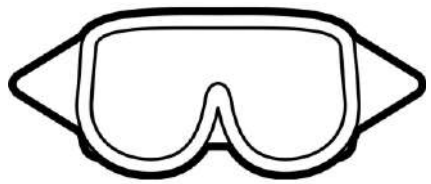





Identification of local options for quality testing of personal protective equipment (PPE) during COVID-19 Pandemic



IFC webinar
PPE Specifications




ASTM INTERNATIONAL

Association for the Advancement of Medical Instrumentation® (AAMI)

National Institute for Occupational Safety and Health

British Standards

World Health Organization

Presented by –
Dr. Mohidus Samad Khan
PhD (Monash U, AUS), Post-Doc (McGill U, CAN)
Principal Investigator, Bio- and Env Engineering (BET) Group, and
Associate Professor, Department of Chemical Engineering, BUET

World Health Organization

COVID-19 v 4

Disease Commodity Packages Operational Support & Logistics

INTERVENTION		COMMODITY	TECHNICAL DESCRIPTION	
PREVENTION & CONTROL	Triage/Screening PPE	Gloves, examination, non-sterile	Gloves, examination, nitrile, powder-free, non-sterile, single-use Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm. Sizes: small, medium, large	• EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • EN 374 • ANSI/ISEA 105 • ASTM D6319
		Mask, surgical – health care worker	Surgical mask, good breathability, internal and external faces should be clearly identified Type II or higher.	• EU MDD Directive 93/42/EEC Category III or equivalent, • EN 14683 Type II, IR, IIR • ASTM F2100 minimum Level 1 or equivalent.
		Mask, surgical – patient	Surgical mask, good breathability, internal and external faces should be clearly identified Type I.	• EN 14683 any type including Type I • ASTM F2100 any level or equivalent

INTERVENTION		COMMODITY	TECHNICAL DESCRIPTION	
	PPE Health Care Facilities	Gloves, examination, non-sterile	Gloves, examination, nitrile, powder-free, non-sterile, single-use Gloves should have long cuffs, reaching well above the wrist, ideally to mid-forearm Sizes: small, medium, large	• EU MDD Directive 93/42/EEC Category III • EU PPE Regulation 2016/425 Category III • EN 455 • EN 374 • ANSI/ISEA 105, • ASTM D6319,
		Face shield	Made of clear plastic and providing good visibility to both the wearer and the patient Adjustable band to attach firmly around the head and fit snuggly against the forehead, fog-resistant (preferable). Completely covers the sides and length of the face. May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.	• EU PPE Regulation 2016/425 • EN 166 • ANSI/ISEA Z87.1 or equivalent
		Particulate respirator, grade N95 or higher.	N95 or FFP2 respirator, or higher Good breathability with a design that does not collapse against the mouth (e.g. duckbill, cup-shaped).	• Minimum "N95" respirator according to FDA Class II, under 21CFR 878.4040, and CDC NIOSH, or • Minimum "FFP2 according to EN 149, EU PPE • Regulation 2016/425 Category III, or equivalent
		Mask, surgical – health care worker.	Surgical mask, good breathability; internal and external faces should be clearly identified Type II or higher.	• EU MDD Directive 93/42/EEC Category III or equivalent • EN 14683 Type II, IR, IIIR • ASTM F2100 minimum level 1 or equivalent
		Mask, surgical – patient	Surgical mask, good breathability; internal and external faces should be clearly identified Type I.	• EN 14683 any type including Type I • ASTM F2100 minimum level 1 or equivalent
		Scrubs, tops	Tunic/tops, woven, scrubs, reusable or single-use, short-sleeved (tunic/tops), worn underneath the coveralls or gown	
		Scrubs, pants	Trouser/pants, woven, scrubs, reusable or single-use, worn underneath the coveralls or gown	
		Apron, heavy duty	Straight apron with bib, Fabric: 100%polyester with PVC coating, or 100%PVC, or 100%rubber, or other fluid-resistant coated material. Waterproof, sewn strap for neck and back fastening Minimum weight: 300 g/m2 Covering size: 7090 cm (width) x 120–150 cm (height) Reusable (provided appropriate arrangements for decontamination are in place)	• EN ISO 13688 • EN 14126-B and partial protection (EN 13034 or EN 14605) • EN 343 for water and breathability or equivalent
		Gown	Single-use, length mid-calf.	• EU PPE Regulation 2016/425 and EU MDD Directive 93/42/EEC • FDA Class I or II medical device, or equivalent • EN 13795 any performance level, or • AAMI PB70 all levels acceptable, or equivalent
		Gloves, cleaning	Outer glove should have long cuffs, reaching well above the wrist, ideally to mid-forearm, Minimum 280 mm total length Sizes: small, medium, large Reusable	Puncture-resistant, FDA compliant

Classifications:

Association for the Advancement of Medical Instrumentation® (AAMI)

ASTM INTERNATIONAL

2020

Type of PPE	Feature Tested	Standard Designation	Sub headings	Description	Applicability
Gowns	Liquid Barrier Performance	AAMI PB70:2012		Classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical gowns	Liquid barrier performance is not related to the strength of the material. This standard references several other standards
			Level 1	• Used for MINIMAL risk situations • Provides a slight barrier to small amounts of fluid penetration • Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	basic care, standard hospital medical unit

			Level 2	• Used in LOW risk situations
				• Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking
				• Two tests are conducted to assess barrier protection performance:
				  ◦ Water impacting the surface of the gown material
				  ◦ Pressurizing the material
					Blood draw from a vein, Suturing, Intensive care unit, Pathology lab

			Level 3	• Used in MODERATE risk situations
				• Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2
				• Two tests are conducted to test barrier protection performance:
				  ◦ Water impacting the surface of the gown material
				  ◦ Pressurizing the material
					Arterial blood draw, Inserting an IV, Emergency Room, Trauma

			Level 4	• Used in HIGH risk situations • Prevents all fluid penetration for up to 1 hour • May prevent VIRUS penetration for up to 1 hour • In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods

EN

Summary of Infectious Agent Resistance Tests in EN 14126

Below are the four tests included in EN 14126 to assess fabric used for garments to protect against infectious agents.

