Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

April 27, 2020

COVID-19 PPE Testing Services

As announced earlier, Cambridge Materials Testing has been approved as a Covid-19 PPE testing facility by Health Canada.

The following are some of the types of Covid-19 PPE products we currently are testing. Please contact us directly to discuss any Covid-19 PPE testing you require for products you are manufacturing or securing.

Disposable Surgical Masks (ASTM F2100)

AQL (Acceptance Quality Level) of 4% shall be used for all required testing to establish conformance.

Test	Typical Canada/US ASTM F2100		
	Level 1	Level 2	Level 3
Bacterial Filtration Efficiency, %	≥95	≥98	≥98
Differential Pressure mm H_2O/cm^2 (Pa/cm^2)	<4.0 <39.2	<5.0 <49.0	<5.0 <49.0
Submicron particulate filtration efficiency at 0.1 micron, %	≥95	≥98	≥98
Splash Resistance/Synthetic Blood Resistance, mmHg	80	120	160
Flame Spread	Class 1	Class 1	Class 1

The government makes reference to ASTM F2100-11 under Buy & Sell, and we make reference to ASTM F2100-19 in quoting and reporting. The main difference being the differential pressure readings are higher and test methodology is more current. Under the following website the government makes reference to the 2019 edition

CMTL TESTS:

- **Synthetic Blood Penetration (ASTM F1862/F1862M)**

Requires 32 masks per set of samples for testing at either Level 1 (80mmHg), Level 2 (120mmHg) or Level 3 (160mmHg) barrier. Preconditioning of masks at 21±5ºC and 85±5% relative humidity for a minimum of 4-hours prior to testing.

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

- **Differential Pressure (EN 14683:2019 Annex C)**

Requires minimum of 2 masks per set of samples for differential pressure measurements. Pre-conditioning of masks at 21±5ºC and 85±5% relative humidity for a minimum of 4-hours prior to testing. To be performed by CMTL if client not interested in conducting the bacteria filtration efficiency test.

- **Flame Spread (16 CFR 1610)**

Requires a minimum of 5 masks per set of samples for flame spread measurements. Condition of masks at 105±3ºC for 30-minutes followed by desiccator to cool for at least 15 minutes.

- **Bacteria Filtration Efficiency (incl. Differential Pressure)**

Requires a minimum of 10 masks per set of samples (five for BFE and five for Delta P). A minimum of 5 masks required for EN 14683; where each specimen must be either 4x4 inches minimum or full face masks. To be outsourced to Intertek or Nelson with expected turnaround time of approximately 20 business days.

- **Particle Filtration Efficiency**

Require a minimum of 5 masks per set of samples, where each specimen must be either 5x5 inches (12x12 cm) minimum or full face masks. Particle size to be 0.1-micron for ASTM F2100. To be outsourced to Intertek or Nelson with expected turnaround time of approximately 20 business days.

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Disposable N95 Masks (NIOSH Pre-Certification)

- **Sodium Chloride (NaCl)**

Requires a minimum of 20 masks per set of samples. To be outsourced to Intertek or Nelson with expected turnaround time of approximately 20 business days.

- **Inhalation and Exhalation**

Requires a minimum of 3 masks per set of samples. To be outsourced to Intertek or Nelson with expected turnaround time of approximately 20 business days.

- **Valve Leak Test**

Requires a minimum of 3 masks per set of samples. To be outsourced to Intertek or Nelson with expected turnaround time of approximately 20 business days.

CMTL TESTS:
For a surgical mask that is also an N95 Respirator and certified by NIOSH as a respirator, you may submit the NIOSH certification number in lieu of filter efficiency performance (BFE & PFE) and differential pressure tests. The following tests are also to be performed and reported

- **Synthetic Blood Penetration (ASTM F1862/F1862M)**
- **Flame Spread (16 CFR 1610)**

Disposable N95 Masks (Not NIOSH Certified)

AQL of 4% shall be used for all required testing to establish conformance.

