Avante | Health Solutions

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800-477-2006 • 502-244-4444 • FAX: 502-244-0369

www.avantehs.com

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2392-2020-08-27

Non-Surgical Isolation Gown

T Style

Features

- Tested for compliance with ANSI/AAMI PB70:2012 Minimal Barrier Performance Level 1, Level 2, and Level 3 Requirements
- Easy to Put On and Take Off
- Gap in End of Sleeve Seal for Thumb
- Long Sleeve, Full Coverage
- Made from Polyethylene (Virgin LLDPE)
- Thickness - 1.5 mil

Please Note

- This product is a Class I device
- Gown Intended for Single Use Only
- This Product is Intended for Non-Surgical Use **ONLY**
- This Product is **NOT** sterilized
- Do **NOT** use in the presence of high intensity he source or flammable gas

These products have been authorized by FDA under an Emergency Use Authorization for use by healthcare providers as personal protective equipment. This product is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1).

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Avante Health Solutions

IDEOPAK packaging solutions

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Ames, Iowa 50011

Prepared For:

Novolex Holdings, LLC
101 East Carolina Ave
Hartsville, SC 29550

Date: 4.27.2020
Project Number: 1104272008

Product(s) Tested:

Evaluation of medical gowns per ANSI/AAMI PB70 (AATCC TM-127-2018) and ASTM D6701.

Figure 1. Medical gown materials as received

ANSI/AAMI PB70 Requirements:
American National Standards Institute (ANSI) and the Association of the Advancement of Medical Instrumentation (AAMI): ANSI/AAMI PB70:2003 describes liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.

ASTM F1868 – sweating hotplate approach to measure the thermal resistance, also evaporative resistance (attached) for textiles. This method also considers the wind effect (environmental factors).

Table 1—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 % 4 %	20 %
3	AATCC 42 AATCC 127	≤ 1.0 g ≥ 50 cm	4 % 4 %	20 %
4	ASTM F1671 (surgical gowns, isolation gowns and other protective apparel) ASTM F1670 (surgical drapes and drape accessories)	Pass Pass	4 % 4 %	20 % 20 %

1. Blotter paper used with the AATCC method must meet the specifications provided in section 5.2.1.2 of this standard.

Standard Test Method:

Water Resistance: Hydrostatic Pressure Test per AATC TM-127-2018

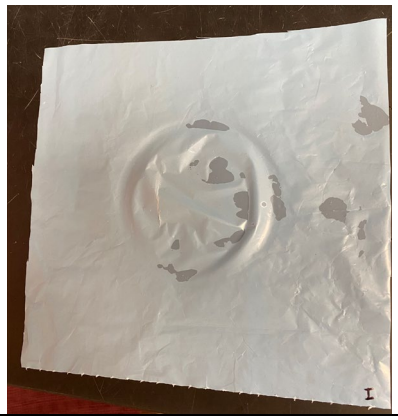
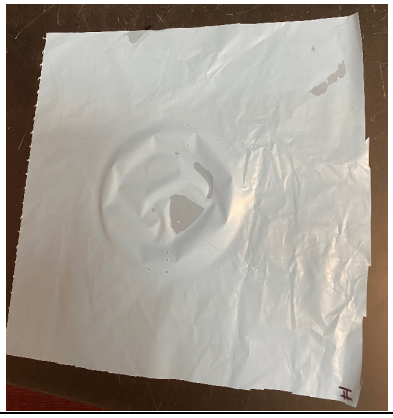
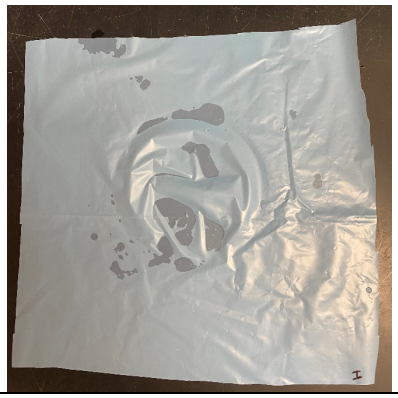
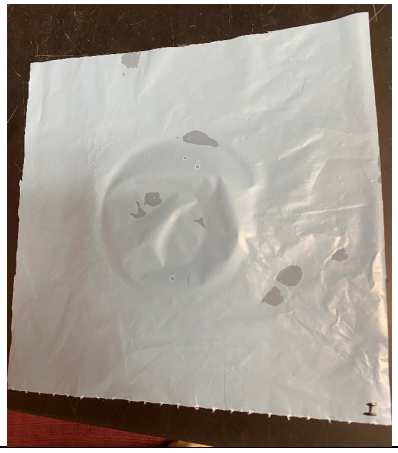
The hydrostatic pressure test was investigated according to AATCC TM-127-2018 (AATCC, 2018), with three specimens per sample evaluated. The test was conducted using the Hydro II® Portable Hydrostatic Pressure Tester, with the pressure of 60 mbar set using a diaphragm. All specimens resisted the pressure applied, not displaying any failure during an evaluation time of one minute for Levels 1, 2, and 3 per Table 2. Table 3 shows the pictures of each specimen after testing.