Each assesses resistance to different types of fabric penetration. In each cases, resistance is assessed using bacteria, with penetration being identified through the growth of bacterial cells on the reverse side of the fabric

1. **Clause 4.1.4.1**
   ISO/FDIS 16604: Resistance to penetration by contaminated liquids under pressure

   Tests resistance to infectious agents that are transmitted in pressurised liquids such as body fluids. This includes many diseases - the important test for protection against Ebola

   Note there is no classification for the ISO/FDIS 16603 which is purely a pre-cursor test for ISO/FDIS 16604 (16603 identifies "strike-through" only by visual identification)

Class	Hydrostatic pressure at which the materials passes the test
6	20 kPa
5	14 kPa
4	7 kPa
3	3.5 kPa
2	1.75 kPa
1	0 kPa a

a this means that the materials is only exposed to the hydrostatic pressure of the liquid in the test cell

2. **Clause 4.1.4.2**
   EN 14126: Annex A: Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids

   Measures the time until a breakthrough for contamination by mechanical contact with a wet surface in which the liquid is contaminated with a bacteria. Thus it might be important for garments that might rub against contaminated surfaces.

   Note that the "Annex A" test in the standard has been superceded by EN 22610. The 14126 standard has not yet been updated to reflect this

Class	Breakthrough time. T. Min.
6	$t > 75$
5	$60 < t \leq 75$
4	$45 < t \leq 60$
3	$30 < t \leq 45$
2	$15 < t \leq 30$
1	≤ 15

3. **Clause 4.1.4.3**
   ISO/DIS 22611: Resistance to penetration by contaminated liquid aerosols

   Measures the resistance to bacteria or infectious agents contain in light aerosol sprays of liquids

Class	Penetration ratio (log)
3	$log > 75$
2	$3 < \log \leq 5$
1	$1 < \log \leq 3$

4. **Clause 4.1.4.4**
   ISO/DIS 22612: Resistance to penetration by contaminated solid particles

   Measures the resistance to solid particles that may be contaminated with a bacteria or infectious agents

Class	Penetration (log cfu)
3	≤ 1
2	$1 < \log$ cfu ≤ 2
1	$2 < \log \leq 3$

Gowns and Aprons:

Fluid Resistant → **Sterile** → **Level - 1**

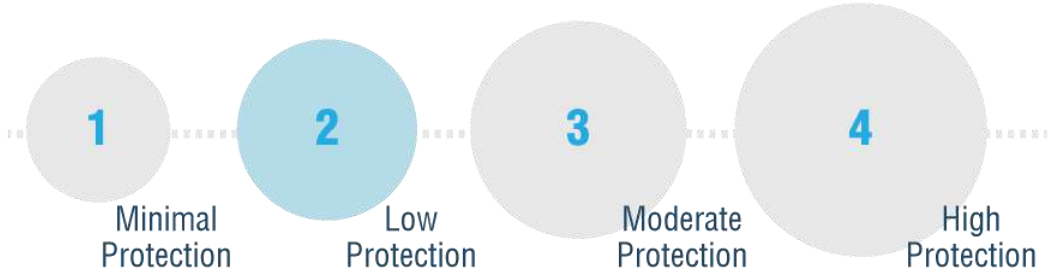
Disposable → **Non-Sterile** → **Level - 2**

Level - 3

Level - 4

Special Conditions:

- All items MUST have product specification sheet
- All items Must have SOP to use and to dispose.
- All items Must be individually packaged;
- All items Must be latex free (surgical or no-surgical);
- All surgical items Must be supplied **Sterile**;
- All **Sterile items** Must be packaged in a **Sterile facilities**.



General relationships between barrier performance and anticipated exposure risks (cont.)

(ANSI/AAMI PB70 Barrier Performance)

ANSI/AAMI PB70 Barrier Performance	Fluid Amount	Fluid Spray or Splash	Pressure on Gown or Drape	Examples of Procedures with Anticipated Exposure Risks
Level 1	Minimal	Minimal	Minimal	Minimum risk, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit. Simple/excisional biopsies Excision of "lumps and bumps" Opthalmological procedures Simple eye, nose, and throat (ENT) procedures
Level 2	Low	Low	Low	Low risk, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab. Endoscopic gastrointestinal procedures; Simple orthopedic procedures with tourniquets; Tonsillectomies and adenoidectomies; Open hernia repair; Minimally invasive surgery Interventional radiology/catheter lab procedures
Level 3	Moderate	Moderate	Moderate	Moderate risk, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases. Arthroscopic orthopedic procedures Endoscopic urological procedures(e.g., transurethral prostate resections) Open gastrointestinal and genito-urinary procedures; Mastectomies
Level 4	High	High	High	To be used, for example, during long, fluid intense procedure, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne) Any procedure in which the surgeon's hands and arms are in a body cavity. Orthopedic procedures without a tourniquet; Open cardiovascular/thoracic procedures; Trauma procedures; Caesarean sections

Gowns and Coveralls:

