNTC	Acceptable
N.K.	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 plagues.

TNTC= PFUs were too numerous to count.



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The statement of conformity in this test report is only based on measured values by the laboratory and does not 一派 take their uncertainties into consideration.

***End of Report*



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SL52115295490401TX



Date:September 15,2021



国际互认 检测 TESTING CNAS L0599

中国认可

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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 Dimension : 175 Sample Color : (A)Blue

Composition : (A)SMS Non-woven

Style No : TTK-C02

Model No. : M

Lot No. : TTK-20200418

Lot Size : 1

Factory : Wujiang Tutaike Textiles & Finishing Co.,Ltd

Country of Origin : China

Proposed Care Instruction ::

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

Sample Receiving Date : Jun 10, 2021 & Jun 11, 2021
Testing Period : Aug 04, 2021 - Sep 15, 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 Gais

Helen Than

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Date:September 15,2021

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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)

1.4 (Material)

Compatibility ratio: 1.8 (Seam)

N/A (Tie attachment)

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.

Test specimen: Material

		. 12		-17	
Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
1	No penetration	2.1×10 ⁸	1.0×10 ⁸	<1	Pass
2	No penetration	2.1×10 ⁸	1.0×10 ⁸	<1	Pass
3	No penetration	2.1×10 ⁸	1.0×10 ⁸	<1	Pass
4	No penetration	2.8×10 ⁸	1.4×10 ⁸	<1	Pass
5	No penetration	2.8×10 ⁸	1.4×10 ⁸	<1	Pass
6	No penetration	2.8×10 ⁸	1.4×10 ⁸	<1	Pass
×17	No penetration	1.9×10 ⁸	1.1×10 ⁸	<1.	Pass
8	No penetration	1.9×10 ⁸	1.1×10 ⁸	XUT	Pass
9	No penetration	1.9×10 ⁸	1.1×10 ⁸	//×1	Pass
10	No penetration	2.1×10 ⁸	1.1×10 ⁸	1 <1	Pass
11	No penetration	2.1×10 ⁸	1.1×10 ⁸	<1	Pass
12	No penetration	2.1×10 ⁸	1,1×108	< 1	Pass



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SGS	S	NEXT THE			
Test Report 13	SL5211529549040		September 15,20	V7-	Page 3 of 6
·	No penetration	1.9×10 ⁸	1.3×10 ⁸	<1	Pass
14	No penetration	1.9×10 ⁸	1.3×10 ⁸	< 1	Pass
15	No penetration	1.9×10 ⁸	1.3×10 ⁸	<1	Pass
16	No penetration	1.7×10 ⁸	1.2×10 ⁸	<1	Pass
17	No penetration	1.7×10 ⁸	1.2×10 ⁸	<1	Pass
18	No penetration	1.7×10 ⁸	1.2×10 ⁸	< 1	Pass
19	No penetration	2.1×10 ⁸	1.2×10 ⁸	<1	Pass
20	No penetration	2.1×10 ⁸	1.2×10 ⁸	<1	Pass
121	No penetration	2.1×10 ⁸	1.2×10 ⁸		Pass
22	No penetration	2.0×10 ⁸	1.2×10 ⁸	1 41	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	1.7×10 ⁸	1.1×10³	<1	Pass
26	No penetration	1.7×10 ⁸	1.1×10 ⁸	<1	Pass
27	No penetration	1.7×10 ⁸	1.1×10 ⁸	<1	Pass
28	No penetration	2.5×10 ⁸	1.5×10 ⁸	<1	Pass
29	No penetration	2.5×10 ⁸	1.5×10 ⁸	<1	Pass
30	No penetration	2.5×10 ⁸	1.5×10 ⁸	<1	Pass
31	No penetration	2.9×10 ⁸	1.6×10 ⁸	< 1,/_	Pass
32	No penetration	2.9×10 ⁸	1.6×10 ⁸	(\$1)	Pass
Numb	er of Test Specimen Pa	ssed:		32	
	Overall result:	1		Acceptable	1
Test Article Number		Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
Negative Control for specimen 1-3		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	waling neneralian	N/A	N/A	< 1	Acceptable
Positive Control for specimen 4-9	Denetration	N/A	N/A	TNTC	Acceptable
Negative Control		N/A	N/A	<1.X	Acceptable
for specimen 10-13 Positive Control for specimen 10-13	Penetration	N/A	N/A	TNTO	Acceptable
Negative Control for specimen 16-2	No penetration	N/A	N/A	<1	Acceptable
Positive Control for specimen 16-2	1 Penetration	N/A	N/A	TNTC	Acceptable
Negative Control for specimen 22-24	No cenetration	N/A	N/A	<1	Acceptable



