Cambridge
materials testing limited

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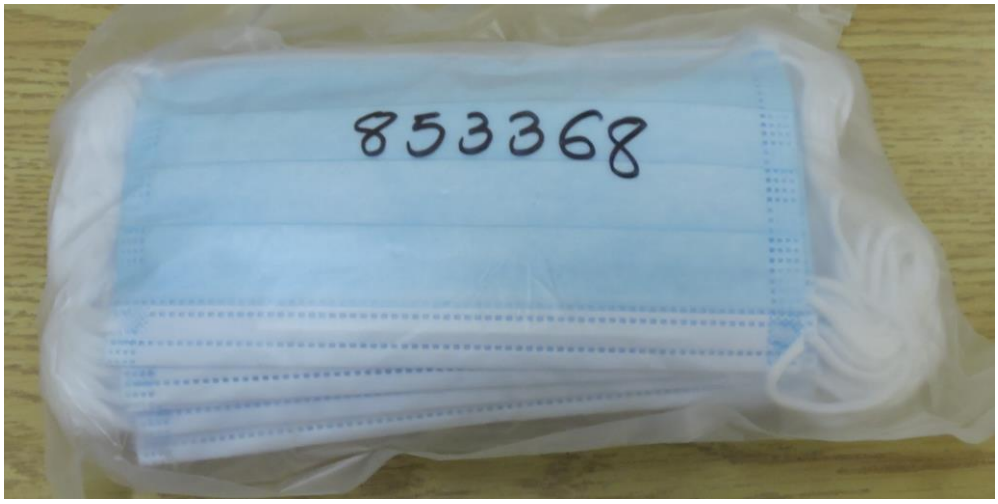
Report For:	Canadian Guardians 505 Apple Creek Boulevard, Unit #4 Markham, Ontario L3R 5B1 Phone: 647-808-6308 Email: kleung@canadianguardians.com management@venturesolutionscorp.ca	**Laboratory #:** **Report Date:** **Received Date:**	853368-21 REVISED January 15, 2021 January 11, 2021
Attention:	Kei Leung/Jennifer Shen		
Specimen:	#1: Face mask-202006		

TEST REPORT

One specimen, consisting of face masks, was submitted to be tested for synthetic blood penetration to determine acceptability with level barrier classification under ASTM F2100-19 requirements as well as Bacterial Filtration Efficiency, Differential Pressure, Particle Filtration Efficiency and Flame Spread, which were previously tested under Laboratory Number 850550-20.



Revision: Results for Bacterial Filtration Efficiency, Differential Pressure, Particle Filtration Efficiency and Flame Spread, represented by Laboratory Number 850550-20, were added to this report.
Revision Date: January 15, 2021

Cambridge Materials Testing Limited

Per Stwe Brown
Authorized By Stephen Brown

Per Anamaria Rojas Pineda.
Technician, Anamaria Rojas-Pineda

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Medical Face Mask Material Requirements

Characteristic	**Level 1 Barrier**	**Level 2 Barrier**	**Level 3 Barrier**	**Summary Results**
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	**Pass Any Level[1]**
Differential Pressure, mm H_2O/cm^2	<5.0	<6.0	<6.0	**Pass Any Level[2]**
Sub-Micron Particulate Filtration Efficiency at 0.1 micron, %	≥95	≥98	≥98	**Pass Any Level[3]**
Synthetic Blood Penetration minimum pressure in mmHg for pass result	80	120	160	**Pass Level 3**
Flame Spread	Class 1	Class 1	Class 1	**Pass Any Level[4]**
OVERALL PERFORMANCE LEVEL	**Complete – Level 3**			

[1]Note: Results for Bacterial Filtration Efficiency are represented by Laboratory Number 850550-C-20.

[2]Note: Results for Differential Pressure are represented by Laboratory Number 850550-B-20.

[3]Note: Results for Particle Filtration Efficiency are represented by Laboratory Number 850550-D-20.

[4]Note: Results for Flame Spread are represented by Laboratory Number 850550-E-20.

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SYNTHETIC BLOOD PENETRATION
ASTM F1862/F1862M-17 at 160 mmHg pressure

RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens	**FINAL RESULT**
1	160	32	31	**Pass for Level 3**

Note: Acceptable Quality Limit of 4.0% is met for single sampling plan when 29 or more of the 32 tested specimens show pass results.