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per AAMI Standards)				Remarks
			Level 1 (minimal)	Level 2 (low)	Level 3 (moderate)	Level 4 (high)	
1.	Tensile Strength (ASTM D5034, ASTM D1682)	N	>30	>60	>100	>250	[a] For isolation gown Levels (1,2,3,4) ≥ 30N
2.	Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424)	N	>5	>10	>50	>100	[a] For isolation gown Levels (1,2,3,4)≥10N
3.	Seam Strength (ASTM D751 (stretch woven or knit))	N	≥30	≥30	≥30	≥30	ASTM F3352-19 Ref: ASTM D1683/D1683M
4.	Water vapor transmission (breathability) (ISO 11092:2014(EN); ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75; or equivalent	m^2Pa/W	-	-	<30 (for coveralls)	<30 (for coveralls)	ISO11092:2014(EN)
		mm/s	AP > 100	5 < AP < 100	AP ≤ 5	-	ASTM D737-75 Re: EN14058:2017(E)
5.	Water Resistance: Hydrostatic Test (**AATCC 127**; BS EN 13795:2019)	cm H_2O	N/A	>20	>50 (sterile)	>100 (sterile)	No data available for Level 1
					>57.3 (fluid resistant)	>91 (fluid resistant)	
6.	Water Resistance: Impact Penetration Test (**AATCC 42** or equivalent (e.g., AATCC 35*))	g	<=4.5	<=1	<=1	<=1	No data available for Level 4. Emphasis given on breathability test
7.	Synthetic Blood Penetration Test (ASTM **F1670** or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	*** PPE importers must present relevant documents and certification**
8.	Viral Penetration Test (ASTM **F1671** or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	

*** The alternate protocol/provision is allowed temporarily until test facilities are developed and established locally, as per proposed standard(s) .**

** Acceptance Quality Limit: AQL 4%

Surgical Mask:

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per ASTM F2100)			Remarks
			Level 1 barrier	Level 2 barrier	Level 3 barrier	
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, or equivalent)	mm H_2O/cm^2	<5.0	<6.0	<6.0	ASTM F2100
2.	Particulate Filtration Efficiency (F2299, or equivalent) @ 0.1 µ, **0.3 µ ***	%	≥95	≥98	≥98	
3.	Splash Resistance/ Synthetic Blood Resistance ((ASTM F1862-07), or equivalent)	mmHg	80	120	160	*** PPE importers must present relevant documents and certification**
4.	Test Bacterial Filtration Efficiency (EN14683, ASTM F2101, or equivalent)	%	≥95	≥98	≥98	

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per EN 14683:2019)				Remarks
			Type I	Type II	Type IR	Type IIR	
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, or equivalent)	Pa/cm^2	<40	<40	<40	<60	EN 14683:2019
2.	Particulate Filtration Efficiency (F2299, or equivalent) @ 0.1 µ, **0.3 µ ***	%	≥95%	≥98%	≥95%	≥98%	ASTM F2100
3.	Splash Resistance/ Synthetic Blood Resistance ((ASTM F1862-07), or equivalent, e.g. ISO22609:2004 (EN))	mmHg	80	120	80	160	*** PPE importers must present relevant documents and certification**
4.	Test Bacterial Filtration Efficiency (EN14683, ASTM F2101, or equivalent)	%	≥95%	≥98%	≥95%	≥98%	

*** The alternate protocol/provision is allowed temporarily until test facilities are developed and established locally, as per proposed standard(s) .**

** Acceptance Quality Limit: AQL 4%

Respirator: N95 Mask and KN95 Mask

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per ASTM F2100)			Remarks
			Level 1 barrier	Level 2 barrier	Level 3 barrier	
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, or equivalent)	mm H_2O/cm^2	<5.0	<6.0	<6.0	ASTM F2100
2. *	Particulate Filtration Efficiency (F2299, or equivalent) @ 0.1 μ, **0.3 μ ***	%	≥95	≥98	≥98	
3. *	Particulate Filtration Efficiency (NIOSH 42 CFR 84.181, or equivalent) @ 0.075 ± 0.020 μ	%	≥95	≥98	≥98	* Optional
4.	Splash Resistance/ Synthetic Blood Resistance ((ASTM F1862-07), or equivalent, e.g. ISO22609:2004 (EN))	mmHg	80	120	160	* PPE importers must present relevant documents and certification
5.	Test Bacterial Filtration Efficiency (EN14683, ASTM F2101, or equivalent)	%	≥95	≥98	≥98	

*** The alternate protocol/provision is allowed temporarily until test facilities are developed and established locally, as per proposed standard(s) .**

** Acceptance Quality Limit: AQL 4%

Report Template

Page 1:

- Client Info,
- Sample Info,
- Test Info,
- Results, etc.

Page 2:

- Minimum/Maximum Required values of DGDA/WHO-PAHO recommended test parameters

** Letter Head **

Ref. No.: Date:

Client Name: Client ID:

Client Address:

Sample Type: Gowns (Fluid Resistant) Batch No.:

Table 1: Parameter Analysis of Biomedical PPE – Gowns (Fluid Resistant)

Serial No.	Test parameter	Standard (as per DGDA/WHO-PAHO recommended parameters)	Unit	Result		Comment
				Average Value	Sample Number (n), ± St. Dev	
01.	Tensile Strength	ASTM D5034				
02.	Tear resistance	ASTM D5587(woven)				
03.	Seam Strength	ASTM D751				
04.	Water vapor transmission (breathability)	ISO 11092:2014(EN)				
05.	Water Resistance: Hydrostatic Test	AATC 127				
06.	Water Resistance: Impact Penetration Test	AATCC 42				

Result Analysis and Overall Comment:

Tests Performed by: **Countersigned by:**

XXYYZZ
Affiliation
Address

YYZZXX
Affiliation
Address

ZZXXYY
Affiliation
Address

Page 1

Disclaimer: Test was performed as per the samples were supplied (where applicable) and valid for exactly identical samples. Wherever applicable, XXYYZZ is not responsible for any error/omission occurred during the sampling by the client.