A surgical mask (i.e. KN95) that is not a NIOSH certified N95 respirator the BFE, PFE and differential pressure tests are at least required to be performed. These tests are to be outsourced to Intertek or Nelson (see previous page). The following tests are also to be performed on surgical masks that are not NIOSH certified:

- **Synthetic Blood Penetration (ASTM F1862/F1862M)**
- **Flame Spread (16 CFR 1610)**

Face Shields & Goggles (ANSI Z87.1-2020 & CSA Z94.3-2020)

(Last Modified: April 14, 2020)

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Eye protection includes safety glasses, safety goggles and face shields, and must meet the following specifications:

	Goggles	Face Shields
Hazard Corrected	Impact and splash	Splash from hazardous material
Safety Features	Shield entire eyes Impact-resistant lenses Ability to wear over eye glasses	Shield entire face Easily removable in case of accidents Impact resistant as necessary
Material	Polycarbonate (clear)	Polycarbonate, Propionate, Acetate, Polyvinyl chloride, Polyethylene terephthalate
Reusable	Yes	Yes
Head strap	Yes	Yes
Liquid resistant	Yes	Yes
Dimensions	Adjustable strap Minimum 20cm wide at the top	Minimum 24 cm high, 36 cm wide
Medical Device Classification	Yes Level : 1	Yes Level : 1

Face shields (visors) are made of shatterproof plastic, fit over the face and are held in place by head straps or caps. These visors need to be easily disinfected to be reusable by the health care workers. If reusable, manufacturer to provide validated cleaning instructions with any reusable device. These face shields must be able to cover the entirety of the face. Face shields that do not provide fog resistance, anti-fog spray must be provided.

Goggles for splash and impact protection should be worn over normal prescription eye glasses and contact lenses. Googles need to be easily disinfected to be reusable by the health care workers. Manufacturer to provide validated cleaning instructions with any reusable device. Goggles that do not provide fog resistance, anti-fog spray must be procured.

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Minimum specifications in urgent manufacturing scenarios

Health Canada recognizes that if access to face shields becomes limited, improvised production may occur. Whenever possible, manufacturers of face shields should comply with the standards outlined above. However, in the event that **urgent** production of face shields is required in Canada, Interim Order or MDEL requirements would continue to apply and Health Canada would expect that the following minimum specifications would be incorporated into the design and verification to ensure safe and effective face shields:

- Device must provide adequate coverage (CSA Z94.3 Sections 10.2.1/10.2.2/10.3/10.4).
- Device should made of optically clear, distortion free, lightweight materials (refer to CSA Standard Z94.3.1-16 and [1])
- Device should be free of visible defects or flaws that would impede vision (ANSI Z87.1 Section 9.4)
- The device should allow adequate space between the wearer's face and the inner surface of the visor to allow for the use of ancillary equipment (medical/surgical mask, respirator, eyewear, etc.) [1].
- Device should fit snugly to afford a good seal to the forehead area and to prevent slippage of the device [1].
- Device should withstand impact from sharp or fast projectiles (ANSI Z87.1 Section 9.2 and 9.3, CSA Z94.3 Section 10.1)
- If available, device should display anti-fog behavior on inside and outside of shield. (CSA Standard Z94.3.1-16)
- User contacting materials should provide adequate material biocompatibility (skin sensitivity and cytotoxic testing) (ISO 10993-5, 10)

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Face Shields & Goggles (ANSI Z87.1-2020 & CSA Z94.3-2020)

CMTL TESTS FOR FACE SHIELDS:
(ANSI Z87.1-2020 & CSA Z94.3-2020)

- **Physical Requirements – Drop-Ball & High-Mass Impact**

Requires 8 face shields per set of samples. Requirements as stated within sections 5.2.1 and 7.1.4.1. Not sections 9.2 and 9.3 as stated by the government on updated website (April 18/20).