Material construction type	Not provided / unknown
Supplier	Canadian Guardians
Lot number	Not provided/unknown
Date of receipt	January 11, 2021
Date of test	January 14, 2021
Fluid velocity (cm/s)	638
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	Outside Blue ripple area
Distance from tip cannula to mask (in)	12
Technique to enhance visual detection	Cotton swab used to lightly daub on the inside surface
Conditioning parameters	21±5°C, 85±5% R.H for minimum of 4 hours

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BACTERIAL FILTRATION EFFICIENCY

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 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 $x10^3$ – $3.0x10^3$ colony forming units (CFU) per test article with a mean particle size of 3.0 ± 0.3 µm. 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 Microbe: *Staphylococcus aureus* ATCC 6538
Test Side: User side facing challenge
Area Tested: ~38.5 cm^2
Flow Rate: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level: 1.7x 10^3 CFU
Mean Particle Size: 2.9 µm

Requirements ASTM F2100-19:
Bacterial filtration efficiency (%)
Level 1 Barrier: ≥95
Level 2 Barrier: ≥98
Level 3 Barrier: ≥98

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	<1	>99.9	Pass	**Pass any Level**
1-2	1	99.9	Pass	
1-3	1	99.9	Pass	

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU recovered downstream of test article

Note: Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E1P5

Note: Results for BFE are represented by Laboratory Number 850550-C-20.

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FLAME SPREAD

The specimen, consisting of 5 masks, was tested in accordance to 16 CFR 1610 (1-1-16 Edition).

	Specimen #	RESULT	CONCLUSION
Specimen #1	1-1	IBE	**Classified as Class 1 Pass any Level**
	1-2	IBE	
	1-3	IBE	
	1-4	IBE	
	1-5	IBE	

IBE: Ignited but extinguished

Test: Flame Resistance 45˚ angle test. One-Second Flame Impingement.
Type of fabric: Without a raised fiber surface
Surface tested: Face
Type of test: Original State
Direction tested: Length
Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator
Requirements: The flame spread time for textile products without a raised fibre surface must be greater than 3.5 seconds.

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.

Note: Results for Flame Spread are represented by Laboratory Number 850550-E-20.

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DIFFERENTIAL PRESSURE

EN 14683:2019 edition Annex C
Each specimen was conditioned for 4 hours minimum at 21+/-5 C and 85+/-5 % R.H.
Requirements ASTM F2100-19:
Differential Pressure (mmH_2O/cm^2)
Level 1 Barrier: <5.0
Level 2 Barrier: <6.0
Level 3 Barrier: <6.0

RESULTS

Specimen ID	Area ID	Differential Pressure ($mmH2O/cm^2$)	Specimen Pass/Fail	FINAL RESULT
1-1	1	3.0	Pass	Pass any Level
	2	3.0		
	3	2.8		
	4	3.9		
	5	3.0		
	AVERAGE	3.2		
1-2	1	2.9	Pass	
	2	3.0		
	3	3.0		
	4	2.9		
	5	3.4		
	AVERAGE	3.0		
1-3	1	3.4	Pass	
	2	3.0		
	3	2.9		
	4	2.9		
	5	3.0		
	AVERAGE	3.0		
1-4	1	2.9	Pass	
	2	3.1		
	3	3.2		
	4	2.6		
	5	3.0		
	AVERAGE	3.0		
1-5	1	3.1	Pass	
	2	3.0		
	3	3.5		
	4	3.4		
	5	3.5		
	AVERAGE	3.3		

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm^2)
Air Flow Rate: 8 L/min
Mask Location Specimen taken from: 5 Areas from each specimen distributed all surface wide
Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.
Note: Results for Differential Pressure are represented by Laboratory Number 850550-B-20.

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PARTICLE FILTRATION EFFICIENCY

Particles: Monodispersed polystyrene latex spheres (PSL)
Particles Counter: TSI scanning mobility particle sizer spectrometer 3082 and CPC
Tested as per ASTM F2299, non-neutralized aerosol challenge measured over 3 minutes (test specimen / control counts before and after test specimen and averaged)

Test Side: Inside
Area Tested: 21.7 cm2
Particle Size: 0.1 µm
Laboratory Conditions: 23°C, 38% relative humidity (RH)

Requirements ASTM F2100-19:
Particle filtration efficiency at 0.1 micron (%)
Level 1 Barrier: ≥95
Level 2 Barrier: ≥98
Level 3 Barrier: ≥98

RESULTS

Specimen #	Specimen Counts	Average Control Counts	Filtration Efficiency (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	200,156	1,259	99	Pass	**Pass any Level**
1-2	200,366	2,315	99	Pass	
1-3	203,529	2,258	99	Pass	
1-4	218,163	1,833	99	Pass	
1-5	204,421	1,517	99	Pass	

Note: The PFE equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON, M5T 1R4.

