

Bacterial filtration efficiency test report

Customer Name and Address Information:

Vira Teb Termeh Negar Company
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Test Place Name and Address Information:

KiaNanoBioVista laboratory
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Reference Standards and Conformity Methods:

- ASTM F2101-19 "Evaluation the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus*"
- ISO 6138-1399 "single-use face masks for use in health care-requirements and test methods"
- BS EN 14683:2019+AC-Annex B "Medical face masks – Requirements and test methods"
- ASTM F2100-11:2018 "Standard specification for performance of materials used in medical face masks"

Time Schedule:

Sample receiving date:	29/08/2022	Start test date:	29/08/2022
End test date:	05/09/2022	Issue date:	06/09/2022

Sample Identification:

Name:	Disposable Protective Clothing (Tamam Ghad)		
Manufacturer:	Vira Teb Termeh Negar Company - Iran		
Sterilization method:	-		
Sample Lab code:	N010606-29-01	Case Lab number:	0106-0020
Manufacturing Date:	16/08/2022	Expiry date:	16/08/2025
LOT Number:	-	REF Number:	EP60

Test Summary Report:

Test type	Test method	Test results
Medical Mask bacterial filtration efficiency	ASTM F2101 BS EN 14683: 2019	Normal BFE ≥98.504%

KNB
KiaNanoBioVista
Sajjad Mohammadi
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Acceptance criteria:

- The test conditions will be satisfied if no bacterial challenge counted during the collection of the negative control.
- The test conditions will be satisfied if approximately 1700-3000 CFU counted during the collection of positive controls.
- The mean particle size (MPS) in the bacterial challenge should be maintained at $3.0 \pm 0.3 \mu\text{m}$.
- The sample will be approved if bacteria filtration efficiency comply with the criteria given below:

Table1- The pharmaceutical criteria for bacteria filtration efficiency (BFE %)

	Example of applications	BFE %
level 1	For general purpose medical procedures, where the wearer is not at risk of blood or body fluid splash or to protect staff and/or the patient from droplet exposure to microorganisms (e.g. patient with upper respiratory tract infection visits general practitioner)	≥ 95
level 2	For use in emergency departments, dentistry, changing dressings on small wounds where minimal blood droplet exposure may possible occur (e.g. endoscopy procedures)	≥ 98
level 3	For all surgical procedures, major trauma first aid or in any area where the health care worker is at risk of blood or body fluid splash (e.g. orthopedic, cardiovascular procedures)	≥ 98

Results:

The percent bacteria filtration efficiency and standard deviation are shown in table2.

Table2- microorganisms counted (CFU) in samples and controls

	Samples					Positive Controls		Negative Control
	No.1	No.2	No.3	No.4	No.5	No.1	No. 2	
Cascade 1	7	8	8	6	9	385	372	0 CFU
Cascade 2	6	7	7	7	6	372	340	0 CFU
Cascade 3	5	5	6	5	7	363	338	0 CFU
Cascade 4	4	6	5	4	2	340	322	0 CFU
Cascade 5	1	4	3	2	2	323	305	0 CFU
Cascade 6	2	0	0	1	0	288	262	0 CFU
Total	23	24	26	22	24	2071	1939	0
BFE %	98.753	98.504	98.554	98.753	98.703	-	-	-
Average	98.653					2005		0
Mean particle size (MPS): 3.3µm								

Expanded uncertainty= ± 0.31 % Reading *Expanded uncertainty: An interval about the measurement result that encompasses 95% of probability density function of measurement result.

Conclusion:

On the basis of the results, interpreted according to ASTM F2101 the test sample `` Disposable Protective Clothing (Tamam Ghad) Model 60EP - Vira Teb Termeh Negar Company `` had a **Normal Bacteria Filtration Efficiency** and satisfied the requirements of the test.

Record filing:

The study program and all raw data will be retained in Kiananobiovista Lab archives for a period of 10 years from the issue of the final report. An original copy of the report is available at Kiananobiovista Lab.

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