- **Physical Requirements – Ignition**

Requires 1 face shield per set of samples. Requirements as stated within sections 5.2.2. No visible requirement from government literature sources.

- **Physical Requirements – Adequate Coverage**

Requires 1 face shield per set of samples. Requirements as stated within sections 5.2.4 of ANSI, and sections 10.2.1, 10.3 and 10.4 of CSA. Requirement from government is that the device must provide adequate coverage (April 18/20) and shield entire face (April 14/20).

- **Optical Requirements – Luminous Transmittance and Haze**

Requires 1 face shield per set of samples. Requirements as stated within sections 5.1.2 and 5.1.3 of ANSI, and sections 6.4.5 and 6.4.6 of CSA. Haze causes blurring and is impediment to vision. Requirement from government is that the device should be made of optically clear, distortion free, lightweight materials; also that it be free of visible defects or flaws that would impede vision (April 18/20).

- **Droplet & Splash Requirement**

Requires 1 face shield per set of samples. Requirement as stated within sections 7.3.2 of ANSI, and section 10.2.2 of CSA. Requirement from government is that the device must provide adequate coverage (April 18/20), and be protected against splash from hazardous material (April 14/20).

CMTL TESTS FOR GOGGLES:
(ANSI Z87.1-2020 & CSA Z94.3-2020)

- **Drop-Ball & High-Mass Impact**

Requires 8 goggles per set of samples. Requirements as stated within sections 5.2.1 and 7.1.4.1. Requirement from government is that the device must provide adequate protection against impact (April 14/20).

- **Droplet & Splash Requirement**

Requires 2 goggles per set of samples. Requirement as stated within sections 7.3.1 of ANSI. Requirement from government is that the device must be protected against splash from hazardous material (April 14/20).

- **Ventilation Requirement**

Requires 1 goggle per set of samples. Requirement as stated within sections 5.4.1 of ANSI, and section 8.2 of CSA. Requirement from government is that the device must provide adequate protection against fogging (April 14/20).

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

- **Fitting Requirement**

Requires 1 goggle per set of samples. Requirement as stated within Annex K.11 of ANSI, and sections 6.8 and 6.9 of CSA for Class 2. Requirement from government is that the device should shield the entire eyes (April 14/20).

- **Field of View Requirement**

Requires 1 goggle per set of samples. Requirement as stated within section 8.1 of CSA. No visible requirement from government literature sources.

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Gowns (CSA Z314 & ANSI PB70)

We have obtained a copy of CSA Z314 to review for both current-job and future quoting of gown testing. We are currently conducting testing of isolation gowns to ASTM F3352 requirements to classify based on American standard ANSI/AAMI PB70 for Southlake Regional Hospital in Newmarket.

CMTL/CTT GROUP TESTS FOR ISOLATION GOWNS:
(ASTM F3352 & ANSI/AAMI PB70)

AQL of 4% shall be used for all required testing to establish conformance.

- **Barrier Performance – Impact Penetration (AATCC 42)**

Requires 5 gowns per set of sample. Evaluation of classification with Level 1, 2 or 3 requirements for low/high risk protection.

- **Barrier Performance – Hydrostatic Pressure (AATCC 127)**

Requires 1 gown per set of sample. Evaluation of classification with Level 1, 2 or 3 requirements for low/high risk protection. To be outsourced to CTT Group for testing.

- **Blood Penetration Resistance (ASTM F1670)**

Requires 1 gown per set of sample. Test three specimens per sample. Conditioning at 21±5ºC and 30-80% relative humidity for a minimum of 24 hours prior to testing.

- **Physical Property Performance – Tensile Strength (ASTM D5034)**

Tested in the dry condition. Five specimens tested in the warp / machine direction. Eight specimens tested in the filling / cross direction. Test specimen size: 100 mm (4”) wide x 150 mm (6”) long with the long dimension parallel to the direction of testing and force application. Preferably, test specimens for a given direction should be spaced along a diagonal of the fabric to allow for different warp and filling yarns, or machine and cross direction areas, in each specimen.