** Letter Head **

Personal Protective Equipment (PPE): Gowns (Fluid Resistant)

Table 2: List of Test Parameters with Recommended Values

Serial. No	Test Parameter	Unit	Minimum/Maximum Requirement (as per AAMI Standards)				Remarks
			Level 1 (minimal)	Level 2 (low)	Level 3 (moderate)	Level 4 (high)	
1.	Tensile Strength (ASTM D5034, ASTM D1682)	N	>30	>60	>100	>250	*For isolation gown Levels (1,2,3,4) ≥30N
2.	Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424)	N	>5	>10	>50	>100	*For isolation gown Levels (1,2,3,4) ≥10N
3.	Seam Strength (ASTM D751 (stretch woven or knit))	N	≥30	≥30	≥30	≥30	ASTM F3352-19 Ref: ASTM D1683/D1683M
4.	Water vapor transmission (breathability) (ISO 11092:2014(EN); ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75; or equivalent (ASTM E96/E96M-16*))	m^2Pa/W	-	-	<30 (for coveralls)	<30 (for coveralls)	ISO11092:2014(EN)
		mm/s	AP>100	5<AP<100	AP≤5	-	ASTM D737-75 Re: EN14058:2017(E)
5.	Water Resistance: Hydrostatic Test (AATCC 127; BS EN 13795:2019)	cm H_2O	N/A	>20	>50 (sterile)	>100 (sterile)	No data available for Level 1
					>57.3 (fluid resistant)	>91 (fluid resistant)	
6.	Water Resistance: Impact Penetration Test (AATCC 42 or equivalent (e.g., AATCC 35*))	g	<=4.5	<=1	<=1	<=1	No data available for Level 4. Emphasis given on breathability test
7.	Synthetic Blood Penetration Test (ASTM F1670 or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	* PPE importers must present relevant documents and certification
8.	Viral Penetration Test (ASTM F1671 or equivalent) *	Pass at Psi/Kpa	N/A	N/A	N/A	No penetration at 2 psi up to 1 hour	

Footnote: The above parameters were developed based on the WHO specifications for personal protective equipment as mentioned in the Disease Commodity Package for COVID-19, and as per expert consultations overseen by DGDA to accommodate critical test parameters during the COVID-19 emergency and current capacity of local accredited testing laboratories.

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Disclaimer: Test was performed as per the samples were supplied (where applicable) and valid for exactly identical samples. Wherever applicable, XXYYZZ is not responsible for any error/omission occurred during the sampling by the client.

Thank You !!

World Health Organization

Appendix

Sample of Product Specification Sheet

3M Science. Applied to Life.™

Technical Data Sheet

3M™ Protective Coverall 4570

The 3M™ Protective Coverall 4570 range of coveralls are designed to help protect against hazardous dusts (Type 5), light liquid splashes (Type 6), low pressure liquid sprays (Type 4) and high pressure liquid jets (Type 3).

Key Features

- Advanced film technology
- Soft material reducing noise from movement
- High levels of chemical hold out and mechanical strength
- Certified to offer protection against radioactive particulates (EN 1073-2) and biological contaminants (EN 14126)
- Anti-static treated (inside only) to EN 1149
- Elastic waist is adhered with glue to minimize potential entry points
- Elastic wrists and ankles for convenience and freedom of movement
- Thumb loops for secure fit during overhead work
- Three-panel hood design for a better fit and compatibility with other PPE
- Chin flap with easy grab sealable tape for ease of use and secure fit
- Two integrated storm-flaps combined with double color-coded zip to create a double seal for added convenience and extra protection
- Large ring-pull zippers for easy donning and doffing when wearing gloves
- Seams are taped with a multi layer co-extruded clear tape which offers a discreet finish and a consistent seal and barrier to hazardous dusts and high pressure liquid jets

Approvals

CE approved under PPE Directive (89/686/ECC), Category III
CE Certificate issue: BTTG Testing and Certification Limited, UK.
Notified Body Number: 0338
Article 11B Supervision: SGS United Kingdom Limited, UK
Notified Body Number: 0120

Comfort and Protection

	Liquid Protection	Type 3 & Type 4 (EN 14605) and Type 6 (EN 13034) Whole suit full and reduced spray test (EN ISO 17491-5)
	Dust Protection	Type 5 (EN ISO 13982-1) Inward Leakage results: Ljmn,82/90 < 30 %; L0,9/10 <15 %.
	Anti-static	Anti-static coating (EN 1149-5:2008)*
	Nuclear	Radioactive particulates (EN 1073-2:2002), Class 2
	Biohazard	Tested according to EN 14126:2003 (Type 5-B, Type 4-B, Type 3-B, Type 6-B) ASTM F1671:2013 ASTM F1670:2008

*All apparel must be suitably grounded for anti-static treatment to be effective. Electrostatic propensity may decrease with wearing time and/or severe conditions.

Materials

Suit	Polypropylene / Polyethylene
Zipper	Metal / Nylon / Polyester Braid
Elastic	Synthetic Rubber (non-latex)
Seam Tape	Polyethylene
Thread	Polyester / Cotton

This product does not contain components made from silicone or natural rubber latex.

Sizing

An appropriate size garment should be selected to allow sufficient movement for the task.

	Height		Chest	
S	64 – 67 in	164 – 170 cm	33 – 36 in	84 – 92 cm
M	68 – 69 in	167 – 175 cm	36 – 38 in	92 – 100 cm
L	68 – 71 in	174 – 181 cm	38 – 43 in	100 – 108 cm
XL	70 – 74 in	179 – 187 cm	43 – 45 in	108 – 115 cm
2XL	73 – 76 in	186 – 194 cm	45 – 49 in	115 – 124 cm
3XL	76 – 78 in	194 – 200 cm	49 – 52 in	124 – 132 cm
4XL	78 – 81 in	200 – 208 cm	52 – 55 in	132 – 140 cm

3M

ProClean® apparel for controlled environments

Our ProClean® brand includes four levels of protection for your controlled environment applications and non-hazardous general manufacturing apparel needs.

