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Istoc-Bagcilar, ISTANBUL
Attn: Emel Atahan

AAMI PB70 Liquid Barrier Performance and Classification

Test Article: Isolation Gown Lot # 02100g

A total of thirty-two (32) specimens were tested from thirty-two (32) test articles. Specimens were chosen from the critical zones as described in AAMI PB70 for an isolation gown. Test specimens were subjected to the following tests:

AATCC 42 Water Resistance: Impact Penetration Test
AATCC 127 Water Resistance: Hydrostatic Pressure Test.

Based on the results of the testing as summarized in the attached reports, numbers 2005698 and 2005699, the product listed above was classified as **AAMI PB70 Level 2.**

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by _____ Date 7.30.20

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

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Lab # 2005698
PO # N/A

Test Article: AAMI Level 2 Gown - Non-Sterile
Part # N/A Lot # 02100g Batch # Cat #021

AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 7/27/2020
Test start date: 7/28/2020
Test termination date: 7/29/2020
SOP No. (current version): LEXLP-074

Procedure: Thirty-two (32) sections each measuring 178 x 330 mm were cut from 32 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for each were preconditioned at 65±2% rh and 21±1ºC for a minimum of 4 hours. Test samples were then clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted beneath the test sample. Deionized Water (DIW) heated to 27± 1°C was poured into the funnel and the water sprayed onto the test article. The blotter paper was removed and re-weighed.

The post-weight for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Post -Weight Gain Acceptance Criteria		
Level 1	Level 2	Level 3
≤ 4.5 gm	≤ 1.0 gm	≤ 1.0 gm

Results: A total of 32 / 32 specimens had a weight gain of ≤ 1.0 gm.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by _____ Tech: GP/AP Date 7-30-20

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Lab # 2005699
PO # N/A

Test Article: AAMI Level 2 Gown - Non-Sterile
Part # N/A Lot # 02100g Batch # Cat #021

AATCC 127 Water Resistance: Hydrostatic Pressure Test

Test article received: 7/27/2020
Test start date: 7/28/2020
Test termination date: 7/29/2020

Procedure: Thirty-two (32) sections each measuring 200 mm x 200 mm were cut from 32 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens were preconditioned at 65±2% rh and 21±1°C for a minimum of 4 hours. Individual specimens were clamped into the Hydrostatic Tester and analyzed.

The hydrostatic pressure required for water penetration for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Hydrostatic Pressure Acceptance Criteria	
Level 2	Level 3
≥ 20 cmH_2O	≥ 50 cmH_2O

Results: A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of ≥ 20 cmH_2O.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 2.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by _____ Tech: AP/GP Date 7.30.20

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