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-13	SGS					ELEXANT.
Te	st Report	SL5211529549040	1TX Date:	:September 15,20	212	Page 4 of 6
	Positive Control for specimen 22-24	Penetration	N/A	N/A	TNTC	Acceptable
	Negative Control for specimen 25-30	No penetration	N/A	N/A	< 1	Acceptable
	Positive Control for specimen 25-30	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

	Positive Control for specimen 31-32	Penetration	N/A	N/A	TNTC	Acceptable
Te	st specimen: Seam					
***	Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
XX	1	No penetration	2.7×10 ⁸	1.2×10 ⁸	<1	Pass
//)	2	No penetration	2.7×10 ⁸	1.2×10 ⁸	<1	Pass
	3	No penetration	2.7×10 ⁸	1.2×10 ⁸	<1	Pass
	4	No penetration	3.0×10 ⁸	1.7×10 ⁸	<1	Pass
	5	No penetration	3.0×10 ⁸	1.7×10 ⁸	<1	Pass
	6	No penetration	3.0×10 ⁸	1.7×10 ⁸	<1	Pass
	7	No penetration	2.4×10 ⁸	1.5×10 ⁸	<1	Pass
	8	No penetration	2.4×10 ⁸	1.5×10 ⁸	<1/2	Pass
	9	No penetration	2.4×10 ⁸	1.5×10 ⁸	1/4 <u>1</u>	Pass
	10	No penetration	3.1×10 ⁸	1.5×10 ⁸	- [X-<1	Pass
	11	No penetration	3.1×10 ⁸	1.5×10 ⁸	<1	Pass
11X	12	No penetration	3.1×10 ⁸	1.5×10 ⁸	<1	Pass
<i>K</i> .	13	No penetration	2.5×10 ⁸	1.7×10 ⁸	<1	Pass
1 >	14	No penetration	2.5×10 ⁸	1.7×10 ⁸	<1	Pass
	15	No penetration	2.5×10 ⁸	1.7×10 ⁸	<1	Pass 1
	16	No penetration	1.8×10 ⁸	× 1.5×10 ⁸	<1	Pass
	17	No penetration	1.8×10 ⁸	1.5×10 ⁸	<1	Pass
	18	No penetration	1.8×10 ⁸	1.5×10 ⁸	<1	Pass
	19	No penetration	2.1×10 ⁸	1.0×10 ⁸	< 1	Pass
	20	No penetration	2.1×10 ⁸	1.0×10 ⁸	5.20	Pass
	21	No penetration	2.1×10 ⁸	1.0×10 ⁸	<1	Pass
	22	No penetration	2.4×10 ⁸	1.0×10 ⁸	<1	Pass
	23	No penetration	2.4×10 ⁸	1.0×10 ⁸	<1	Pass
7-5	24	No penetration	2.4×10 ⁸	1.0×108	<1	Pass