ProClean® 1
Bouffants and beard covers made from spunbond polypropylene fabric.

ProClean® 2
Garments and accessories such as frocks, lab coats, scrubs, sleeves, gowns, bouffants, hoods, beard covers, boot and shoe covers, and sterilization wraps made from a variety of high-quality fabrics.

ProClean® 3
Sterile procedure gowns made from spunbond meltblown spunbond (SMS) fabric with anti-static treatment.

ProClean® 6
Garments made from a microporous composite fabric offer improved non-hazardous light liquid splash protection.

Wide range of applications
DuPont™ ProClean® garments are used in the biotech, pharmaceutical, medical device manufacturing and electronics industries, as well as in other controlled environments. With a wide range of proven, science-based solutions, DuPont products help ensure superior protection for your business-critical systems, equipment and cleanrooms. ProClean® products may also be appropriate for non-hazardous general manufacturing applications.

Customer support—we're here to help
DuPont™ SafeSPEC™
Our powerful web-based tool can assist you with finding the appropriate DuPont garments for controlled environments.
safespec.dupont.com

Certified Industrial Hygienist team
A DuPont Certified Industrial Hygienist can conduct a job hazard assessment to help you determine the best DuPont garment for a specific hazard.

DUPONT

PRODUCT INFORMATION
cleo® saphir
Protective gown for use with cytostatic & biological substances

Application area and properties

+ **Maximum protection and comfort:** Type tested and certified as complex PPE[1] (category III); chemical protective type PB [4], protective clothing against infection type PB [4]-B, partial body protection. Optimal operator and product protection (sterile version); impervious to liquids on the arms and front, which are coated; raised neckline; breathable back, pleasant and comfortable to wear, material is low in lint with low particle generation and latex-free; practical velcro fastening in the neck area; knitted or elasticated cuffs at the sleeve ends.
+ **Area of application:** Protective gown for handling CMR[2] drugs (e.g. cytostatic and virostatic agents) and biological agents[11] (e.g. bacterial and viruses).
+ **Protective barrier:** Liquid-impervious coating. In compliance with EN 14126:2003 a high barrier function of the coated material against bacteria and viruses can be assumed.
+ **Protection capacity:** Protection from all CMR drugs or chemicals cannot be guaranteed! In case of exposition to biological hazardous materials, which do not correspond to the degree of imperviousness of the protective clothing, biocontamination of the wearer is possible.
+ **Directions for use:** Always wear with the coated side on the outside and the seam pointing downwards. Keep away from open flames and heat sources.
+ **Change interval:** Daily, i.e. use up to a maximum of 8 hours[4]; in case of visible contamination immediately! Single use only!
+ **Before use:** Check for any damage! Do not use damaged gowns!
+ **Disposal:** Waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in case of heavy contamination, waste requiring special supervision[5] (waste code: 18 01 08*[6] or 18 01 03*[7]) in accordance with 2000/532/EC); collect and dispose of waste separately!

1: Personal protective equipment. 2: Carcinogenic, mutagenic, toxic to reproduction. 3: Microorganisms, including genetically altered microorganisms, cell cultures and human endoparasites, which could cause infections or allergies or have toxic effects. 4: Dependent on the utilized chemicals / CMR drugs or biological materials. 5: Any waste marked with an asterisk (*) is considered hazardous waste pursuant to Article 1(4), first indent, of Directive 91/689/EEC on hazardous waste. 6: Cytotoxic and cytostatic drugs. 7: Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.

Types

Blue gown with knitted cuffs				
Size	S	M	L	XL
Item No. (non-sterile) 15 pieces	6700	6800	6900	100072 (10 pieces)
Item No. (sterile) 10 pieces	6701	6801	6901	100073

Light blue gown with elasticated cuffs				
Size	S	M	L	XL
Item No. (non-sterile) 15 pieces	-	6500	6550	-
Item No. (sterile) 10 pieces	-	6600	6650	-

Material properties

Material	Spun polypropylene
Material properties	Latex-free
Material weight	42 g/m²

Berner International GmbH
Werner-von-Siemens-Str. 19
D-25337 Elmshorn
Contact
Tel. +49 4121 4556-0
Fax. +49 4121 4556-20
Web
www.berner-safety.de
info@berner-safety.de
GB-12 0212 0.docx
Produced: A. Dobbig - Approved: T. Nörtel
Valid 13. Februar 2020

berner

BERNER

Test	EN 14683			ASTM F2100		
	Type I	Type II	Type IIR	Level 1	Level 2	Level 3
Bacterial filtration efficiency, %	≥95	≥98	≥98	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2 Pa/cm^2	<3.0 <29.4	<3.0 <29.4	<5.0 <49.0	<4.0 <39.2	<5.0 <49.0	<5.0 <49.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	Not Required	Not Required	Not Required	≥95	≥98	≥98
Splash Resistance/ Synthetic Blood Resistance, mmHg Pass Result	Not Required	Not Required	120 (16,0 kPa)	80	120	160
Flame Spread	Not Required	Not Required	Not Required	Class 1	Class 1	Class 1
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30	Not Required	Not Required	Not Required

- Level 1: *Minimal risk*, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit
- Level 2: *Low risk*, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab
- Level 3: *Moderate risk*, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases
- Level 4: *High risk*, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne)

MEDICAL FACE MASK TESTS AND REQUIREMENTS

U.S.A.: ASTM F2100-19 STANDARD SPECIFICATION FOR PERFORMANCE OF MATERIALS USED IN MEDICAL FACE MASKS
EUROPE: EN 14683:2019 MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