- **Physical Property Performance – Tear Resistance (ASTM D5587)**

Tested in the dry condition. Five specimens tested in the warp / machine direction. Five specimens tested in the filling / cross direction. Test specimen size: 75 mm (3”) wide x 150 mm (6”) long with the long dimension parallel to the direction of testing and force application. Preferably, test specimens for a given direction should be spaced along a diagonal of the fabric to allow for different warp and filling yarns, or machine and cross direction areas, in each specimen.

- **Physical Property Performance – Seam Strength (ASTM D1683)**

Five specimens tested in the warp / machine direction. Five specimens tested in the filling / cross direction. Test specimen size: 100 mm (4”) wide x 150 mm (8”) long with the long dimension parallel to the direction of testing and force application as well as perpendicular to the seam to be tested.

- **Flame Spread (16 CFR 1610)**

Requires a minimum of 1 gown per set of samples for flame spread measurements. Condition of gown at 105±3ºC for 30-minutes followed by desiccator to cool for at least 15 minutes.

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Note that we are also able to conduct testing on surgical gowns per ASTM F2407 to classify based on ANSI/AAMI PB70 for barrier performance. There also appears to be no real requirement for flame spread within ASTM, except meeting either the Class 1 or II standard per FDA

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Gloves (ASTM D3578)

The Canadian requirement is for gloves to be compliant to ASTM D3578 depending on their material, or there is ASTM D6319 (Nitrile) and ASTM D5250 (PVC). The government again makes reference to 2005 standard, whereas the below is from the most current 2019 standard.

TABLE 1 Performance Requirements

Characteristic	Related Defects	Inspection Level	AQL
Sterility	fails sterility	[A]	N/A
Freedom from holes	holes	I	2.5
Dimensions	width, length, and thickness	S-2	4.0
Physical properties	before aging, after accelerated aging	S-2	4.0
Powder Free Residue	Exceeds Maximum Limit	N=5	N/A
Protein Content	Exceeds Recommended Maximum Limit	N=3	N/A
Powder Amount	Exceeds Recommended Maximum Limit	N=2	N/A
Antigenic Protein Content	Exceeds Recommended Maximum Limit	N=1	N/A

[A] See U.S. Pharmacopeia.

CMTL TESTS FOR GLOVES:

- **Freedom from Holes (ASTM D5151)**
- **Dimensions (ASTM D3767)**
- **Physical Properties, incl. Tensile Properties (ASTM D412) & Rubber Deterioration (ASTM D573)**
- **Powder Free Residue & Powder Amount (ASTM D6124)**

- **Sterility (USP)** – needs further review (possibly)
- **Permeation of Liquids and Gases (ASTM F739)** – needs further review (possibly)

Cambridge
materials testing limited

1177 Franklin Blvd,
Cambridge, Ont. N1R 7W4
Tel: (519) 621-6600 Fax: (519) 621-6082

Hand Sanitizer

The hand sanitizers must contain one of these approved active medicinal ingredients:

Common name	Source material	Quantity	Product form
Alcohol	Ethanol	60 - 80%	Liquid
Anhydrous alcohol	Ethanol	60 - 80%	Gel, solution, spray foam, liquid
Ethanol	Ethanol	60 - 80%	Gel, solution, spray, foam, liquid, aerosol
Ethyl alcohol	Ethanol	60 - 80%	Liquid
Grain alcohol	Ethanol	60 - 80%	Gel, solution, spray, foam, liquid, tincture
Isopropanol	Isopropanol	60 - 75%	Liquid, pad
Isopropryl alcohol	Isopropanol	60 - 75%	Gel, solution, liquid, tincture, swab

CMTL TESTS FOR HAND SANITIZER:

- **Alcohol Content by Gas Chromatography (Internal Methodology)**