Note: Results for Particle Filtration Efficiency are represented by Laboratory Number 850550-D-20.

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Aiming the best "Quality" – Services & Solutions

Commissioning Report for
ISO 8 Cleanroom
Testing & Certification

CLIENT: CANADIAN GUARDIAN INC.

SITE LOCATION: 505 APPLE CREEK BLVD
UNIT#4, MARKHAM ON

Document Number: PROJECT#21014

Document Version: R0

Date: 20-FEB-2021

INTRODUCTION

A cleanroom for Canadian Guardian was constructed previously and testing is needed to be performed to certify its ISO 8 classification. This test was performed by ACH Engineering's contractor as per IEST-RP-CC006.3 standard on February 17, 2021 at 505 Apple Creek Blvd Unit 4, Markham ON. For an ISO 8 cleanroom, an air change per hour between 5-48 is required.

RESULTS AND DISCUSSION

Airflows were measured on February 17, 2021 at each of the diffusers in one anteroom and one cleanroom.

Materials Airlock (1 Diffuser)	
Room Area, ft^2	64
Room Height, ft	8'
Room Volume, ft^3	512

Personnel Airlock (1 Diffuser)	
Room Area, ft^2	200
Room Height, ft	8'
Room Volume, ft^3	1600

Cleanroom (19 Diffusers)	
Room Area, ft^2	3000
Room Height, ft	8'
Room Volume, ft^3	24000

Air Flow Test (Material Airlock)

Diffuser (refer to room layout)	CFM
1	135
Total Main Room CFM	**135**

Air Flow Test (Personnel Airlock)

Diffuser (refer to room layout)	CFM
1	105
Total Main Room CFM	**105**

Air Flow Test (Cleanroom)

Diffuser	CFM	Diffuser	CFM	Diffuser	CFM	Diffuser	CFM
1	530	**6**	375	**11**	401	**16**	436
2	490	**7**	431	**12**	324	**17**	478
3	516	**8**	382	**13**	437	**18**	490
4	514	**9**	275	**14**	343	**19**	383
5	438	**10**	381	**15**	496	**-**	-
Total Main Room CFM	**7737**						

Air Change per Hour (ACH)

$$Air\ Change\ Per\ Hour = \frac{Supply\ CFM * 60}{Volume\ of\ Room}$$

	ACH (As per test 03-Mar-2020)
Material Airlock	**5**
Personnel Airlock	**13**
Cleanroom	**19**

According to FS 209E and ISO 14644 classifications guideline and IEST-RP-CC006.3 standard, an ISO 8 (Class 100,000) cleanroom should have an ACH rate from 5 to 48. Both the rooms **PASS** the ISO 8 standard based on the actual reading.

Particle Count Survey

The particle count was tested at 24 locations evenly distributed within the cleanrooms, 3 locations for material airlock and 6 locations for personnel airlocks. The average particle count based on the 24 locations meets the requirement for ISO 8 inside the cleanroom. The limit for amount of particles inside the clean room is 3.5 million and the test results show there were <1 million. This **passes** the particle count test.

	Limit (/m^3)	Actual Average (concn/m^3)	Result
≥0.5 µm Particles in **Material Airlock** (3 Locations)	3,520,000	196,963.3	**PASS**

	Limit (/m^3)	Actual Average (concn/m^3)	Result
≥0.5 µm Particles in **Personnel Airlock** (6 Locations)	3,520,000	817,147	**PASS**

	Limit (/m^3)	Actual Average (concn/m^3)	Result
≥0.5 µm Particles in **Cleanroom** (24 Locations)	3,520,000	-Refer Test data	**PASS**

Pressure Differential Test

A pressure test was performed to see the direction of airflow and to insure the cleanrooms had a positive pressure compared to the outside corridor. All the pressures were positive and **passes** the pressure differential test.

Room "From to To"	" W.C.	Pascals	Remarks
Cleanroom to Material Air lock	+0.027	6.73	N/A
Material Airlock to unclassified	+0.05	12.45	N/A
Cleanroom to Personnel Air lock	+0.026	6.48	N/A
Personnel Airlock to unclassified	+0.1	24.91	N/A

The pressure differential reading showed good movement of air flow throughout the cleanrooms.

HEPA Leak Test

A HEPA filter leak test was performed to see the integrity of the HEPA filters. There was no leak observed. Air volume readings were taken off the diffuser in the room. All HEPA found ok in functionality.

CONCLUSIONS & RECOMMENDATIONS

Conclusions

The cleanrooms at Canadian Guardian PASSES the requirement for an ISO 8 Cleanroom. The Air changes were more than the minimum required of 5.