		ASTM F2100-19			EN 14683:2019 Barrier Levels		
		Level 1	Level 2	Level 3	Type I	Type II	Type IIR
Barrier Testing	BFE % ASTM F2101, EN 14683	≥95	≥98		≥95	≥98	
	PFE % ASTM F2299	≥95	≥98		Not required		
	Synthetic Blood ASTM F1862, ISO22609	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Not required		Pass at ≥ 16.0 kPa (>120 mmHg)
Physical Testing	Differential Pressure EN 14683	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2		<40 Pa/cm^2		<60 Pa/cm^2
Safety Testing	Flammability 16 CFR Part 1610	Class 1 (≥ 3.5 seconds)			See European Medical Directive (2007/47/EC, MDD 93/42/EEC)		
	Microbial Cleanliness ISO 11737-1	Not required			≤30 cfu/g		
	Biocompatibility ISO 10993	510 K Guidance recommends testing to ISO 10993			Complete an evaluation according to ISO 10993		
Sampling ANSI/ASQC Z1.4 ISO 2859-1		• AQL 4% for BFE, PFE, Delta P • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing) • 14 masks for Flammability			• Minimum of 5 masks up to an AQL of 4% for BFE, Delta P and Microbial Cleanliness • 32 masks for Synthetic Blood (Pass = ≥29 passing, Fail = ≤28 passing)		

Mask	Thickness mm	Weight gm/m^2	Pore Size µm		Synthetic Blood Resistance (% Passed)		
			Mean	Max.	80 mm Hg	120 mm Hg	160 mm Hg
1	0.3345	66.908	23.97	41.74	70	0	0
2	0.2339	58.657	19.29	43.27	100	100	50
3	0.4417	95.775	16.90	27.19	100	100	100
4	0.6137	140.828	35.06	87.74	0	0	0
5	0.3607	145.760	51.00	146.60	0	0	0
6	0.4742	164.405	31.72	92.12	0	0	0

WHICH MASK IS MORE EFFECTIVE?

Mask Rating & Certification Comparison

Mask Type	Standards	Filtration Effectiveness		
Single-Use Face Mask 	**China:** YY/T0969	3.0 Microns: ≥95% 0.1 Microns: ✗		
Surgical Mask 	**China:** YY 0469	3.0 Microns: ≥95% 0.1 Microns: ≥30%		
	USA: ASTM F2100	Level 1	Level 2	Level 3
		3.0 Microns: ≥95% 0.1 Microns: ≥95%	3.0 Microns: ≥98% 0.1 Microns: ≥98%	3.0 Microns: ≥98% 0.1 Microns: ≥98%
	Europe: EN 14683	Type I	Type II	Type III
		3.0 Microns: ≥95% 0.1 Microns: ✗	3.0 Microns: ≥98% 0.1 Microns: ✗	3.0 Microns: ≥98% 0.1 Microns: ✗
Respirator Mask 	**USA:** NIOSH (42 CFR 84) **China:** GB2626	N95 / KN95	N99 / KN99	N100 / KN100
		0.3 Microns: ≥95%	0.3 Microns ≥99%	0.3 Microns ≥99.97%
	Europe: EN 149:2001	FFP1	FFP2	FFP3
		0.3 Microns: ≥80%	0.3 Microns: ≥94%	0.3 Microns: 99%

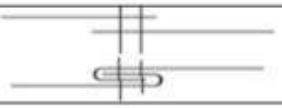
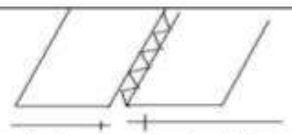
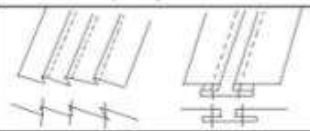
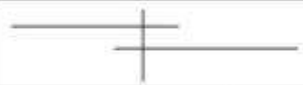
3.0 Microns: Bacteria Filtration Efficiency standard (BFE).

0.1 Microns: Particle Filtration Efficiency standard (PFE).

0.3 Microns: Used to represent the most-penetrating particle size (MPPS), which is the most difficult size particle to capture.

✗: No requirements.

https://smartairfilters.com/en/blog/comparison-mask-standards-rating-effectiveness/

Seam Types	Schematic view	Properties	End Uses
Seam Class-1: **Superimposed Seam**		Edge are placed one over another & sewing is done alongside of edge.	Top side of the garments
Seam Class-2: **Lapped Seam**		Sewing is done on overlapping portion.	Lungi, side seam & inseam of jeans.
Seam Class-3: **Bound Seam**		Edge of the fabric is bound by another stripe of fabric.	Decorative purpose, to sewn the part of garments such as waist band, pocket etc.
Seam Class-4: **Flat Seam**		Edges are placed in side by side & sewing them.	Cut & sew garments also called Raglan seam.
Seam Class-5: **Decorative Seam**		One or more adjacent stitch lines in one or more layer of fabrics then stitching.	Decorative purpose.
Seam Class-6: **Edge Neatening Seam**		Binding the edge of the fabrics, so that yarn cannot be drowning off.	Mostly used in knitted garments hemming.
Seam Class-7		For attaching the additional part of garments.	Lace, elastic joining etc.

AAMI Classification System

- **There are four levels of barrier performance, level 4 being the highest protection available**

Least Protective

Most Protective

Level	Test	Result
1	AATCC 42 Water Impact (WI)	≤ 4.5 g
2	AATCC 42, WI AATCC 127 Hydro Head (HH)	≤ 1.0 g ≥ 20 cm
3	AATCC 42, WI AATCC 127, HH	≤ 1.0 g ≥ 50 cm
4	ASTM F1671, Gowns ASTM F1670, Drapes	Pass Pass

- AAMI - Association for the Advancement of Medical Instrumentation

EN 14126:2003

Protective clothing against infective agents

- This standard is used to demonstrate the performance of protective garments against infective agents. This is not a 'stand-alone' standard and needs to be combined with standards for Type 1, 2, 3, 4, 5 and/or 6 protective garments, as listed in Clause 4.3, Table 5. Types 1, 2 and 5 protective garments are required to be of the 'full body' type. Type 3, 4 and 6 protective garment standards include partial body 'PB' garments covering only a part of the body.

