

GÜLSAN SENTETİK DOKUMA SAN. VE TIC.A.Ş.

TEST REPORT

SCOPE OF WORK

Performance Testing of Surgical Gowns to
ANSI/AAMI PB70:2012 American National Standard for
Liquid Barrier Performance and Classification of
Protective Apparel and Drapes Intended for
Use in Health Care Facilities

REPORT NUMBER

104366460CRT-004

ISSUE DATE

July 8, 2020

PAGES

5

DOCUMENT CONTROL NUMBER

RT-L-US-Test-3470 (9/1/2017)

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Report No.: 104366460CRT-004

Date Issued: July 8, 2020

MANUFACTURER

Gülsan Sentetik Dokuma San. ve Tic.A.Ş.
Organize Sanayi Bolgesi 2. Cadde No:18
27620 Gaziantep
Turkey

TEST STANDARD

ANSI/AAMI PB70:2012 American National Standard on Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities using ASTM F1671 / F1671M - 13: 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

AUTHORIZATION

Quote Number: Qu-01085425-2

PRODUCT DESCRIPTION

Sample Type: Gown Material

ID Number: 55gsm Breathable Laminate for Protective Clothing / Coverall Suit – S064

SAMPLE INFORMATION

Dates Samples Received: June 22, 2020

Condition of Samples: Production Run

Date of Testing: July 7, 2020

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SECTION 1 CONCLUSION

This test report completes the testing covered by quote number Qu-01085425-2.

The observations and test results in this report are relevant only to the sample tested. Intertek makes no representations or warranties, express or implied, regarding units that were not tested including, but not limited to, units that may be part of the same lot.

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Project Owner:	Kimberly Lea
Title:	Engineer, PPE Bio Lab
Signature:	
Date	08-07-2020

Project Reviewer:	Kristine Perrotti
Title:	Engineer, Chem/Bio/Clothing Team Lead
Signature	
Date:	08-07-2020

SECTION 2

ASTM F1671 / F1671M – 13 TEST DATA SHEETS

PRODUCT DESCRIPTION: 55gsm Breathable Laminate for Protective Clothing / Coverall Suit – S064

CONDITIONING: At a temperature of $21 \pm 5^{\circ}\text{C}$ and a relative humidity of 30-80% until equilibrium is reached or for at least 24 hours, whichever is shorter.

TESTING PROCEDURE USED: Procedure A: 0 psig for 5 minutes, 2 psig for 1 minute, 0 psig for 54 minutes.
No, stainless steel retaining screen used.

TEST RESULTS:

Quality Control Samples	PFU/ml	Results
Negative Control	0	Acceptable (valid test)
Pre-test Bacteriophage Titer	3.0×10^8	Acceptable (valid test)
Post Test Bacteriophage Titer	3.0×10^8	Acceptable (valid test)
Settle Plate(s)	0	Acceptable (valid test)

Sample Number	Sample Thickness (mils)	Sample Weight (g)	Assay Volume (mls)	Number of Plaques		Assay Titer (PFU/ml)	Test Terminated Due to Liquid Penetration	Pass/Fail
				Plate 1	Plate 2			
1	10	0.3259	5	0	0	0	No	Pass
2	10	0.3273	5	0	0	0	No	Pass
3	9	0.3135	5	0	0	0	No	Pass
Averages	10	0.3222						

SECTION 3

ANSI/AAMI PB70:2012 CLASSIFICATION of BARRIER PERFORMANCE of SURGICAL GOWNS, ISOLATION GOWNS, OTHER PROTECTIVE APPAREL, SURGICAL DRAPES, and DRAPE ACCESSORIES

Level	Test	Result	AQL requirement (Alpha = .05)	RQL requirement (Beta = 0.10)
1	AATCC 42	≤4.5 g	4%	20%
2	AATCC 42 AATCC 127	≤1.0 g ≥20 cm	4%	20%
3	AATCC 42 AATCC 127	≤1.0 g ≥50 cm	4%	20%
4	ASTM F1671 (surgical gowns, isolation gowns and other protective apparel)	Pass	4%	20%
	ASTM F1670 (surgical drapes and drape accessories)	Pass	4%	20%