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	- DAY	li .		R		K'T'
-14	SGS		K-XIII III			1
Té		SL5211529549040	1TX Date:	September 15,20	21 F	Page 5 of 6
	25	No penetration	2.4×10 ⁸	1.3×10 ⁸	<1	Pass
	26	No penetration	2.4×10 ⁸	1.3×10 ⁸	<1	Pass
4.	27	No penetration	2.4×10 ⁸	1.3×10 ⁸	< 1	Pass
. 1	28	No penetration	3.0×10 ⁸	1.3×10 ⁸	<1	Pass
	29	No penetration	3.0×10 ⁸	1.3×10 ⁸	<1	Pass
	30	No penetration	3.0×10 ⁸	1.3×10 ⁸	< 1	Pass
	31	No penetration	2.3×10 ⁸	1.1×10 ⁸	<1	Pass
	32	No penetration	2.3×10 ⁸	1.1×10 ⁸	<1	Pass
	Number of	of Test Specimen Pa	ssed:		32	
	<u> </u>	Overall result:	XX		Acceptable	
x 1/2	Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
/X^	Negative Control for specimen 1-3	No penetration	N/A	N/A	<1	Acceptable
//	Positive Control for specimen 1-3	Penetration	N/A	NA	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 10-15	No penetration	N/A	N/A	<1	Acceptable
	Positive Control for specimen 10-15	Penetration	WA	N/A	TNTC	Acceptable
	Negative Control for specimen 16-21	No penetration	N/A	N/A	- 1/3	Acceptable
19	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
N.K.	Positive Control for specimen 22-24	Penetration	N/A	N/A	TNTC	Acceptable
	Negative Control for specimen 25-30	No penetration	N/A	N/A	<1	Acceptable
	Positive Control for specimen 25-30	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 plagues.

TNTC= PFUs were too numerous to count.



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SL52115295490401TX

Date:September 15,2021

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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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中国认可 国际互认 检测 TESTING CNAS L0599

Date: November 01,2021

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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 Dimension 175 Sample Color (A)Blue

Composition (A)SMS Nonwoven fabric

Style Nov TTK-C02

Model No.

TTK-20200420 Lot No.

Lot Size

Factory Wujiang Tutaike Textiles & Finishing Co.,Ltd

Country of Origin China Retest Nó

Proposed Care Instruction

Test Performed Selected test(s) as requested by applicant

Sample Receiving Date Jun 10, 2021 & Jun 11, 2021 **Testing Period** Sep 06, 2021 - Nov 01, 2021

Unless otherwise stated the results shown in this test report refer only to the Test Result(s)

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:

Product standard

ANSI AAMI PB70:2012

Number of test specimens:

64(32 per test article)

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:
1.0 (Material)
1.0 (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

