

Laboratory # 889967-22 Prescient-X

## BACTERIA FILTRATION EFFICIENCY

The results of this test are detailed in the report from GAP Labs, under GAP Project Number: A15692-3226, which is attached below.

**REMARKS:** The bacterial filtration efficiency results were found to satisfy the requirements of FDA/NIOSH MOU 225-18-006 with a filtration efficiency of  $\geq$ 98%.



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Date: 21-Jun-22	GAP Project Number: A15692-3226					
Report to:						
	Cambridge Materials Testing Ltd.					
	Attn: Rany El-Roz					
	13-6991 Millcreek Drive					
	Mississauga, ON L5N 6B9					
	Tel: 905-812-3856 Fax:					
En	Email: ranyel-roz@cambridgematerials.com					
GAP Sample Number	: 3226					
Test Article	889967					
Received Date	: 15-Jun-22					
Test Date	: 16-Jun-22					
Challenge Microbe: Staphylococcus aureus ATCC 6538						
Test Side	Thicker side facing challenge.					
Area Tested	: ~38.5 cm <sup>2</sup>					
Flow Rate	: 28.3 LPM					
Test Article Conditioning	: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours					

ASTM F2101-19: Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using Biological Aerosol of Staphylococcus aureus

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101 to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of *S. aureus* was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of  $1.7 \times 10^3 - 3.0 \times 10^3$  colony forming units (CFU) per test article with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu$ m. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Level (Positive Control): 2.2x10^3 CFU Mean Particle Size of Challenge: 3.1 μm Negative Control Count: <1 CFU

Results:

Test Article	Total CFU Recovered	Bacterial Filtration Efficiency (%)	
1	2	99.9%	
2	<1	>99.9%	
3	1	>99.9%	
4	<1	>99.9%	
5	<1	>99.9%	



1 of 3

GAP EnviroMicorbial Services Ltd. E\GAP QUALITY SYSTEM\Forms QM\GAP-F-152 - Bacterial Filtration Efficienty (BFE) Final Report-3.xlsx



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I	Date: 21-Jun-22	GAP Project Number: A15692-3226			
Where:	C = Challenge Level T = Total CFU reco	$\% BFE = \frac{C - T}{C} \times 100$			
$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6}$					
Where:	Cx = raw count (on	cut-off diameter for the x <sup>th</sup> stage as indicated by the manufacturer stages 1 and 2) or the "probable hit" count determined using the positive art from the cascade impactor manual (for stages 3 through 6) on the x <sup>th</sup>			
Notes:					

If you have any questions regarding the analysis pleae do not hesitate to contact the lab anytime at (519) 681-0571

Reported By: Shawn Hess Position: Analyst

Manager Approval: Shawn Verhoeven Position: Technical Manager

Signature: \_\_\_\_\_

Signature: <u>LUer</u>

These test results relate only to the samples submitted and the analyses requested. This test report cannot be reproduced except in full, without written permission from GAP.





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GAP Project Number: A15692-3226

## Appendix

Table 1: Raw counts from each stage of the 6 stage cascade air sampler as required in ASTM F2101 Section 14.8. The numbers presented for stage 1 and 2 represent the total bacterial colonies present and stages 3 through 6 represent a "positive-hole" count. For stages 3 through 6, the air flow through the impactor follows the jet pattern produced by the 400-holes present in these stages. As a result, the count must be corrected using a positive hole correction table based on the principle where the chance of a viable cell/particle impacting in a new, unoccupied, "jet" hole decreases as the total viable particles increase.

Stage Number	Test Article				
	1	2	3	4	5
1 - Raw Count	0	0	0	0	0
2 - Raw Count	0	0	1	0	0
3 - Positive Hole	0	0	0	0	0
4 - Positive Hole	2	0	0	0	0
5 - Positive Hole	0	0	0	0	0
6 - Positive Hole	0	0	0	0	0

Table 2: Counts obtained from each stage,	including the "po	ositive-hole" corre	ection for stages 3 thorugh 6
Table 21 counts obtained from cach stage,	mendaning ene pe	opicitie note conte	control stages o choragh o

Stage Number	Test Article				
	1	2	3	4	5
1 - Raw Count	0	0	0	0	0
2 - Raw Count	0	0	1	0	0
3 - Positive Hole	0	0	0	0	0
4 - Positive Hole	2	0	0	0	0
5 - Positive Hole	0	0	0	0	0
6 - Positive Hole	0	0	0	0	0