- The type of protective garment claimed will be relative to the type and severity of protection claimed for the garment

Suit type	Standard	PB Option	Common Suit Name
1	EN 943-1:2015	No	Gas tight
1ET	EN 943-2:2002	No	Gas tight
2	EN 943-1:2002	No	Ventilated (PPE annex II approval only)
3	EN 14605:2005+A1:2009	Yes	Jet or splash tight
4	EN 14605:2005+A1:2009	Yes	Spray or light splash tight
5	EN ISO 13982-1:2004+A1:2010	No	Dust tight
6	EN 13034:2005+A1:2009	Yes	Light spray tight
1-6	ISO 16602:2007+A1:2012	Yes (3, 4 & 6 only)	As above for type (PPE annex II approval only)

- Other products that may be combined with EN 14126 but are not listed in Clause 4.3, Table 5, are:.

Product type	Standard	Common name
Powered filtering devices incorporating a hood, half-suit or suit	EN 12941:1998+A2:2008	PAPR hood, half-suit or suit
Airline breathing apparatus incorporating a hood, half-suit or suit	EN 14594:2005	Air hood, half-suit or suit
Ventilated protective clothing	EN 1073-1:2016	Nuclear air suit
Non-ventilated protective clothing	EN 1073-2:2002	Nuclear coverall

- Manufacturers should not be confused by the term chemical protective suit for the above types of protective garment. In order to comply with the requirements of EN 14126, Clause 4.3, the garment has to be marked with the type e.g. Type PB[4]-B. By marking the protective garment with the type, this infers that it complies with all of the applicable requirements of the protective garment standard, including the requirements for material properties

- The following tests are performed in addition the tests identified in EN 14126:
  - Abrasion resistance EN 530 method 2 - Minimum Class 1
  - Flex cracking resistance ISO 7854 method B - Minimum Class 1
  - Flex cracking resistance at -30°C ISO 7854 method B - Minimum Class 1 (Optional)
  - Tear resistance (trapezoidal test specimen) ISO 9073-4 – Minimum Class 1
  - Tensile strength ISO 13934-1 - Minimum Class 1
  - Puncture resistance EN 863 - Minimum Class 1
  - Seam strength ISO 13935-2 - Minimum Class 1
  - Type 3 Jet test EN17491-3
  - Type PB[3] Jet test EN17491-3 (seams, joins and assemblages only)
  - Type 4 Spray test EN17491-4
  - Type PB[4] Spray test EN17491-4 – This is specifically excluded in EN 14605, Clause 4.3.4.1, however manufacturers may optionally carry out this test to verify the spray tightness of the partial body garment seams
  - Permeation resistance of the material and seams to any claimed chemicals or pharmaceuticals is tested using EN 16523-1:2015 or EN ISO 6529, Method A or B ├ Minimum Class 1

- Level 1: *Minimal risk*, to be used, for example, during basic care, standard isolation, cover gown for visitors, or in a standard medical unit
- Level 2: *Low risk*, to be used, for example, during blood draw, suturing, in the Intensive Care Unit (ICU), or a pathology lab
- Level 3: *Moderate risk*, to be used, for example, during arterial blood draw, inserting an Intravenous (IV) line, in the Emergency Room, or for trauma cases
- Level 4: *High risk*, to be used, for example, during long, fluid intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne)

EN 13034:2005+A1:2009

Protective clothing against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)

- Type 6 chemical protective clothing for limited resistance to penetration by liquids shall pass the low level spray test, and shall have materials that demonstrate liquid penetration resistance and repellency.
- Partial body protection garments offer protection to specific parts of the body against liquid chemicals. Examples of such garments are laboratory coats, jackets, trousers, aprons, sleeves, hoods (not air supplied), etc. As partial body protection leaves some parts of the body unprotected, only the performance requirements for the clothing material and the seams are required.
- The following tests are performed in addition the tests identified in EN 14126:
  - Abrasion resistance EN 530 method 2 - Minimum Class 1
  - Tear resistance (trapezoidal test specimen) ISO 9073-4 – Minimum Class 1
  - Tensile strength ISO 13934-1 - Minimum Class 1
  - Puncture resistance EN 863 - Minimum Class 1
  - Seam strength ISO 13935-2 - Minimum Class 1
  - Type 6 Modified low level spray test EN17491-4
  - Type PB[6] Modified low level spray test EN17491-4 – This is specifically excluded in EN 13034, Clause 5.1, however manufacturers may optionally carry out this test to verify the spray tightness of the partial body garment seams.
  - For claimed chemical protection, liquid repellency EN ISO 6530:2005 – Minimum Class 3 and resistance to penetration by liquids EN ISO 6530:2005 - Minimum Class 2 shall be obtained for at least one of the chemicals referred to in EN 14325:2004, Clause 4, table 9.
  - Additional Permeation resistance of the material and seams to any claimed chemicals or pharmaceuticals may be provided from testing using EN 16523-1:2015 or EN ISO 6529, Method A or B

DIFFERENTIATION	AAMI	EUROPEAN NORMS 13795
Resistance to liquid penetration (water)	AAMI differentiates 4 barrier performance levels based on fluid impermeability Level 1-minimal Level 2-low Level 3-moderate Level 4-high	YES
Resistance to microbial penetration (dry,wet)	_	YES
Cleanliness(microbial, particulate matter) linting	_	YES
Tensile strength (dry,wet)	_	YES
Bursting strength (dry,wet)	_	YES
Specifications of the performance levels	Labelling requirements and test methods	Technical data sheets according to DIN EN 13795