Table 2: Results of Hydrostatic Pressure Test

Sample	Method	Level Threshold	Results	
2.0 mil	AATCC 127/ANSI/AAMI PB 70 Standard	Level 1	Pass	> 60 mbar
2.0 mil	AATCC 127/ANSI/AAMI PB 70 Standard	Level 2	Pass	> 60 mbar
2.0 mil	AATCC 127/ANSI/AAMI PB 70 Standard	Level 3	Pass	> 60 mbar

Sample	Method	Level Threshold	Results	
1.5	AATCC 127/ANSI/AAMI PB 70 Standard	Level 1	Pass	> 60 mbar
1.5	AATCC 127/ANSI/AAMI PB 70 Standard	Level 2	Pass	> 60 mbar
1.5	AATCC 127/ANSI/AAMI PB 70 Standard	Level 3	Pass	> 60 mbar

Table 3. Specimens after the Hydrostatic Pressure Test

Specimen / Sample	1.5 mil	2.0 mil
1		
2		
3		

References:

AATCC. TM 127-2018, Water Resistance: Hydrostatic Pressure Test. Research Triangle Park, NC: American Association of Textile Chemists and Colorists; 2018.

ASTM D6701-16, Standard Test Method for Determining Water Vapor Transmission Rates Through Nonwoven and Plastic Barriers, ASTM International, West Conshohocken, PA, 2016.

Standard Test Method:

ASTM F1868-17 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate (Part C)

Test Conditions: Sweating guarded hotplate temperature 35±0.1^{o}C, ambient temperature 25±0.5 ^{o}C, RH 65±2%, air velocity 1±0.1m/s.

Results:

Table 3. Average values of tested and calculated items

Sample	Rct (°C m^2/W),	Ret (Pa·m^2/W)	Rcf (°C m^2/W)	Ref (Pa·m^2/W)	THL (W/m^2)
1.5	0.0788	315.40	0.0029	309.90	244.5
2.0	0.0784	321.86	0.0025	316.36	246.6

Note:

Rct (°C m^2/W), total thermal insulation of sweating guarded hotplate, material, and boundary air.

Ret (Pa·m^2/W), total evaporative resistance of sweating guarded hotplate, material, and boundary air.

Rcf (°C ·m^2/W), intrinsic thermal insulation of the material only.

Ref (Pa·m^2/W), intrinsic evaporative resistance of the material only.

THL (W/m^2), the total heat loss (THL) predicted with **Rct** and **Ret** in a 25°C, 65% RH environment.

Figure 3. Samples as tested

Disclaimer:

July 16, 2020

To whom it may concern:

Novolex is a supplier of flexible and rigid packaging primarily for foodservice, grocery, construction, industrial and medical markets. We have 61 manufacturing facilities globally- 56 of those in North America. For more information about our business, please visit us at novolex.com.

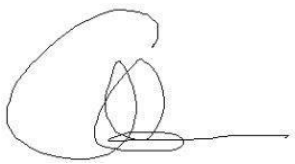
We have diverted several of our North American facilities to manufacturing PPE products- namely polyethylene gowns and PET face shields for use by medical professionals and first responders.

These products have been authorized by the FDA under an Emergency Use Authorization for use by healthcare providers as personal protective equipment. This product is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

Novolex Isolation Gowns have been independently tested and comply with ANSI/AAMI PB70 Barrier Performance Level 1-3.

All Isolation Gowns we have produced since inception have been cleared to go to market by our legal department as they comply with the FDA EUA under Section 564(b)(1) of the Act, 21 USC 360bbb 3(b)(1). This includes the 250,000 gowns that were shipped on July 2, 2020.

Sincerely,



Adrianne Tipton
Sr. Vice President, Innovation