The particle counts were well below the maximum limit for both the cleanrooms. There were no concerns with the leak test of the HEPA filters and the air was flowing in the right direction according to the pressure tests.

Recommendations

To have annual tests to ensure Canadian Guardian meets the ISO 8 requirements.

Chirag Shah P.Eng PMP

President
ACH Engineering Inc.

REFERENCES/APPENDICES

Appendix 1 – Photographs/Notes

Appendix 2 – Site Layout Drawing - Cleanrooms

Appendix 3 – Technical Test Results

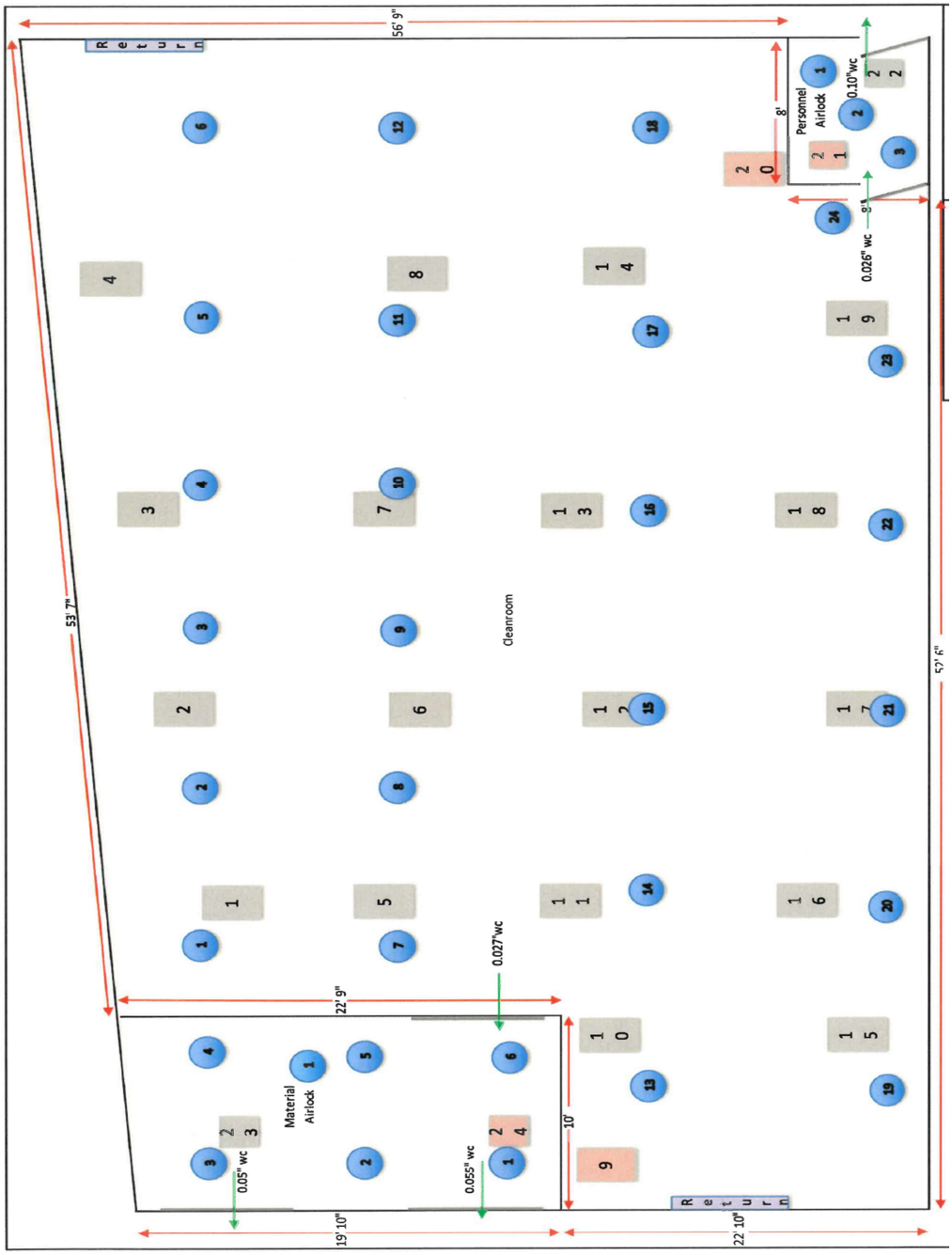
Appendix 1:

Photographs/Notes


AEROEX
IRII-1500

Appendix 2:

Layout Drawing for Final Test Lab



Appendix 3:

Technical Test Results