

Testing parameters to be performed for Gowns, Coveralls, Surgical Mask and Respirator: N95 Mask and KN95 Mask

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 ² Pa/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 ₂ O	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

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)	
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 ₂ O/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 ₂ O/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%.

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

Biosafety Level

- **Biosafety Level 1 (BSL 1) :**
 - **i) Work with agents with Little Potential Hazard to lab personnel and the environment**
 - **ii) Using Fume Hoods and Biosafety Cabinets are preferred**
 - **iii) Contaminated samples need to be disposed**
 - **iv) similar to a high school biology lab**
- **Biosafety Level 2 (BSL 2) :**
 - **i) Work with agents with Moderate Potential Hazard to lab personnel and the environment**
 - **ii) 100% air filtration required**
 - **iii) Contaminated samples need to be disposed**
 - **iv) Access to the laboratory is limited to the trained personnel.**
- **Biosafety Level 3 (BSL 3) :**
 - **i) BSL 3 is required to work on Infectious Disease Research**
 - **ii-iv) BSL2 requirements**
 - **v) Continuous Power supply.**
- **Biosafety Level 4 (BSL 4) :**
 - **i) Work with Dangerous Agents that pose a high risk of Aerosol Transmitted Infections**
 - **ii-v) BSL 3 requirements.**

Directorate General of Drug Administration (DGDA) enlisted Laboratory testing capability of Gowns, Coveralls, Surgical Mask and Respirator: N95 Mask and KN95 Mask

Gowns and Coveralls:

Serial. No	Test Parameter	Available Facilities						
		ULVS Bangladesh Ltd	TUV SUD Bangladesh (pvt) Ltd.	ITS Labtest Bangladesh Ltd	Dysin International Ltd	SGS Bangladesh Ltd	TÜV Rheinland Bangladesh Pvt. Ltd.	Geo Chem Consumer Products Services (CPS) Ltd.
1.	Tensile Strength (ASTM D5034, ASTM D1682)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2.	Tear resistance (ASTM D5587(woven), ASTM D5587 (nonwoven), ASTM D1424)	Yes	Yes	Yes	Yes	Yes	Yes	Yes
3.	Seam Strength (ASTM D751 (stretch woven or knit))	No	Yes	Yes	Yes	Yes	Yes	Yes
4.	Water vapor transmission (breathability) (ISO 11092:2014(EN); ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75; or equivalent	No	Yes <u>Overseas Testing</u>	Yes	No	Yes	Yes <u>Overseas Testing</u>	Yes
5.	Water Resistance: Hydrostatic Test (AATCC 127; BS EN 13795:2019)	Yes	Yes <u>Overseas Testing</u>	Yes	Yes	Yes	Yes	Yes
6.	Water Resistance: Impact Penetration Test (AATCC 42 or equivalent (e.g., <u>AATCC 35*</u>))	Yes	Yes	Yes	Yes	Yes	Yes	Yes
7.	Synthetic Blood Penetration Test (ASTM F1670 or equivalent) *	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
8.	Viral Penetration Test (ASTM F1671 or equivalent) *	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>

Surgical Mask:

Serial. No	Test Parameter	Available Facilities						
		ULVS Bangladesh Ltd	TUV SUD Bangladesh (pvt) Ltd.	ITS Labtest Bangladesh Ltd	Dysin International Ltd	SGS Bangladesh Ltd	TÜV Rheinland Bangladesh Pvt. Ltd.	Geo Chem Consumer Products Services (CPS) Ltd.
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, or equivalent)	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes (Conjunction from AIRY Equipment & Services)	Yes	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
2.	Particulate Filtration Efficiency (F2299, or equivalent) @ 0.1 µ, <u>0.3 µ</u> *	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes (Conjunction from AIRY Equipment & Services)	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
3.	Splash Resistance/ Synthetic Blood Resistance ((ASTM F1862-07), or equivalent)	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
4.	Test Bacterial Filtration Efficiency (EN14683, ASTM F2101, or equivalent)	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>

Respirator: N95 Mask and KN95 Mask:

Serial. No	Test Parameter	Available Facilities						
		ULVS Bangladesh Ltd	TUV SUD Bangladesh (pvt) Ltd.	ITS Labtest Bangladesh Ltd	Dysin International Ltd	SGS Bangladesh Ltd	TÜV Rheinland Bangladesh Pvt. Ltd.	Geo Chem Consumer Products Services (CPS) Ltd.
1.	Breathing Resistance, Differential Pressure (EN 14683:2019, ASTM F2100, or equivalent)	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes (Conjunction from AIRY Equipment & Services)	Yes	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
2.	Particulate Filtration Efficiency (F2299, or equivalent) @ 0.1 μ , 0.3 μ *	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes (Conjunction from AIRY Equipment & Services)	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
3.	Particulate Filtration Efficiency (NIOSH 42 CFR 84.181, or equivalent) @ 0.075 \pm 0.020 μ	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
4.	Splash Resistance/ Synthetic Blood Resistance ((ASTM F1862-07), or equivalent, e.g. ISO22609:2004 (EN))	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>
5.	Test Bacterial Filtration Efficiency (EN14683, ASTM F2101, or equivalent)	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	No	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>	Yes <u>Overseas Testing</u>

Directorate General of Drug Administration (DGDA) acknowledges the contributions of WHO, USAID, JAICA, BUET, ICDDR,B and experts from local and International testing and inspection firms who participated in the discussions leading to the establishment of these minimum standards.