	XA		-//		
Test Article Number	Visual Penetration	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result
1	No penetration	2.7×10 ⁸	1.6×10 ⁸	< 1	Pass
2	No penetration	2.7×10 ⁸	1.6×10 ⁸	< 1	Pass
3	No penetration	2.7×10 ⁸	1.6×10 ⁸	<1	Pass
7.14	No penetration	1.7×10 ⁸	1.1×10 ⁸	<1	Pass
5	No penetration	1.7×10 ⁸	1.1×10 ⁸	< 1 - X	Pass
6	No penetration	1.7×10 ⁸	1.1×10 ⁸	<1	Pass
7	No penetration	1.4×10 ⁸	1.0×10 ⁸	<1	Pass
8	No penetration	1.4×10 ⁸	1.0×10 ⁸	<1	Pass
9	No penetration	1.4×10 ⁸	1.0×10 ⁸	< 1	Pass
10	No penetration	2.0×10 ⁸	1.1×10 ⁸	< 1	Pass
11	No penetration	2.0×10 ⁸	1.1×10 ⁸	< 1	Pass
12	No penetration	2.0×10 ⁸	1.1×10 ⁸	< 1	Pass_
13 X	No penetration	1.9×10 ⁸	1.0×10 ⁸	< 1	Pass
14/	No penetration	1.9×10 ⁸	1.0×10 ⁸	<1	Pass
15	No penetration	1.9×10 ⁸	1.0×10 ⁸	< 1, (Pass
716	No penetration	2.1×10 ⁸	1.2×10 ⁸	<1.5	Pass
17	No penetration	2.1×10 ⁸	1.2×10 ⁸	- 787	Pass
18	No penetration	2.1×10 ⁸	1.2×10 ⁸	<1	Pass
19	No penetration	1.8×10 ⁸	1.5×10 ⁸	<1	Pass
20	No penetration	1.8×10 ⁸	1.5×10 ⁸	< 1	Pass
21	No penetration	1.8×10 ⁸	1.5×10 ⁸	< 1	Pass
22	No penetration	2.2×10 ⁸	1.3×10 ⁸	< 1	Pass
23	No penetration	2.2×10 ⁸	1.3×10 ⁸	< 1	Pass
24	No penetration	2.2×10 ⁸	1.3×10 ⁸	< 1	Pass
25	No penetration	2.8×10 ⁸	1.4×10 ⁸	<1	Pass
26	No penetration	2.8×10 ⁸	1.4×10 ⁸	<1/1	Pass
27	No penetration	2.8×10 ⁸	1.4×10 ⁸	JX(1)	Pass
28	No penetration	2.0×10 ⁸	1.0×10 ⁸	X/ × 1	Pass
29	No penetration	2.0×10 ⁸	1.0×10 ⁸	× <1	Pass
30	No peneiration	2.0×10 ⁸	1.0×10 ⁸	< 1	Pass



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SGS	S			**************************************	XZ W	
Test Report	SL52115308158	001TX D	ate:November 01	2021	Page 4 of 7	
31	No penetration	2.3×10 ⁸	1.1×10 ⁸	<1	Pass	
32	No penetration	2.3×10 ⁸	1.1×10 ⁸	<1	Pass	
Number	of Test Specimen Pas Overall result:	ssed:		32 Acceptable		X
Test Article Number	Visual Penetration	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result	/) <i>'</i>
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 4-6	No penetration	N/A	N/A	< 1	Acceptable	
Positive Control for specimen 4-6	Penetration	N/A	N/A	TNTC	Acceptable	
Negative Control for specimen 7-12	No penetration	N/A	N/A	< 1	Acceptable	
Positive Control	Penetration	N/A	N/A	TNTC	Acceptable	
Negative Control for specimen 13-18 Positive Control	No penetration	N/A	N/A)	< 1	Acceptable	
for specimen 13-18 Negative Control	Penetration	N/A	- N/A	TNTC	Acceptable	
for specimen 19-21 Positive Control	No penetration	N/A	N/A	< 1	Acceptable	
for specimen 19-21 Negative Control	Penetration	N/A	N/A	TNTC	Acceptable	
for specimen 22-24 Positive Control	No penetration	N/A	N/A	<1//>	Acceptable	
for specimen 22-24 Negative Control	Penetration	N/A	N/A	INIC	Acceptable	
for specimen 25-30 Positive Control	No penetration	N/A	N/A	< 1 TNTC	Acceptable	
for specimen 25-30 Negative Control	Penetration No constration	N/A	N/A	TNTC	Acceptable	1/2
for specimen 31-32 Positive Control	No penetration	N/A	N/A	< 1 TNTC	Acceptable	12 Y
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	1.8×10 ⁸	1.0×10 ⁸	< 1	Pass
2	No penetration	1.8×10 ⁸	1.0×10 ⁸	< 1	Pass
3	No penetration	1.8×10 ⁸	1.0×10 ⁸	< 1	Pass
4	No penetration	2.2×10 ⁸	1.4×10 ⁸	<1 /	Pass
12.5	No penetration	2.2×10 ⁸	1.4×10 ⁸	< 1-	Pass
6	No penetration	2.2×10 ⁸	1.4×10 ⁸	×17.	Pass
7	No penetration	2.1×10 ⁸	1.6×10 ⁸	XX 1×1	Pass
8	No penetration	2.1×10 ⁸	1.6×10 ⁸	<1	Pass
9	No penetration	2.1×10 ⁸	1.6×10 ⁸	< 1	Pass
10	No penetration	2.5×10 ⁸	2.2×10 ⁸	< 1	Pass
11	No penetration	2.5×10 ⁸	2.2×10 ⁸	< 1	Pass
12	No penetration	2.5×10 ⁸	-2.2×10 ⁸	< 1	Pass
13	No penetration	1.5×10 ⁸	1.0×10 ⁸	< 1	Pass
14	No penetration	1.5×10 ⁸	1.0×10 ⁸	< 1	Pass
15/	No penetration	1.5×10 ⁸	1.0×10 ⁸	<1 /	Pass
16	No penetration	1.8×10 ⁸	1.5×10 ⁸	<1//	Pass
17	No penetration	1.8×10 ⁸	1.5×10 ⁸	13.17	Pass
18	No penetration	1.8×10 ⁸	1.5×10 ⁸	LP1	Pass
19	No penetration	2.7×10 ⁸	1.2×10 ⁸	<1	Pass
20	No penetration	2.7×10 ⁸	1.2×10 ⁸	< 1	Pass
21	No penetration	2.7×10 ⁸	1.2×10°	< 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	1.8×10 ⁸	1.0×10 ⁸	< 1	Pass
26	No penetration	1.8×10 ⁸	1.0×10 ⁸	<1 ,	Pass
27	No penetration	1.8×10 ⁸	1.0×10 ⁸	</td <td>Pass</td>	Pass
28	No penetration	1.4×10 ⁸	1.1×10 ⁸	***1	Pass
29	No penetration	1.4×10 ⁸	1.1×10 ⁸	×1 <1	Pass
30	No penetration	1.4×10 ⁸	1.1×10 ⁸	< 1	Pass
31	No penetration	2.5×10 ⁸	1.2×10 ⁸	< 1	Pass
			4.//		<u> </u>