A) ANSI/AAMI PB70

Rank	Test	Criteria
Level 1	AATCC 42	< = 4.5 g
Level 2	AATCC 42	< = 1.0 g
	AATCC 127	> = 20 cm (1.96 kPa)
Level 3	AATCC 42	< = 1.0 g
	AATCC 127	> = 50 cm (4.90 kPa)
Level 4	ASTM F1670	pass 2 psi (13.8 kPa)
	ASTM F1671	pass 2 psi (13.8 kPa)

B) EN 14126:2003

Rank	Test	Criteria
Class 1	ISO 16603 & 16604	0 kPa
Class 2	ISO 16603 & 16604	1.75 kPa
Class 3	ISO 16603 & 16604	3.5 kPa
Class 4	ISO 16603 & 16604	7.0 kPa
Class 5	ISO 16603 & 16604	14.0 kPa
Class 6	ISO 16603 & 16604	20.0 kPa

https://doi.org/10.1371/journal.pone.0211827.t001

ANSI/AAMI PB70 Barrier Performance	Test Method	Test Definition	Requirement
Level 1	Water Resistance: Impact Penetration **AATCC 42**	**AATCC 42** Measures the resistance of fabrics to the liquid penetration of water by impact.	Water Impact </= 4.5 g
Level 2	Water Resistance: Impact Penetration **AATCC 42** Water Resistance: Hydrostatic Pressure **AATCC 127**	**AATCC 42** Measures the resistance of fabrics to the liquid penetration of water by impact. **AATCC 127** Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Spray Impact </= 1.0 g Hydrostatic Pressure >/= 20 cm
Level 3	Water Resistance: Impact Penetration **AATCC 42** Water Resistance: Hydrostatic Pressure **AATCC 127**	**AATCC 42** Measures the resistance of fabrics to the liquid penetration of water by impact. **AATCC 127** Measures the resistance of fabrics to the liquid penetration of water by impact under constant and increasing hydrostatic pressure.	Spray Impact </= 1.0 g Hydrostatic Pressure >/= 50 cm
Level 4	Viral Penetration **ASTM F1671**	**ASTM F1671** Measures the resistance of fabrics to bloodborne pathogens using viral penetration at 2psi and ambient pressure.	Total Impervious

Levels of Barrier Protection – AAMI PB70:2012[1]

Choose the right gown by matching the color on the neck binding to the AAMI level on the chart.

	LEVEL 1	LEVEL 2		LEVEL 3	
Test	AATCC 42:2000	AATCC 42:2000	AATCC 127:1998	AATCC 42:2000	AATCC 127:1998
Requirements at 4% AQL	Water impact ≤ 4.5 g	Spray impact ≤ 1.0 g	Hydrostatic Pressure ≥ 20 cm	Spray Impact ≤ 1.0 g	Hydrostatic pressure ≥ 50 cm
Anticipated Risk of Exposure	Low	Moderate		Moderate to High	

A) ANSI/AAMI PB70

Rank	Test	Criteria
Level 1	AATCC 42	< = 4.5 g
Level 2	AATCC 42	< = 1.0 g
	AATCC 127	> = 20 cm (1.96 kPa)
Level 3	AATCC 42	< = 1.0 g
	AATCC 127	> = 50 cm (4.90 kPa)
Level 4	ASTM F1670	pass 2 psi (13.8 kPa)
	ASTM F1671	pass 2 psi (13.8 kPa)

B) EN 14126:2003

Rank	Test	Criteria
Class 1	ISO 16603 & 16604	0 kPa
Class 2	ISO 16603 & 16604	1.75 kPa
Class 3	ISO 16603 & 16604	3.5 kPa
Class 4	ISO 16603 & 16604	7.0 kPa
Class 5	ISO 16603 & 16604	14.0 kPa
Class 6	ISO 16603 & 16604	20.0 kPa

https://doi.org/10.1371/journal.pone.0211827.t001

Level	Test	Result	AQL
1	AATCC 42 (Spray Impact Test)	≤ 4.5 g.	4%
2	AATCC 42	≤ 1.0 g	4%
	AATCC 127 (Hydrostatic Head Test)	≥ 20cm	4%
3	AATCC 42	≤ 1.0 g	4%
	AATCC 127	≥ 50cm	4%
4	ASTM F1670 *(Synthetic Blood Test for Drapes and Drape Accessories Only)*	Pass	4%
	ASTM F1671 *(Bacteriophage Test for Surgical Gowns and Other Protective Apparel)*	Pass	4%

[1]The maximum number of defects per hundred units that, for purposes of inspection, can be considered satisfactory as a process average

Level 1 – least protective; Level 4 – most protective; AQL = Acceptable Quality Level

– AATCC 42 – Spray Impact Penetration Test (amount of water that penetrates test fabric and soaks into blotter on the other side is weighed by grams). **The lower the better**

– AATCC 127 – Hydrostatic Pressure Test (the amount of pressure required to force the water through the fabric is measured in centimeter (cm of water pressure). **The higher the force in cm the better**

– ASTM F1670 – Penetration by synthetic blood (for surgical drapes)

– ASTM F1671 – Penetration by blood borne pathogens using Phi-X174 bacteriophage virus (in 0.0017µm – smaller than HIV, HBV…)

Criteria for Isolation Gowns:

1- Coverage

2- Filtration efficiency (BFE, VFE)

3- Fuild barrier adequecy

4- Comfort

5- Removable without shelf-contamination

6- Single-use

7-Adequate supply always available

Source: CDC, Infection Control Today

Ref: https://8m2umc.wordpress.com/2014/08/25/isolation-gown-construction/