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	SGS						
.1.	Test Report	SL52115308158	001TX D	ate:November 01	,2021	Page 6 of 7	7
	32	No penetration	2.5×10 ⁸	1.2×10 ⁸	< 1	Pass	
	Number of Test Specimen Passed:			32			X
	Overall result:			Acceptable			XXI
	Test Article Number	Visual Penetration	Per-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Test Result	XXX
	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 4-6	No penetration	N/A	N/A	<1	Acceptable	
	Positive Control for specimen 4-6	Penetration	N/A	N/A	TNTC	Acceptable	-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X-X
	Negative Control for specimen 7-12	No penetration	N/A	N/A	XXI	Acceptable	
	Positive Control for specimen 7-12	Penetration	N/A	N/A	TNTC	Acceptable	
	Negative Control for specimen 13-18	No penetration	N/A	N/A	<1	Acceptable	
	Positive Control for specimen 13-18	Penetration	N/A	N/A	TNTC	Acceptable	
	Negative Control for specimen 19-21	No penetration	N/A	N/A	< 1	Acceptable	
	Positive Control for specimen 19-21	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 25-30 Positive Control	No penetration	N/A	N/A	-1/57	Acceptable	
	for specimen 25-30 Negative Control	Penetration	N/A	N/A	TNTC	Acceptable	1/2
	for specimen 31-32 Positive Control	No penetration	N/A	N/A	<1	Acceptable	
	for specimen 31-32	Penetration	N/A	N/A	TNTC	Acceptable	(A)
	*A value of <1 PFU/ ml TNTC= PFUs were too		praces snowing no	piagues:		-1%	,
	A HE KINE YOUR THE REAL PROPERTY OF THE PERTY OF THE PERT		模			7.	
6	H.		& '		Y XX		

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



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End of Report



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